From:	Erika Agius
To:	Cosmetic Surgery Review
Subject:	Independent review into cosmetic surgery
Date:	Friday, 25 March 2022 3:19:53 PM

To whom it may concern-

I am an Anaesthetic consultant with over 20 years experience . Over this time I have witnessed multiple surgeons (usually a general surgical background but not always) of “average ability” do a weekend course in some aspect of cosmetic surgery ,only to find them advertising their ability to do quite complex plastic surgical procedures they have never done before.

I was shocked to see that a general surgeon I knew, who had only just become a consultant the previous year, advertise on her website the willingness to correct paediatric "bat ears” in addition to vaginoplasties.

I have also had the misfortune to anaesthetise patients who have had infective complications from a cosmetic surgeon in the private sector, having to come to the public sector where a properly trained plastic surgeon could sort out the mess.

I have heard stories of very questionable sedation/“anaesthetic “techniques for breast implantations that concern me greatly, but I have not witnessed this first hand.

There are aspects of this industry that appear completely unregulated and driven primarily by cost efficiencies. I am concerned by any professional who feels a weekend training course sufficiently prepares them for any surgical procedure.

A plastic surgeon spends years honing their craft in a supervised environment- cosmetic surgery should be no different

Yours sincerely

Dr Erika Agius

VMO Anaesthetist

Response template for submissions to the *Independent review of the regulation of medical practitioners who perform cosmetic surgery*

You are invited to have your say about the regulation of medical practitioners (doctors) who perform cosmetic surgery by making a submission to this independent review.

The consultation questions from the consultation paper are outlined below. Submissions can address some or all of these questions, and you can include any evidence or examples that you think are relevant.

Submissions can be emailed to:

Mr Andrew Brown, Independent Reviewer
marked '*Submission to the independent review on cosmetic surgery*' at CSReview@ahpra.gov.au.

The closing date for submissions is 5.00pm AEST 14 April 2022.

Your details

Name	Bianca Aiono
Organisation (if applicable)	
Email address	[redacted]

Your responses to the consultation questions

Codes and Guidelines

1. Do the current *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures* adequately address issues relevant to the current and expected future practice of cosmetic surgery and contribute to safe practice that is within a practitioner's scope, qualifications, training and experience?
No, because they do not have an expected standard of training and experience.
2. What changes are necessary and why? What additional areas should the guidelines address to achieve the above purpose?
3. Please provide any further comment in relation to the use of codes and guidelines relevant to the practice of cosmetic surgery.

Management of notifications

4. Having regard to Ahpra and the Medical Board's powers and remit, what changes do you consider are necessary to the approach of Ahpra and the Medical Board in managing cosmetic surgery notifications, including their risk assessment process, and why?
5. Please provide any further relevant comment in relation to the management of notifications about medical practitioners involved in cosmetic surgery.

Advertising restrictions

6. Is Ahpra and the Medical Board's current approach to regulating advertising in cosmetic surgery sufficient?
7. What should be improved and why and how?

8. Do the current Guidelines for advertising a regulated health service adequately address risks in relation to advertising of cosmetic surgery, or is a more specific regulatory response required?
9. Does the promotion of cosmetic surgery via social media raise any issues that are not adequately addressed by the advertising guidelines, or that require any specific regulatory response?
10. Please provide any further relevant comment in relation to the regulation of advertising.

Title protection and endorsement for approved areas of practice

11. To what extent would establishing an endorsement in relation to the practice of cosmetic surgery address relevant issues of concern in the sector (including patient safety issues)?
I think it is essential if the public is to be protected. Cosmetic surgery is not a specialty and so there are no official specialists. Other than word of mouth and the doctor's own website and advertisements, the public has no way of knowing if he or she trained in cosmetic surgery or not. If doctors who are properly trained and competent are endorsed to practice cosmetic surgery by the authorities, the public would be able to choose an endorsed doctor. Why would Ahpra and the Medical Board NOT want to protect the public in this way?

12. Would establishing an endorsement in relation to cosmetic surgery provide more clarity about the specific skills and qualifications of practitioners holding the endorsement?
Yes
13. What programs of study (existing or new) would provide appropriate qualifications?
I do not know but obviously, it must be specifically about cosmetic surgery.
14. Please provide any further relevant comment in relation to specialist title protection and endorsement for approved areas of practice relevant to cosmetic surgery.
Only doctors or specialists who are endorsed in cosmetic surgery should be allowed to call themselves cosmetic surgeons.

Cooperation with other regulators

15. Are there barriers to effective information flow and referral of matters between Ahpra and the Medical Board and other regulators?
16. If yes, what are the barriers, and what could be improved?
.
17. Do roles and responsibilities require clarification?
18. Please provide any further relevant comment about cooperating with other regulators.

Facilitating mandatory and voluntary notifications

19. Do the Medical Board's current mandatory notifications guidelines **adequately explain the mandatory reporting obligations?**
20. Are there things that prevent health practitioners from making notifications? If so, what?
21. What could be improved to enhance the reporting of safety concerns in the cosmetic surgery sector?
22. Please provide any further relevant comment about facilitating notifications

Information to consumers

23. Do the Medical Board's current codes and guidelines adequately describe the obligations of practitioners who perform cosmetic surgery to provide sufficient information to consumers and obtain informed consent?
24. If not, what improvements could be made?
25. Should codes or guidelines include a requirement for practitioners to explain to patients how to make a complaint if dissatisfied?

26. In the context of cosmetic surgery, does the Ahpra website and public register of practitioners provide sufficient information about medical practitioners to inform consumer choices?
No. As explained earlier, with no specialty and no endorsement for cosmetic surgery yet, the public register provides no relevant information about a practitioner's cosmetic surgery expertise or otherwise.
27. If not, what more could/should Ahpra and the Medical Board do to inform consumer choices?
Introduce an endorsement for doctors who have met a competency standard in cosmetic surgery and show this on the public register.
28. Is the notification and complaints process understood by consumers?
29. If not, what more could/should Ahpra and the Medical Board do to improve consumer understanding?
30. Please provide any further relevant comment about the provision of information to consumers.

Further comment or suggestions

31. If you have any further comment relevant to Ahpra's and the Medical Board's regulation of cosmetic surgery including and/or suggestions for enhancements not mentioned in response to the above questions, please provide it here.
It seems obvious that endorsement should be introduced. It will protect the public from untrained and unsafe practitioners. It is hard to think of any reason the public or anyone without a vested interest would not welcome it.

Response template for submissions to the *Independent review of the regulation of medical practitioners who perform cosmetic surgery*

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The consultation questions from the consultation paper are outlined below. Submissions can address some or all of these questions, and you can include any evidence or examples that you think are relevant.

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Mr Andrew Brown, Independent Reviewer
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The closing date for submissions is 5.00pm AEST 14 April 2022.

Your details

Name	Muhammad M Alam
Organisation (if applicable)	
Email address	[redacted]

Your responses to the consultation questions

Codes and Guidelines

1. Do the current *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures* adequately address issues relevant to the current and expected future practice of cosmetic surgery and contribute to safe practice that is within a practitioner's scope, qualifications, training and experience?

1. These could indeed be improved. Currently there is no recognised specialty of Cosmetic Surgery, nor can there be, without a change in the National Law. Therefore no training programme is recognised by the AMC for cosmetic surgery, and the title "cosmetic surgeon" may be used by any medical practitioner. Patients are at risk, because they are unable to identify if the doctor offering cosmetic surgery has the relevant *specific* training and skill. Currently it is impossible to determine if a practitioner is operating within their scope of practice.

2. What changes are necessary and why? What additional areas should the guidelines address to achieve the above purpose?

1. The Endorsement model for practitioners performing cosmetic surgery should be adopted to protect the public. Those endorsed medical practitioners who have met a National Accreditation Standard should be on a public register.

3. Please provide any further comment in relation to the use of codes and guidelines relevant to the practice of cosmetic surgery.

1. This standard would ensure that practitioners not only have a core surgical competence, but also that they have reached an acceptable level of competence and skill *specifically* in Cosmetic surgery. The practitioners would be required to be part of a

recertification programme specific to cosmetic surgery. To ensure patient safety, this model would need to be applied to *all doctors* who perform cosmetic surgery irrespective of their prior backgrounds.

Management of notifications

4. Having regard to Ahpra and the Medical Board's powers and remit, what changes do you consider are necessary to the approach of Ahpra and the Medical Board in managing cosmetic surgery notifications, including their risk assessment process, and why?

5. Please provide any further relevant comment in relation to the management of notifications about medical practitioners involved in cosmetic surgery.

Advertising restrictions

6. Is Ahpra and the Medical Board's current approach to regulating advertising in cosmetic surgery sufficient?

7. What should be improved and why and how?

8. Do the current Guidelines for advertising a regulated health service adequately address risks in relation to advertising of cosmetic surgery, or is a more specific regulatory response required?

9. Does the promotion of cosmetic surgery via social media raise any issues that are not adequately addressed by the advertising guidelines, or that require any specific regulatory response?

10. Please provide any further relevant comment in relation to the regulation of advertising.

Title protection and endorsement for approved areas of practice

11. To what extent would establishing an endorsement in relation to the practice of cosmetic surgery address relevant issues of concern in the sector (including patient safety issues)?

. Establishing an endorsement model would essentially protect patients from adverse outcomes. Those practitioners, who are endorsed to practice cosmetic surgery, would have the appropriate training and experience in cosmetic surgery. This would be clear to patients, because there would be an AHPRA administered Cosmetic Surgery Register identifying doctors who are endorsed for cosmetic surgery. Patients could then be rest assured that they are being treated by doctors who are operating within their scope of practice. A title restriction should be linked to a competency-based accreditation Standard/Register as proposed by the College (ACCSM) by means of the Endorsement pathway provided for in Section 98 of National Law.

12. Would establishing an endorsement in relation to cosmetic surgery provide more clarity about the specific skills and qualifications of practitioners holding the endorsement?

Establishing an endorsement model would provide clarity to the consumer, about the specific skills and qualifications of practitioners holding the endorsement. It would identify those practitioners who have the core surgical training and competence, and *specific* cosmetic surgical training and competence as well as on-going professional education in cosmetic surgery.

13. What programs of study (existing or new) would provide appropriate qualifications?

13. The Australian College of Cosmetic Surgery and Medicine (ACCSM) is a well-recognised college, which has been established well over 30 years ago. This college is well equipped to provide appropriate qualifications for those practitioners to be endorsed in Cosmetic Surgery and Medicine.

14. Please provide any further relevant comment in relation to specialist title protection and endorsement for approved areas of practice relevant to cosmetic surgery.

Specialist title protection is reserved for medical specialists who have been recognised by the AMC. Until this point, Cosmetic surgery and Cosmetic Medicine have not been specialist pathways recognised by the AMC, because there is no burden of disease. Failing being recognised by the AMC as a medical specialty, the endorsement model would be an appropriate way in which to regulate the cosmetic surgical industry. The title ‘Cosmetic Surgeon’ should be protected for those practitioners who have had specific recognised training in Cosmetic surgery. It is clear that specialist surgeons as recognised by the AMC do not have specific training in Cosmetic Surgery and specialist plastic surgeons qualify with a ‘gap’ in the area.

Cooperation with other regulators

15. Are there barriers to effective information flow and referral of matters between Ahpra and the Medical Board and other regulators?

16. If yes, what are the barriers, and what could be improved?

17. Do roles and responsibilities require clarification?

18. Please provide any further relevant comment about cooperating with other regulators.

Facilitating mandatory and voluntary notifications

19. Do the Medical Board's current mandatory notifications guidelines adequately explain the mandatory reporting obligations?
20. Are there things that prevent health practitioners from making notifications? If so, what?
21. What could be improved to enhance the reporting of safety concerns in the cosmetic surgery sector?
22. Please provide any further relevant comment about facilitating notifications

Information to consumers

23. Do the Medical Board's current codes and guidelines adequately describe the obligations of practitioners who perform cosmetic surgery to provide sufficient information to consumers and obtain informed consent?
The Medical Board's current codes and guidelines do not specifically outline a practitioners training in cosmetic surgery. Currently consumers are left in doubt as to whether their surgeon has had any *specific* training in cosmetic surgery, even if their surgeon is a specialist surgeon as recognised by the AMC.
24. If not, what improvements could be made?
If the endorsement model is adopted for cosmetic surgery, it would allow the public to identify doctors who are trained and competent in cosmetic surgery, provide protection for patients before something goes wrong, facilitate AHPRA taking action more readily against doctors who may be practicing outside of their scope of practice, and by being competency-based and independently set and assessed, be fair to all practitioners and not favour any particular group of doctors on the basis of their non-cosmetic surgical training and qualifications
25. Should codes or guidelines include a requirement for practitioners to explain to patients how to make a complaint if dissatisfied?

26. **In the context of cosmetic surgery, does the Ahpra website and public register of practitioners provide sufficient information about medical practitioners to inform consumer choices?**
The AHPRA website, and public register of practitioners does not provide adequate information to consumers to safely choose their cosmetic surgeon. There should be a list of endorsed practitioners available for consumers to readily identify those practitioners who are adequately trained in cosmetic surgery.
27. **If not, what more could/should Ahpra and the Medical Board do to inform consumer choices?**
AHPRA could provide a register of identified practitioners who have the necessary training in cosmetic surgery to perform such procedures safely
28. **Is the notification and complaints process understood by consumers?**
29. **If not, what more could/should Ahpra and the Medical Board do to improve consumer understanding?**
30. **Please provide any further relevant comment about the provision of information to consumers.**
It should be clear to consumers which doctor is trained *specifically* in cosmetic surgery, irrespective of their other previous training.

Further comment or suggestions

31. **If you have any further comment relevant to Ahpra's and the Medical Board's regulation of cosmetic surgery including and/or suggestions for enhancements not mentioned in response to the above questions, please provide it here.**
It is vital that consumers are made aware of the *specific* experience and qualifications of their cosmetic surgeon, in order for them to make informed choices regarding their surgery and choice of surgeon. I support the proposal for a national competency-based accreditation Standard for *all* doctors performing cosmetic surgery. There should be a register of Endorsement of those who have met, and maintain the national standard. Restriction of the title 'Cosmetic Surgeon' should be applied to those medical practitioners who appear on the Register, administered by AHPRA. Since the Australasian College of Cosmetic Surgery and Medicine is the *only* training body in Australia specifically focused on training practitioners in Cosmetic Medicine and Surgery, this college would be best equipped to train practitioners and enable them to maintain their level of competence and skill.

Response template for submissions to the *Independent review of the regulation of medical practitioners who perform cosmetic surgery*

You are invited to have your say about the regulation of medical practitioners (doctors) who perform cosmetic surgery by making a submission to this independent review.

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Mr Andrew Brown, Independent Reviewer
marked '*Submission to the independent review on cosmetic surgery*' at CSReview@ahpra.gov.au.

The closing date for submissions is 5.00pm AEST 14 April 2022.

Your details

Name	Dr. Walid Al-Bermani
Organisation (if applicable)	Beautiphi Cosmetic Studio
Email address	[redacted]

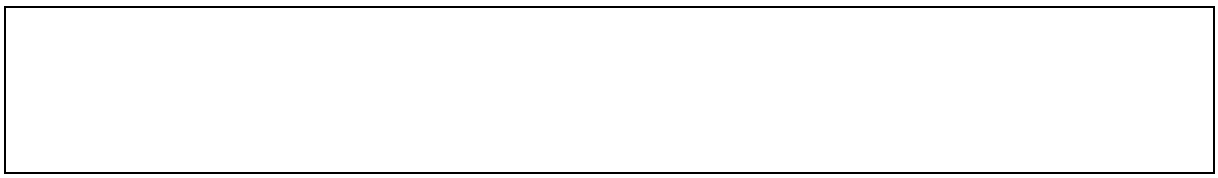
Your responses to the consultation questions

Codes and Guidelines

1. Do the current *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures* adequately address issues relevant to the current and expected future practice of cosmetic surgery and contribute to safe practice that is within a practitioner's scope, qualifications, training and experience?
1. These could indeed be improved. Currently there is no recognised specialty of Cosmetic Surgery, nor can there be, without a change in the National Law. Therefore no training programme is recognised by the AMC for cosmetic surgery, and the title "cosmetic surgeon" may be used by any medical practitioner. Patients are at risk, because they are unable to identify if the doctor offering cosmetic surgery has the relevant *specific* training and skill. Currently it is impossible to determine if a practitioner is operating within their scope of practice.
2. What changes are necessary and why? What additional areas should the guidelines address to achieve the above purpose?
1. The Endorsement model for practitioners performing cosmetic surgery should be adopted to protect the public. Those endorsed medical practitioners who have met a National Accreditation Standard should be on a public register.
3. Please provide any further comment in relation to the use of codes and guidelines relevant to the practice of cosmetic surgery.
1. This standard would ensure that practitioners not only have a core surgical competence, but also that they have reached an acceptable level of competence and skill *specifically* in Cosmetic surgery. The practitioners would be required to be part of a recertification programme specific to cosmetic surgery. To ensure patient safety, this model would need to be applied to *all doctors* who perform cosmetic surgery irrespective of their prior backgrounds.

Management of notifications

4. Having regard to Ahpra and the Medical Board's powers and remit, what changes do you consider are necessary to the approach of Ahpra and the Medical Board in managing cosmetic surgery notifications, including their risk assessment process, and why?
5. Please provide any further relevant comment in relation to the management of notifications about medical practitioners involved in cosmetic surgery.



Advertising restrictions

6. Is Ahpra and the Medical Board's current approach to regulating advertising in cosmetic surgery sufficient?
7. What should be improved and why and how?
8. Do the current Guidelines for advertising a regulated health service adequately address risks in relation to advertising of cosmetic surgery, or is a more specific regulatory response required?
9. Does the promotion of cosmetic surgery via social media raise any issues that are not adequately addressed by the advertising guidelines, or that require any specific regulatory response?
10. Please provide any further relevant comment in relation to the regulation of advertising.

Title protection and endorsement for approved areas of practice

11. To what extent would establishing an endorsement in relation to the practice of cosmetic surgery address relevant issues of concern in the sector (including patient safety issues)?
. Establishing an endorsement model would essentially protect patients from adverse outcomes. Those practitioners, who are endorsed to practice cosmetic surgery, would have the appropriate training and experience in cosmetic surgery. This would be clear to patients, because there would be an AHPRA administered Cosmetic Surgery Register identifying doctors who are endorsed for cosmetic surgery. Patients could then be rest assured that they are being treated by doctors who are operating within their scope of practice. A title restriction should be linked to a competency-based accreditation Standard/Register as proposed by the

College (ACCSM) by means of the Endorsement pathway provided for in Section 98 of National Law.

12. Would establishing an endorsement in relation to cosmetic surgery provide more clarity about the specific skills and qualifications of practitioners holding the endorsement?
Establishing an endorsement model would provide clarity to the consumer, about the specific skills and qualifications of practitioners holding the endorsement. It would identify those practitioners who have the core surgical training and competence, and *specific* cosmetic surgical training and competence as well as on-going professional education in cosmetic surgery.
13. What programs of study (existing or new) would provide appropriate qualifications?
13. The Australian College of Cosmetic Surgery and Medicine (ACCSM) is a well-recognised college, which has been established well over 30 years ago. This college is well equipped to provide appropriate qualifications for those practitioners to be endorsed in Cosmetic Surgery and Medicine.
14. Please provide any further relevant comment in relation to specialist title protection and endorsement for approved areas of practice relevant to cosmetic surgery.
Specialist title protection is reserved for medical specialists who have been recognised by the AMC. Until this point, Cosmetic surgery and Cosmetic Medicine have not been specialist pathways recognised by the AMC, because there is no burden of disease. Failing being recognised by the AMC as a medical specialty, the endorsement model would be an appropriate way in which to regulate the cosmetic surgical industry. The title 'Cosmetic Surgeon' should be protected for those practitioners who have had specific recognised training in Cosmetic surgery. It is clear that specialist surgeons as recognised by the AMC do not have specific training in Cosmetic Surgery and specialist plastic surgeons qualify with a 'gap' in the area.

Cooperation with other regulators

15. Are there barriers to effective information flow and referral of matters between Ahpra and the Medical Board and other regulators?
16. If yes, what are the barriers, and what could be improved?
17. Do roles and responsibilities require clarification?

18. Please provide any further relevant comment about cooperating with other regulators.

Facilitating mandatory and voluntary notifications

19. Do the Medical Board's current mandatory notifications guidelines adequately explain the mandatory reporting obligations?
20. Are there things that prevent health practitioners from making notifications? If so, what?
21. What could be improved to enhance the reporting of safety concerns in the cosmetic surgery sector?
22. Please provide any further relevant comment about facilitating notifications

Information to consumers

23. Do the Medical Board's current codes and guidelines adequately describe the obligations of practitioners who perform cosmetic surgery to provide sufficient information to consumers and obtain informed consent?

The Medical Board's current codes and guidelines do not specifically outline a practitioners training in cosmetic surgery. Currently consumers are left in doubt as to whether their surgeon has had any *specific* training in cosmetic surgery, even if their surgeon is a specialist surgeon as recognised by the AMC.

24. If not, what improvements could be made?

If the endorsement model is adopted for cosmetic surgery, it would allow the public to identify doctors who are trained and competent in cosmetic surgery, provide protection for patients before something goes wrong, facilitate AHPRA taking action more readily against doctors who may be practicing outside of their scope of practice, and by being competency- based and independently set and assessed, be fair to all practitioners and not favour any particular group of doctors on the basis of their non-cosmetic surgical training and qualifications

25. Should codes or guidelines include a requirement for practitioners to explain to patients how to make a complaint if dissatisfied?

26. In the context of cosmetic surgery, does the Ahpra website and public register of practitioners provide sufficient information about medical practitioners to inform consumer choices?

The AHPRA website, and public register of practitioners does not provide adequate information to consumers to safely choose their cosmetic surgeon. There should be a list of endorsed practitioners available for consumers to readily identify those practitioners who are adequately trained in cosmetic surgery.

27. If not, what more could/should Ahpra and the Medical Board do to inform consumer choices?

AHPRA could provide a register of identified practitioners who have the necessary training in cosmetic surgery to perform such procedures safely

28. Is the notification and complaints process understood by consumers?

29. If not, what more could/should Ahpra and the Medical Board do to improve consumer understanding?

30. Please provide any further relevant comment about the provision of information to consumers.
It should be clear to consumers which doctor is trained *specifically* in cosmetic surgery, irrespective of their other previous training.

Further comment or suggestions

31. If you have any further comment relevant to Ahpra's and the Medical Board's regulation of cosmetic surgery including and/or suggestions for enhancements not mentioned in response to the above questions, please provide it here.
It is vital that consumers are made aware of the *specific* experience and qualifications of their cosmetic surgeon, in order for them to make informed choices regarding their surgery and choice of surgeon. I support the proposal for a national competency-based accreditation Standard for *all* doctors performing cosmetic surgery. There should be a register of Endorsement of those who have met, and maintain the national standard. Restriction of the title 'Cosmetic Surgeon' should be applied to those medical practitioners who appear on the Register, administered by AHPRA. Since the Australasian College of Cosmetic Surgery and Medicine is the *only* training body in Australia specifically focused on training practitioners in Cosmetic Medicine and Surgery, this college would be best equipped to train practitioners and enable them to maintain their level of competence and skill.

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The closing date for submissions is 5.00pm AEST 14 April 2022.

Your details

Name	DR AHMED ALSULTAN
Organisation (if applicable)	ACCSM
Email address	[redacted]

Your responses to the consultation questions

Codes and Guidelines

1. Do the current *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures* adequately address issues relevant to the current and expected future practice of cosmetic surgery and contribute to safe practice that is within a practitioner's scope, qualifications, training and experience?

" Future practice of cosmetic surgery ". This is the exact keyword. A future of any medical /surgical specialty is defined to what we are doing today for the future. Historically if we ask the same questions about specialities that were not recognised/accredited at the time. Plastic surgery, urology, ENT specialities at some stage were not accredited or recognised. These specialities advancement today would not have happened if their recognition/accreditation got declined decades ago. We know 100 years ago there were less specialities than current and we know in 100 years time no doubt there will be more specialities than current. However, unfortunately at any stage when there is a new emerging speciality there is always " medical politics" involved as no speciality would want some of their field to be shared with other specialities.

We know General practitioner in the past used to have much diverse skills than today. So what happened to their speciality ? it has evolved and re-shaped . This is natural. Hand surgery is shared between orthopaedic and plastic surgeon (for historical reasons) but now there is a training full 4 years just to become a hand surgeon (overseas) as in independent pathway. More countries in the future may follow. This is an evidence of how globally we are having additional specialities emerging.

One specific training pathway via one college with same uniform generic baseline training is not the case when it comes for example with dermatology training. It can be as an independent pathway via Australasian college dermatologist or as an advanced training via RACP in New Zealand.

Currently cosmetic surgeons whether trained or not can still call themselves cosmetic surgeons. Same as GP whether or not you had a fellowship in general practice you still can call yourself a GP. Public often do not even know the difference between GP who has a fellowship and GP who do not have a fellowship. The distinction is only about the type of registration they hold. This is nothing to do with the clinical input rather than Medicare and rebate.

Cosmetic surgeon are exactly like GP these days. A title that is not protected , public getting confused who is trained or not and what is the difference.

I personally could have just called myself a cosmetic surgeon and teach myself in unsupervised manner and structureless way and start working as cosmetic surgeon from day 1 and some do that by the way. However, instead, I joined a training program , paid $45k in tuition fees and accepted a $250k reduction in my salary for every year for 3 years, going through rigorous training, research, board examination both written and oral and have sleepless nights to achieve a benchmark in order to be a **SAFE and COMPETENT** cosmetic surgeons. The current system puts all "cosmetic surgeons" in one basket , trained or not trained. Public may not be aware of this and even a lot of health professionals.

2. 'What changes are necessary and why? What additional areas should the guidelines address to achieve the above purpose?

1. The Endorsement model for practitioners performing cosmetic surgery should be adopted to protect the public. Those endorsed medical practitioners who have met a National Accreditation Standard should be on a public register. The endorsement model would encourage improvement in quality of trainings to meet an initial benchmark sat by AMC for example. New Zealand medical council has an endorsement model for cosmetic medicine.

3. Please provide any further comment in relation to the use of codes and guidelines relevant to the practice of cosmetic surgery.
1. This standard would ensure that practitioners not only have a core surgical competence, but also that they have reached an acceptable level of competence and skill *specifically* in Cosmetic surgery. The practitioners would be required to be part of a recertification programme specific to cosmetic surgery. To ensure patient safety, this model would need to be applied to *all doctors* who perform cosmetic surgery irrespective of their prior backgrounds.

Management of notifications

4. Having regard to Ahpra and the Medical Board's powers and remit, what changes do you consider are necessary to the approach of Ahpra and the Medical Board in managing cosmetic surgery notifications, including their risk assessment process, and why?
Cosmetic surgery notification should focus mainly on safety and clinical relevance and not just because patient did not feel they liked how they look like afterword. This is like a patient did not like their scar afterword and they just want to complain about it.
5. Please provide any further relevant comment in relation to the management of notifications about medical practitioners involved in cosmetic surgery.

Advertising restrictions

6. Is Ahpra and the Medical Board's current approach to regulating advertising in cosmetic surgery sufficient?	
I think so	
7. What should be improved and why and how?	
8. Do the current Guidelines for advertising a regulated health service adequately address risks in relation to advertising of cosmetic surgery, or is a more specific regulatory response required?	
9. Does the promotion of cosmetic surgery via social media raise any issues that are not adequately addressed by the advertising guidelines, or that require any specific regulatory response?	
10. Please provide any further relevant comment in relation to the regulation of advertising.	

Title protection and endorsement for approved areas of practice

11. To what extent would establishing an endorsement in relation to the practice of cosmetic surgery address relevant issues of concern in the sector (including patient safety issues)?	
. Establishing an endorsement model would essentially **protect** patients from adverse outcomes. Those practitioners, who are endorsed to practice cosmetic surgery, would have the appropriate training and experience in cosmetic surgery. This would be clear to patients, because there would be an AHPRA administered Cosmetic Surgery Register identifying doctors who are endorsed for cosmetic surgery. Patients could then be rest assured that they are being treated by doctors who are operating within their scope of practice. A title restriction should be linked to a competency-based accreditation Standard/Register as proposed by the	

College (ACCSM) by means of the Endorsement pathway provided for in Section 98 of National Law. New Zealand medical council already has an endorsement model for cosmetic medicine.

12. Would establishing an endorsement in relation to cosmetic surgery provide more clarity about the specific skills and qualifications of practitioners holding the endorsement?

Establishing an endorsement model would provide clarity to the consumer, about the specific skills and qualifications of practitioners holding the endorsement. It would identify those practitioners who have the core surgical training and competence, and *specific* cosmetic surgical training and competence as well as on-going professional education in cosmetic surgery.

13. What programs of study (existing or new) would provide appropriate qualifications?

14. The Australian College of Cosmetic Surgery and Medicine (ACCSM) is a well-recognised college, which has been established well over **30** years ago. This college has in the past and continue currently to advocate for patient safety in cosmetic surgery. Historically it has asked for recognition/accreditation and now it is asking for endorsement. I think for any training entity once recognised it be rigorously regulated so their quality can even improve further.

Majority of surgical specialities in the past started with little structures in their program and not even an examination. Their accreditation/recognition or endorsement is the first step to enhance their quality

15. Please provide any further relevant comment in relation to specialist title protection and endorsement for approved areas of practice relevant to cosmetic surgery.

Specialist title protection is reserved for medical specialists who have been recognised by the AMC. Until this point, Cosmetic surgery and Cosmetic Medicine have not been specialist pathways recognised by the AMC, because there is no burden of disease. Failing being recognised by the AMC as a medical specialty, the endorsement model would be an appropriate way in which to regulate the cosmetic surgical industry. The title ‘Cosmetic Surgeon’ should be protected for those practitioners who have had specific recognised training in Cosmetic surgery. It is clear that specialist surgeons as recognised by the AMC do not have specific training in Cosmetic Surgery and specialist plastic surgeons qualify with a ‘gap’ in the area.

Cooperation with other regulators

16. Are there barriers to effective information flow and referral of matters between Ahpra and the Medical Board and other regulators?

17. If yes, what are the barriers, and what could be improved?

18. Do roles and responsibilities require clarification?
19. Please provide any further relevant comment about cooperating with other regulators.

Facilitating mandatory and voluntary notifications

20. Do the Medical Board's current mandatory notifications guidelines **adequately explain the mandatory reporting obligations?**
21. Are there things that prevent health practitioners from making notifications? If so, what?
22. What could be improved to enhance the reporting of safety concerns in the cosmetic surgery sector?
23. Please provide any further relevant comment about facilitating notifications

Information to consumers

24. Do the Medical Board's current codes and guidelines adequately describe the obligations of practitioners who perform cosmetic surgery to provide sufficient information to consumers and obtain informed consent?

The Medical Board's current codes and guidelines do not specifically outline a practitioners training in cosmetic surgery. Currently consumers are left in doubt as to whether their surgeon has had any *specific* training in cosmetic surgery, even if their surgeon is a specialist surgeon as recognised by the AMC.

25. If not, what improvements could be made?

If the endorsement model is adopted for cosmetic surgery, it would allow the public to identify doctors who are trained and competent in cosmetic surgery, provide protection for patients before something goes wrong, facilitate AHPRA taking action more readily against doctors who may be practicing outside of their scope of practice, and by being competency- based and independently set and assessed, be fair to all practitioners and not favour any particular group of doctors on the basis of their non-cosmetic surgical training and qualifications

26. Should codes or guidelines include a requirement for practitioners to explain to patients how to make a complaint if dissatisfied?

We should not strip medicine from its nature. Patients should be encouraged to have an open discussion with their doctors /nurse about their feeling and get the opportunity to rectify any cause of their dissatisfaction in stressless manner instead of brining a culture of "how to complain"

27. In the context of cosmetic surgery, does the Ahpra website and public register of practitioners provide sufficient information about medical practitioners to inform consumer choices?

The AHPRA website, and public register of practitioners does not provide adequate information to consumers to safely choose their cosmetic surgeon. There should be a list of endorsed practitioners available for consumers to readily identify those practitioners who are adequately trained in cosmetic surgery.

28. If not, what more could/should Ahpra and the Medical Board do to inform consumer choices?

AHPRA could provide a register of identified practitioners who have the necessary training in cosmetic surgery to perform such procedures safely

29. Is the notification and complaints process understood by consumers?

30. If not, what more could/should Ahpra and the Medical Board do to improve consumer

understanding?

31. Please provide any further relevant comment about the provision of information to consumers.
It should be clear to consumers which doctor is trained ***specifically*** in cosmetic surgery, irrespective of their other previous training as cosmetic surgery is not necessarily and extension of other speciality but a speciality on its own.

Further comment or suggestions

32. If you have any further comment relevant to Ahpra's and the Medical Board's regulation of cosmetic surgery including and/or suggestions for enhancements not mentioned in response to the above questions, please provide it here.
It is vital that consumers are made aware of the *specific* experience and qualifications of their cosmetic surgeon, in order for them to make informed choices regarding their surgery and choice of surgeon. I support the proposal for a national competency-based accreditation Standard for *all* doctors performing cosmetic surgery. There should be a register of Endorsement of those who have met, and maintain the national standard. Restriction of the title 'Cosmetic Surgeon' should be applied to those medical practitioners who appear on the Register, administered by AHPRA. Since the Australasian College of Cosmetic Surgery and Medicine is the ***only*** training body in Australia **specifically** focused on training practitioners in Cosmetic Medicine and Surgery, this college would be best equipped to train practitioners and enable them to maintain their level of competence and skill.

Response template for submissions to the *Independent review of the regulation of medical practitioners who perform cosmetic surgery*

You are invited to have your say about the regulation of medical practitioners (doctors) who perform cosmetic surgery by making a submission to this independent review.

The consultation questions from the consultation paper are outlined below. Submissions can address some or all of these questions, and you can include any evidence or examples that you think are relevant.

Submissions can be emailed to:

Mr Andrew Brown, Independent Reviewer
marked '*Submission to the independent review on cosmetic surgery* 'at CSReview@ahpra.gov.au.

The closing date for submissions is 5.00pm AEST 14 April 2022.

Your details

Name	Mahyar Amjadi
Organisation (if applicable)	
Email address	[redacted]

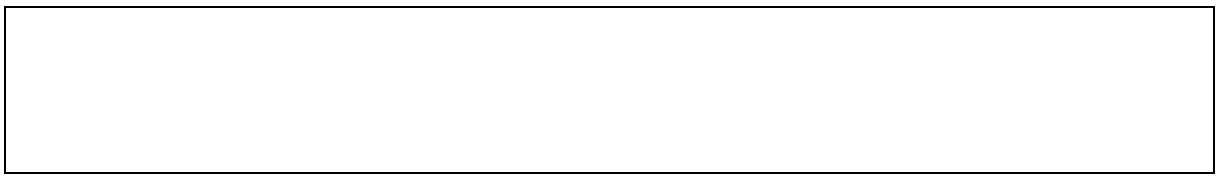
Your responses to the consultation questions

Codes and Guidelines

1. Do the current *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures* adequately address issues relevant to the current and expected future practice of cosmetic surgery and contribute to safe practice that is within a practitioner's scope, qualifications, training and experience?
The current guidelines are a good starting point. The issue remains that they are guidelines only, and as such not enforceable. Over the past decades cosmetic surgery has become a specialised branch of surgery, and is recognised as such in most developed nations. So long as cosmetic surgery is not recognised as an independent branch of surgery in Australia, the guidelines remain inadequate in addressing the required qualifications for performing such procedures.
2. What changes are necessary and why? What additional areas should the guidelines address to achieve the above purpose?
There are several areas that require refinement. One is the issue of title, the other is scope of practice and qualifications. Ideally, the national governing body should recognise that the skills learned in other areas of surgery are not necessary transferrable to cosmetic surgery, and will recognise it as a stand alone branch of surgery. In the absence of this, a well defined scope of practice needs to be establish to determine which practitioners are qualified to perform this type of surgery. It is clear that simply having obtained qualification in surgery by a public hospital-based training program, does in wise equip the trainee to provide cosmetic surgery services, regardless of the branch. It has been well established, both here and overseas, that the skills leaned in public hospital settings such as reconstructive surgery are not transferrable to another field, such as cosmetic surgery. A stand-alone set of qualification criteria, not dictated by the self interests of any particular specialty, is the only way to ensure the public receive service from a well trained practitioner.
3. Please provide any further comment in relation to the use of codes and guidelines relevant to the practice of cosmetic surgery.

Management of notifications

4. Having regard to Ahpra and the Medical Board's powers and remit, what changes do you consider are necessary to the approach of Ahpra and the Medical Board in managing cosmetic surgery notifications, including their risk assessment process, and why?
As long as cosmetic surgery is not recognised as a spelt, inspire of the opinion of the majority of the public to the contrary, AHPRA and its associated regulatory bodies remain ill equipped to translate any recommendations and findings into enforceable standard of practice through a specialty society.
5. Please provide any further relevant comment in relation to the management of notifications about medical practitioners involved in cosmetic surgery.



Advertising restrictions

6. Is Ahpra and the Medical Board's current approach to regulating advertising in cosmetic surgery sufficient?
It cannot be reasonably expected of AHPRA to police every post in every social media outlet. Currently the guidelines for advertising are very clear, but their enforcement is not practical, and apart from addressing each individual case as it is brought to the attention of the regulatory bodies, as is currently the case, I cannot see another way pf monitoring the advertisings.
7. What should be improved and why and how?
It would be more practical to legislate guidelines for the platforms that sell advertising space, as well social media influencers, to control the standards of cosmetic surgery advertising.
8. Do the current Guidelines for advertising a regulated health service adequately address risks in relation to advertising of cosmetic surgery, or is a more specific regulatory response required?
If the guidelines are fully adhered to, the current guidelines are more than adequate to protect the current savvy consumers of cosmetic surgery.
9. Does the promotion of cosmetic surgery via social media raise any issues that are not adequately addressed by the advertising guidelines, or that require any specific regulatory response?
Each practitioner can post a limitless number of posts per day on a number of social media platforms, and it is simply not practical to expect the regulatory bodies to monitor all the posts of all the practiser on all the sites at all times. A much more practical option is to regulate the providers of the platforms as to what posts and advertising they will be allowed to sell and display.
10. Please provide any further relevant comment in relation to the regulation of advertising.

Title protection and endorsement for approved areas of practice

11. To what extent would establishing an endorsement in relation to the practice of cosmetic surgery address relevant issues of concern in the sector (including patient safety issues)?
In the absence of recognising cosmetic surgery as a specialty, establishing an endorsement system, that allows practitioners to be recognised as cosmetic surgeons based on the number of procedures that they have performed or assisted at or directly observed, ie a competency-based register, is the only safe option for the consumers.

12. Would establishing an endorsement in relation to cosmetic surgery provide more clarity about the specific skills and qualifications of practitioners holding the endorsement?

As long as the endorsements are not based on lobbied self interests of particular specialties, then an endorsement system is second best option if recognition of cosmetic surgery as a specialty on its own stead is not on the agenda. Care much be taken not to allow any particular group to be allowed to assume competency in this field simply based on their name, and with no evidence to support their claim.

13. What programs of study (existing or new) would provide appropriate qualifications?

As a registered specialist plastic surgeon, one that has completed the optional 6 months trying in cosmetic surgery as part of the blast surgery training, I can say with certainty that in spite of their claims to the contrary, the plastic surgical training in no wise provides adequate training in cosmetic surgery. During my 5 year training, and the two extra years that I worked as unaccredited registrar in the field, having performed more than 4000 surgeries during my training, I can say that I did not perform a single cosmetic procedure during my training program, and witnessed less than 20 procedures in total. By necessity of the nature of the work carried out in public hospital settings, the same holds true for any and all hospital based surgical training programs that are currently recognised by the AMC as a specialist training programs. Currently, the only program dedicated to cosmetic surgery training is one offered by the Australian College of Cosmetic Surgery and Medicine.

14. Please provide any further relevant comment in relation to specialist title protection and endorsement for approved areas of practice relevant to cosmetic surgery.

I would urge the panelists to be mindful of [redacted] behaviour of some specialties in attempting to [redacted] the cosmetic industry under the [redacted]. One needs to only look at the [redacted] If patient safety is truely the centre of attention, then an endorsement system that is not based on the hospital-based training, but rather on actual cosmetic surgery experience, is the safest option for the patients.

Cooperation with other regulators

15. Are there barriers to effective information flow and referral of matters between Ahpra and the Medical Board and other regulators?

I am not aware of any such barriers.

16. If yes, what are the barriers, and what could be improved?

17. Do roles and responsibilities require clarification?

There are some state-based variations, but most practitioners have a good understanding of the role of each of the regulatory bodies.
18. Please provide any further relevant comment about cooperating with other regulators.

Facilitating mandatory and voluntary notifications

19. Do the Medical Board's current mandatory notifications guidelines **adequately explain the mandatory reporting obligations?**
The obligations are made clear in the guidelines and are regularly reinforced through medical board publications, and are reiterated by all medical defence organisations.
20. Are there things that prevent health practitioners from making notifications? If so, what?
I am not aware of any real barriers.
21. What could be improved to enhance the reporting of safety concerns in the cosmetic surgery sector?
If cosmetic surgery is recognised as a specialty the consumer will have a single point of contact to access information, assess the qualifications of their practitioner, and receive information about the pathways for making their concerns heard, as is the case with all other specialties in medicine through their respective colleges.
22. Please provide any further relevant comment about facilitating notifications

Information to consumers

23. Do the Medical Board's current codes and guidelines adequately describe the obligations of practitioners who perform cosmetic surgery to provide sufficient information to consumers and obtain informed consent?

The Codes and Guidelines describe the obligations well and are reasonably comprehensive.

24. If not, what improvements could be made?

Guidelines without support of a system that defines scope of practice for the practitioners is ultimately vulnerable to being sidelined.

25. Should codes or guidelines include a requirement for practitioners to explain to patients how to make a complaint if dissatisfied?

This requirement already exists through Australian Commission on Safety and Quality in Healthcare, for example:

https://www.safetyandquality.gov.au/sites/default/files/2022-01/my_healthcare_rights_-_flyer_for_consumers.pdf

26. In the context of cosmetic surgery, does the Ahpra website and public register of practitioners provide sufficient information about medical practitioners to inform consumer choices?

As Medical Board and AHPRA do not recognise cosmetic surgery as a specialty, and do not register Cosmetic Surgeon as a specialist title, their registry is of little use to consumers looking to assess the qualifications gf their practitioner in this field.

27. If not, what more could/should Ahpra and the Medical Board do to inform consumer choices?

The only way for the consumers to be able to use AHPRA registry of assessing the qualification of their practitioner in cosmetic surgery, is for the title of cosmetic surgeon to be recognised as a stand alone specialty and a protected title.

28. Is the notification and complaints process understood by consumers?

Most consumers are aware through the social media support groups, or advised by their legal representatives of the process of complaints.

29. If not, what more could/should Ahpra and the Medical Board do to improve consumer understanding?

30. Please provide any further relevant comment about the provision of information to consumers.

Further comment or suggestions

31. If you have any further comment relevant to Ahpra's and the Medical Board's regulation of cosmetic surgery including and/or suggestions for enhancements not mentioned in response to the above questions, please provide it here.

From:	Laurence Anderson
To:	Cosmetic Surgery Review
Subject:	cosmetic review
Date:	Wednesday, 9 March 2022 8:14:24 AM

Hi, the review's a good idea. I wrote a well-reviewed book on the subject: https://shop.mja.com.au/product/looking-good/

Yrs, Dr Laurence Anderson

From: Tassia
To: Cosmetic Surgery Review
Subject: AHPRA - Submission to the independent review on cosmetic surgery
Date: Sunday, 10 Apr I 2022 2:21:26 PM
Attachments: image001.png
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- Recently the Australian Medical Council, which is the body in charge of training doctors in Australia, has reported that plastic surgeons have a deficit in their cosmetic training and with the below facts it is easy to see why

In the cosmetic vs plastic turf war, it is important to understand the history and the difference between cosmetic and plastic surgery

The Difference Between Cosmetic and Plastic Surgery

Plastic or reconstructive surgery is to bring back to the normal e g an injury or a defect to make it normal again whereas cosmetic is to improve on the normal

Sir Harry Gillies, a New Zealand otolaryngologist is considered to be the father of modern day plastic surgery

Otolaryngology is the oldest medical specialty in the United States Otolaryngologists are physicians trained in the medical and surgical management and treatment of patients with diseases and disorders of the ear, nose, and throat (ENT)

During the First World War, Sir Gillies took great pity on soldiers who had been disfigured Some of these soldiers would not return home, as they did not want to distress their family at how badly they had been injured

Sir Harry Gillies employed the services of an American wax figure maker to mould faces that were lifelike for these young men He also embarked on the complex skin and muscle transfers to rebuild their face Unfortunately, the first patient died of an infection and he quickly learned that small procedures or steps done sequentially were the safest way to reconstruct some of these horrific injuries Sir Harry Gillies taught what he learnt widely to other surgeons and it was rumoured he was not included in the first plastic surgery college that was formed This was probably the beginning of the turf war with plastic surgeons vs ENT surgeons, general surgeons, orthopaedic hand surgeons and cosmetic surgeons

The reasons behind this are complex but include the fact that soft tissues are very hard to define or draw a boundary around unlike bones for an orthopaedic surgeon or the ears, nose and throat for an ENT surgeon Many orthopaedic surgeons perform hand surgery although in the earlier days they conflicted with plastic surgeons over this piece of surgical turf General surgeons that perform reconstructive breast surgery and plastic surgeons still have this ongoing conflict in some parts of the world

In a recent lecture by a well-known professor of plastic surgery, it was mentioned that the finger pointing between both groups should stop Probably the last turf war will be with the cosmetic surgeons

Cosmetic Surgery Training

During a Plastic Surgeon s training, there is an optional 6-month fellowship on Cosmetic Procedures A Cosmetic Surgeon who is an Australasian College of Cosmetic Surgery(ACCS) fellow undertakes 2 years of mandatory training in Cosmetic Surgery

Type of Surgeon	Minimum Years of Training
Cosmetic Surgeon 12 years **(ACCS Fellow)**	Bachelor of Medicine/Surgery 4-6 years 5 years postgraduate surgery experience **Mandatory 2 years** ACCS dedicated cosmetic surgery training
Plastic Surgeon 12 years **(RACS Fellow and Australian Society of Plastic Surgeons (ASPS) Member)**	Bachelor of Medicine/Surgery 4-6 years 5 years postgraduate surgery experience **Optional 6 months** ASPS dedicated cosmetic surgery training

A recent British journal article letter from a young plastic surgical trainee made it clear some of the problems that plastic surgeons have with the field of cosmetic surgery His main complaint was that he had received no training as a plastic surgeon trainee and this was widespread Most cosmetic surgery is performed in the private sector where plastic surgical training is not based

The British Association of Plastic Surgery stated on their website that the work of a plastic surgeon is predominantly non-cosmetic It must be asked, if the public has paid for plastic surgeons to be trained, should they be losing these reconstructive skills to cosmetic surgery that does not benefit society to the same degree As we are all aware there are long waiting lists for plastic reconstructive surgery and these will probably worsen the more plastic surgeons perform cosmetic surgery

In the turf war, there are many claims made that one should only see a plastic surgeon for this or that procedure A very honest American plastic surgeon admitted that she had performed a labiaplasty and had never been trained to do so! She also admitted many years later that she had only sat in for 5 days with gynaecologists to hone this procedure It must be asked how plastic surgeons can say that "you should only see a plastic surgeon for a cosmetic labiaplasty" when it is a well-known fact that a gynaecologist pioneered this procedure One plastic surgeon that is experienced in cosmetic surgery admitted that he had done most of his fellowship training with cosmetic surgeons When asked why he said they have the most experience and were full time in this area!

It is interesting to note that the use of the word cosmetic was rejected as part of the name for the plastic surgery society Some [redacted] plastic surgeons admit they looked down on cosmetic work and thought that reconstructive was the more important prestigious work to be performed

At [redacted] we have seen this first hand as a local plastic surgeon has asked to be trained in liposuction as he had never performed it in his training The optional cosmetic fellowship is as little as 6 months for a plastic surgeon

What many do not realise is that liposuction was first performed by a gynaecologist and was developed further by a dermatologist The tumescent method of liposuction was developed by a dermatologist

In our theatres, we have had both ENT, plastic and cosmetic surgeons, our theatre nurse said there was no difference in skill or knowledge A US study showed that plastic surgeons were performing too many different types of operations and losing their surgical identity When the general public was asked for examples of breast surgeons, skin surgeons etc plastic surgeons did not come to mind for the majority

It should also be noted eye surgeons or dermatological mohs surgeons do not have a Royal Australian College of surgery qualification but are experts in their field

The government advisor on PIP breast implants was a cosmetic surgeon, not a plastic surgeon A professor of cosmetic plastic surgery in England named him as one of the most experienced surgeons with polyurethane implants worldwide This plastic surgical professor is very fair and even-handed and recognises quality skills whether these come from cosmetic, plastic, ENT or general surgeons

In the recent PR turf war, the media has reported facts incorrectly The [redacted] breast clinic in the eastern states that had multiple cardiac arrests was developed and headed by a plastic surgeon, not cosmetic In Victoria, liposuction death was performed by a plastic surgeon, not cosmetic [redacted] cases where many cosmetic surgeons have performed as many as 7 or 8 thousand The recent Brazilian butt lift study that found that the death rate was 1 in 3000 was amongst plastic surgeons not cosmetic It must be asked why the media is making these omissions

Recently the turf war has extended between plastic surgeons [redacted] It was quite shocking to

see that payments were allegedly being made for bias

There are good and bad in all groups as most people are aware All procedures have complications and good aftercare limits these in most cases Being full time or spending the majority of a doctor s time in a particular field means more experience and practice which common sense tells us is important in performing a procedure

Codes and Guidelines

- These could indeed be improved Currently there is no recognised specialty of Cosmetic Surgery, nor can there be, without a change in the National Law Therefore no training programme is recognised by the AMC for cosmetic surgery, and the title “cosmetic surgeon” may be used by any medical practitioner Patients are at risk, because they are unable to identify if the doctor offering cosmetic surgery has the relevant *specific* training and skill Currently it is impossible to determine if a practitioner is operating within their scope of practice

- The Endorsement model for practitioners performing cosmetic surgery should be adopted to protect the public Those endorsed medical practitioners who have met a National Accreditation Standard should be on a public register
- This standard would ensure that practitioners not only have a core surgical competence, but also that they have reached an acceptable level of competence and skill *specifically* in Cosmetic surgery The practitioners would be required to be part of a recertification programme specific to cosmetic surgery To ensure patient safety, this model would need to be applied to *all doctors* who perform cosmetic surgery irrespective of their prior backgrounds

Title Protection and endorsement for approved areas of practice

- Establishing an endorsement model would essentially protect patients from adverse outcomes Those practitioners, who are endorsed to practice cosmetic surgery, would have the appropriate training and experience in cosmetic surgery This would be clear to patients, because there would be an AHPRA administered Cosmetic Surgery Register identifying doctors who are endorsed for cosmetic surgery Patients could then be rest assured that they are being treated by doctors who are operating within their scope of practice A title restriction should be linked to a competency-based accreditation Standard/Register as proposed by the College (ACCSM) by means of the Endorsement pathway provided for in Section 98 of National Law
- Establishing an endorsement model would provide clarity to the consumer, about the specific skills and qualifications of practitioners holding the endorsement It would identify those practitioners who have the core surgical training and competence, and *specific* cosmetic surgical training and competence as well as on-going professional education in cosmetic surgery
- The Australian College of Cosmetic Surgery and Medicine (ACCSM) is a well-recognised college, which has been established well over 30 years ago This college is well equipped to provide appropriate qualifications for those practitioners to be endorsed in Cosmetic Surgery and Medicine
- Specialist title protection is reserved for medical specialists who have been recognised by the AMC Until this point, Cosmetic surgery and Cosmetic Medicine have not been specialist pathways recognised by the AMC, because there is no burden of disease Failing being recognised by the AMC as a medical specialty, the endorsement model would be an appropriate way in which to regulate the cosmetic surgical industry The title Cosmetic Surgeon should be protected for those practitioners who have had specific recognised training in Cosmetic surgery It is clear that specialist surgeons as recognised by the AMC do not have specific training in Cosmetic Surgery and specialist plastic surgeons qualify with a gap in the area

Information to Consumers

- The Medical Board s current codes and guidelines do not specifically outline a practitioners training in cosmetic surgery Currently consumers are left in doubt as to whether their surgeon has had any *specific* training in cosmetic surgery, even if their surgeon is a specialist surgeon as recognised by the AMC
- If the endorsement model is adopted for cosmetic surgery, it would allow the public to identify doctors who are trained and competent in cosmetic surgery, provide protection for patients before something goes wrong, facilitate AHPRA taking action more readily against doctors who may be practicing outside of their scope of practice, and by being competency-based and independently set and assessed, be fair to all practitioners and not favour any particular group of doctors on the basis of their non-cosmetic surgical training and qualifications
- The AHPRA website, and public register of practitioners does not provide adequate information to consumers to safely choose their cosmetic surgeon There should be a list of endorsed practitioners available for consumers to readily identify those practitioners who are adequately trained in cosmetic surgery
- AHPRA could provide a register of identified practitioners who have the necessary training in cosmetic surgery to perform such procedures safely
- It should be clear to consumers which doctor is trained *specifically* in cosmetic surgery, irrespective of their other previous training

Further Comments of suggestions

It is vital that consumers are made aware of the *specific* experience and qualifications of their cosmetic surgeon, in order for them to make informed choices regarding their surgery and choice of surgeon I support the proposal for a national competency-based accreditation Standard for *all* doctors performing cosmetic surgery There should be a register of Endorsement of those who have met, and maintain the national standard Restriction of the title Cosmetic Surgeon should be applied to those medical practitioners who appear on the Register, administered by AHPRA Since the Australasian College of Cosmetic Surgery and Medicine is the *only* training body in Australia specifically focused on training practitioners in Cosmetic Medicine and Surgery, this college would be best equipped to train practitioners and enable them to maintain their level of competence and skill

Warm Regards

Tassia Anderson

[redacted]

From: [redacted]
To: Cosmetic Surgery Review
Subject: Anonymous not Spam - Independent review of the regulation of health practitioners in cosmetic surgery
Date: Wednesday, 20 April 2022 9:47:40 AM

Dear Sir/Madam,

Thank you for the chance for feedback upon this issue and the greater issues of misrepresentation and possible unsafe medical practice.

My concern with the entire post undergrad training is that for years the Australian Medical Council (AMC) regulated the colleges and only Doctors passing colleges accredited to the standard of the AMC credentialing were regarded as Specialists in a field.

These doctors had extended training with supervision to ensure they had gained enough experience and had robust during-training assessment and formal peer-reviewed examination. Each training rotation required emergency cover so as to learn emergency medical care and clinics/cases to be of significant number and diversity to cover the curriculum.

Each AMC-accredited college has several members whose sole role is to ensure standard at a cost to the college and members. But as it ensures standards it not the cost that is a concern, the intrinsic need to stay to the safe AMC standard.

Nowadays, non-AMC regulated "colleges" are providing their "graduates" the ability to be called "specialists" in a field. These "colleges" do not provide any supervised training or examination at the standard of the AMC colleges. Often the course is a weekend course or an online program of various quality.

[redacted]

This is where the issues comes. Inexperienced doctors who are not ever held to any examination or hand on experience are selling people lies about their level of skill and their level of skill is delivering substandard care. This effects people and their health.

Many say that experience in the field makes up for the difference in training. But like the saying goes - experience without training is just making the same mistake with increasing confidence.

TO BE PROACTIVE, I would recommend APHRA to investigate "Skin Cancer Doctors" who are just GPs who are attending non-AMC accredited colleges and completing simple courses and then are calling themselves "Skin Specialists" or "Skin Cancer Doctors". The absence of good training often leads to over servicing (with the cost going to Medicare) and unnecessary and elaborate treatments which are not required with increased morbidity and mortality.

Proper training with AMC training colleges allows better diagnosis of skin disease and the

appropriate treatment option and the execution of this option.

The amount of times a patient who is referred to me for a skin check having been to a "Skin Cancer Specialist" who is shocked to hear that a biopsy is not needed or treatment is not needed after being reviewed is shocking - they are being over-serviced for the sake of medical rebate or because the doctor is substituting investigation at the cost of Medicare for their absence in training.

Patients also think that "skin cancer doctors" are dermatologists as dermatologists are specialists in skin medicine and these gps are calling themselves "Skin specialists" so they must also be dermatologists. The are being advised medical advise without formal dermatology training.

PLEASE BE PROACTIVE AND PREVENT ANOTHER 4 CORNERS SCANDAL by addressing "SKIN CANCER DRs" now before patients are negatively impacted. This is not about protecting work it is about standards.

The AMC needs to regulate these colleges or APHRA needs to not allow non-AMC college taught doctors to sell the lie of them having any speciality training. If you are trained as a GP with an interest in field, it does not make you a Specialist in that field.

Kind regards

Concerned

Response template for submissions to the *Independent review of the regulation of medical practitioners who perform cosmetic surgery*

You are invited to have your say about the regulation of medical practitioners (doctors) who perform cosmetic surgery by making a submission to this independent review.

The consultation questions from the consultation paper are outlined below. Submissions can address some or all of these questions, and you can include any evidence or examples that you think are relevant.

Submissions can be emailed to:

Mr Andrew Brown, Independent Reviewer
marked '*Submission to the independent review on cosmetic surgery*' at CSReview@ahpra.gov.au.

The closing date for submissions is 5.00pm AEST 14 April 2022.

Your details

Name	Dr Masood Ali Ansari
Organisation (if applicable)	My Cosmetic Clinic
Email address	[redacted]

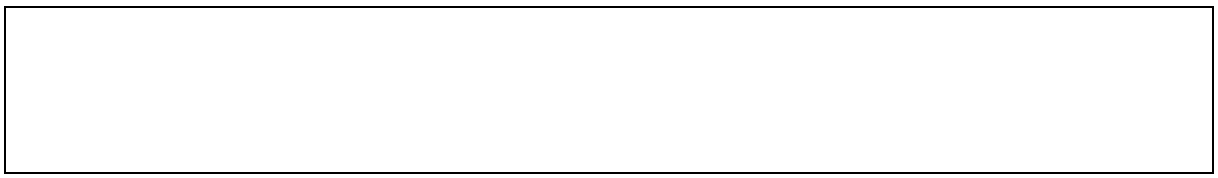
Your responses to the consultation questions

Codes and Guidelines

1. Do the current *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures* adequately address issues relevant to the current and expected future practice of cosmetic surgery and contribute to safe practice that is within a practitioner's scope, qualifications, training and experience?
1. These could indeed be improved. Currently there is no recognised specialty of Cosmetic Surgery, nor can there be, without a change in the National Law. Therefore no training programme is recognised by the AMC for cosmetic surgery, and the title "cosmetic surgeon" may be used by any medical practitioner. Patients are at risk, because they are unable to identify if the doctor offering cosmetic surgery has the relevant *specific* training and skill. Currently it is impossible to determine if a practitioner is operating within their scope of practice.
2. What changes are necessary and why? What additional areas should the guidelines address to achieve the above purpose?
1. The Endorsement model for practitioners performing cosmetic surgery should be adopted to protect the public. Those endorsed medical practitioners who have met a National Accreditation Standard should be on a public register.
3. Please provide any further comment in relation to the use of codes and guidelines relevant to the practice of cosmetic surgery.
1. This standard would ensure that practitioners not only have a core surgical competence, but also that they have reached an acceptable level of competence and skill *specifically* in Cosmetic surgery. The practitioners would be required to be part of a recertification programme specific to cosmetic surgery. To ensure patient safety, this model would need to be applied to *all doctors* who perform cosmetic surgery irrespective of their prior backgrounds.

Management of notifications

4. Having regard to Ahpra and the Medical Board's powers and remit, what changes do you consider are necessary to the approach of Ahpra and the Medical Board in managing cosmetic surgery notifications, including their risk assessment process, and why?
5. Please provide any further relevant comment in relation to the management of notifications about medical practitioners involved in cosmetic surgery.



Advertising restrictions

6. Is Ahpra and the Medical Board's current approach to regulating advertising in cosmetic surgery sufficient?
7. What should be improved and why and how?
8. Do the current Guidelines for advertising a regulated health service adequately address risks in relation to advertising of cosmetic surgery, or is a more specific regulatory response required?
9. Does the promotion of cosmetic surgery via social media raise any issues that are not adequately addressed by the advertising guidelines, or that require any specific regulatory response?
10. Please provide any further relevant comment in relation to the regulation of advertising.

Title protection and endorsement for approved areas of practice

11. To what extent would establishing an endorsement in relation to the practice of cosmetic surgery address relevant issues of concern in the sector (including patient safety issues)?
. Establishing an endorsement model would essentially protect patients from adverse outcomes. Those practitioners, who are endorsed to practice cosmetic surgery, would have the appropriate training and experience in cosmetic surgery. This would be clear to patients, because there would be an AHPRA administered Cosmetic Surgery Register identifying doctors who are endorsed for cosmetic surgery. Patients could then be rest assured that they are being treated by doctors who are operating within their scope of practice. A title restriction should be linked to a competency-based accreditation Standard/Register as proposed by the

College (ACCSM) by means of the Endorsement pathway provided for in Section 98 of National Law.

12. Would establishing an endorsement in relation to cosmetic surgery provide more clarity about the specific skills and qualifications of practitioners holding the endorsement?
Establishing an endorsement model would provide clarity to the consumer, about the specific skills and qualifications of practitioners holding the endorsement. It would identify those practitioners who have the core surgical training and competence, and *specific* cosmetic surgical training and competence as well as on-going professional education in cosmetic surgery.
13. What programs of study (existing or new) would provide appropriate qualifications?
13. The Australian College of Cosmetic Surgery and Medicine (ACCSM) is a well-recognised college, which has been established well over 30 years ago. This college is well equipped to provide appropriate qualifications for those practitioners to be endorsed in Cosmetic Surgery and Medicine.
14. Please provide any further relevant comment in relation to specialist title protection and endorsement for approved areas of practice relevant to cosmetic surgery.
Specialist title protection is reserved for medical specialists who have been recognised by the AMC. Until this point, Cosmetic surgery and Cosmetic Medicine have not been specialist pathways recognised by the AMC, because there is no burden of disease. Failing being recognised by the AMC as a medical specialty, the endorsement model would be an appropriate way in which to regulate the cosmetic surgical industry. The title 'Cosmetic Surgeon' should be protected for those practitioners who have had specific recognised training in Cosmetic surgery. It is clear that specialist surgeons as recognised by the AMC do not have specific training in Cosmetic Surgery and specialist plastic surgeons qualify with a 'gap' in the area.

Cooperation with other regulators

15. Are there barriers to effective information flow and referral of matters between Ahpra and the Medical Board and other regulators?
16. If yes, what are the barriers, and what could be improved?
17. Do roles and responsibilities require clarification?

18. Please provide any further relevant comment about cooperating with other regulators.

Facilitating mandatory and voluntary notifications

19. Do the Medical Board's current mandatory notifications guidelines **adequately explain the mandatory reporting obligations?**
20. Are there things that prevent health practitioners from making notifications? If so, what?
21. What could be improved to enhance the reporting of safety concerns in the cosmetic surgery sector?
22. Please provide any further relevant comment about facilitating notifications

Information to consumers

23. Do the Medical Board's current codes and guidelines adequately describe the obligations of practitioners who perform cosmetic surgery to provide sufficient information to consumers and obtain informed consent?

The Medical Board's current codes and guidelines do not specifically outline a practitioners training in cosmetic surgery. Currently consumers are left in doubt as to whether their surgeon has had any *specific* training in cosmetic surgery, even if their surgeon is a specialist surgeon as recognised by the AMC.

24. If not, what improvements could be made?

If the endorsement model is adopted for cosmetic surgery, it would allow the public to identify doctors who are trained and competent in cosmetic surgery, provide protection for patients before something goes wrong, facilitate AHPRA taking action more readily against doctors who may be practicing outside of their scope of practice, and by being competency- based and independently set and assessed, be fair to all practitioners and not favour any particular group of doctors on the basis of their non-cosmetic surgical training and qualifications

25. Should codes or guidelines include a requirement for practitioners to explain to patients how to make a complaint if dissatisfied?

26. In the context of cosmetic surgery, does the Ahpra website and public register of practitioners provide sufficient information about medical practitioners to inform consumer choices?

The AHPRA website, and public register of practitioners does not provide adequate information to consumers to safely choose their cosmetic surgeon. There should be a list of endorsed practitioners available for consumers to readily identify those practitioners who are adequately trained in cosmetic surgery.

27. If not, what more could/should Ahpra and the Medical Board do to inform consumer choices?

AHPRA could provide a register of identified practitioners who have the necessary training in cosmetic surgery to perform such procedures safely

28. Is the notification and complaints process understood by consumers?

29. If not, what more could/should Ahpra and the Medical Board do to improve consumer understanding?

30. Please provide any further relevant comment about the provision of information to consumers.
It should be clear to consumers which doctor is trained *specifically* in cosmetic surgery, irrespective of their other previous training.

Further comment or suggestions

31. If you have any further comment relevant to Ahpra's and the Medical Board's regulation of cosmetic surgery including and/or suggestions for enhancements not mentioned in response to the above questions, please provide it here.
It is vital that consumers are made aware of the *specific* experience and qualifications of their cosmetic surgeon, in order for them to make informed choices regarding their surgery and choice of surgeon. I support the proposal for a national competency-based accreditation Standard for *all* doctors performing cosmetic surgery. There should be a register of Endorsement of those who have met, and maintain the national standard. Restriction of the title 'Cosmetic Surgeon' should be applied to those medical practitioners who appear on the Register, administered by AHPRA. Since the Australasian College of Cosmetic Surgery and Medicine is the *only* training body in Australia specifically focused on training practitioners in Cosmetic Medicine and Surgery, this college would be best equipped to train practitioners and enable them to maintain their level of competence and skill.

Response template for submissions to the *Independent review of the regulation of medical practitioners who perform cosmetic surgery*

You are invited to have your say about the regulation of medical practitioners (doctors) who perform cosmetic surgery by making a submission to this independent review.

The consultation questions from the consultation paper are outlined below. Submissions can address some or all of these questions, and you can include any evidence or examples that you think are relevant.

Submissions can be emailed to:

Mr Andrew Brown, Independent Reviewer
marked '*Submission to the independent review on cosmetic surgery*' at CSReview@ahpra.gov.au.

The closing date for submissions is 5.00pm AEST 14 April 2022.

Your details

Name	Dr Yves Saint James Aquino
Organisation (if applicable)	Australian Centre for Health Engagement, Evidence and Values, University of Wollongong
Email address	[redacted]

Your responses to the consultation questions

Codes and Guidelines

1. Do the current *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures* adequately address issues relevant to the current and expected future practice of cosmetic surgery and contribute to safe practice that is within a practitioner's scope, qualifications, training and experience?

No. The reasons below will be elaborated in the answers in the succeeding questions.

- The guideline fails to recognise that cosmetic practices are commercial in nature and is primarily driven by service providers, and not always sought by service consumers.
- The guideline contributes to the misconception that cosmetic procedures are or can be therapeutic, which contradicts the guidelines' proposed definition of cosmetic procedure. In addition, medicalising terminologies such as "patient" may not be appropriate in the context of this commercial practice, and "service user" may be more appropriate.
- The guideline does not respond to the trend that some service workers are training overseas, and claiming new expertise without necessarily going through accreditation locally.

2. What changes are necessary and why? What additional areas should the guidelines address to achieve the above purpose?

I suggest making some changes in terminologies and definitions. In page 2, "cosmetic medical and surgical procedures" should be labelled as "invasive and non-invasive cosmetic procedures" to minimise the misconception that these procedures are therapeutic or necessary. In the same page, the definition should be modified: "the dominant purpose of achieving that what the patient or cosmetic service provider perceives to be a more desirable appearance … and so on." The suggested change recognises that cosmetic industry is commercial in nature, and services are often driven by service providers and not always sought by consumers themselves. In the same page, the paragraph on medically justified procedures contradict the very definition stated, as these procedures are considered therapeutic or reconstructive (ie damage or defect due to injury, disease or developmental problems are not "normal bodily features".)

For the rest of the document, I would suggest using the term service consumer rather than patients. The term patient should be reserved for those visiting medical clinics or hospital institutions for medical purposes.

Page 5: Training, experience and qualifications: The guideline should be clearer about what evidence should be presented by service providers (certificates?). Will international or non-Australian training be recognised?

3. Please provide any further comment in relation to the use of codes and guidelines relevant to the practice of cosmetic surgery.

- Guidelines are very important in ensuring quality, safety and standards of practice; as well as provide guidance to practitioners. However, guidelines are not designed to be punitive in cases when service providers or workers violate any of the stated items. It must be clear then within the guideline what frameworks exist outside the guideline that could provide information for malpractice (good example provided is TGA evaluation of advertising materials).

Management of notifications

4. Having regard to Ahpra and the Medical Board's powers and remit, what changes do you consider are necessary to the approach of Ahpra and the Medical Board in managing cosmetic surgery notifications, including their risk assessment process, and why?

The stated regulatory roles of both Ahpra and the Medical Board are very clear and appropriate. However, Ahpra and Medical Board should have a clearer stance on who can practice cosmetic services, as at the moment it is not very clear.

Another complexity arising from cosmetic procedures is that there are very few gold standards of practice because we are dealing with services that are not therapeutic, and are dependent of preference and taste of either the consumer or the service provider. The implication of this complexity is the challenge of Ahpra and Medical Board in setting standards or criteria on what counts as "unsatisfactory" or "poorly undertaken". In addition, are there any time limits for complaints, noting that post-procedure regrets have been reported among very young service consumers of cosmetic procedures.

5. Please provide any further relevant comment in relation to the management of notifications about medical practitioners involved in cosmetic surgery.

Each service provider location should be required to inform consumers that they can report problems or concerns to your organisations.

Advertising restrictions

6. Is Ahpra and the Medical Board's current approach to regulating advertising in cosmetic surgery sufficient?
I believe it's the best it could possibly be. But again, since cosmetic procedures, motivations and outcomes, are very subjective, it would be difficult to set standards for what counts as "false" or "deceptive" information.
7. What should be improved and why and how?
Advertising materials should include information or link to Ahpra/Medical Board website, to encourage the public in reporting problematic advertisements.
8. Do the current Guidelines for advertising a regulated health service adequately address risks in relation to advertising of cosmetic surgery, or is a more specific regulatory response required?
The nature of cosmetic services is very subjective and should have its own guideline. It's a domain where unreasonable expectation is common. In addition the phrase "indirectly encourages the indiscriminate or unnecessary use of regulated health services" is odd when talking about cosmetic services, which are arguable unnecessary (in a medical sense).
9. Does the promotion of cosmetic surgery via social media raise any issues that are not adequately addressed by the advertising guidelines, or that require any specific regulatory response?
Yes, social media is problematic because it tends to skip approval from authorities.
10. Please provide any further relevant comment in relation to the regulation of advertising.

Title protection and endorsement for approved areas of practice

11. To what extent would establishing an endorsement in relation to the practice of cosmetic surgery address relevant issues of concern in the sector (including patient safety issues)?
My concern about endorsement is that it can perpetuate the misconception that cosmetic services are necessary medical procedures, along the lines of reconstructive surgeries and such. Yes, it can promote safety, but that can be done without endorsement. For example, consumer protection is upheld in other non-medical but peripheral industries (cosmetic products for example) without the need for the service to fall under Ahpra.

12. Would establishing an endorsement in relation to cosmetic surgery provide more clarity about the specific skills and qualifications of practitioners holding the endorsement?
I still disagree with the endorsement, but if it must be done, then there should be consistency in language used to delineate cosmetic services as commercial services and not medical services. Use “cosmetic services” instead of “cosmetic surgery”; use “service provider” instead of “cosmetic surgeon”; use consumer instead of patient.
13. What programs of study (existing or new) would provide appropriate qualifications?
The programs of study should include medical ethics, which can help clarify the nuances of cosmetic services and responsibilities of service providers that are not typically covered in mainstream medical education.
14. Please provide any further relevant comment in relation to specialist title protection and endorsement for approved areas of practice relevant to cosmetic surgery.

Cooperation with other regulators

15. Are there barriers to effective information flow and referral of matters between Ahpra and the Medical Board and other regulators?
16. If yes, what are the barriers, and what could be improved?
17. Do roles and responsibilities require clarification?
18. Please provide any further relevant comment about cooperating with other regulators.

Facilitating mandatory and voluntary notifications

19. Do the Medical Board's current mandatory notifications guidelines **adequately explain the mandatory reporting obligations?**
20. Are there things that prevent health practitioners from making notifications? If so, what?
21. What could be improved to enhance the reporting of safety concerns in the cosmetic surgery sector?
22. Please provide any further relevant comment about facilitating notifications

Information to consumers

23. Do the Medical Board's current codes and guidelines adequately describe the obligations of practitioners who perform cosmetic surgery to provide sufficient information to consumers and obtain informed consent?
The current codes and guidelines have clear information on the responsibility of service providers to provide sufficient information to consumers and obtain informed consent. However, the very nature of cosmetic procedures is that they are often not evidence-based, and there are few studies investigating long-term impact of such procedures. Such nature complicates how much patients are really protected when the evidence is missing or unreliable.
24. If not, what improvements could be made?
25. Should codes or guidelines include a requirement for practitioners to explain to patients how to make a complaint if dissatisfied?

Definitely. At leas include in advertising materials or in patient consent form the link to websites for information about safety or for information about complaints.

26. In the context of cosmetic surgery, does the Ahpra website and public register of practitioners provide sufficient information about medical practitioners to inform consumer choices?
Yes, I believe so.
27. If not, what more could/should Ahpra and the Medical Board do to inform consumer choices?
28. Is the notification and complaints process understood by consumers?
29. If not, what more could/should Ahpra and the Medical Board do to improve consumer understanding?
30. Please provide any further relevant comment about the provision of information to consumers.

Further comment or suggestions

31. If you have any further comment relevant to Ahpra's and the Medical Board's regulation of cosmetic surgery including and/or suggestions for enhancements not mentioned in response to the above questions, please provide it here.
This is a great and much-needed initiative to respond to issues raised by cosmetic services within the healthcare context. I'm a medical ethicist who did a PhD research on the ethics of cosmetic surgery, and would welcome further discussion with your organisation about my findings. I can send my publications if needed.

From: Jeremy Archer
To: Cosmetic Surgery Review
Subject: "Submission to the independent review on cosmetic surgery"
Date: Saturday, 12 March 2022 6:54:09 PM

Dear AHPRA

Thank you for seeking feedback on this issue.

Cosmetic surgical procedures (all of which by definition are non-essential) beyond the most basic superficial subcutaneous level procedures, should be performed by those who have undergone extensive in hospital surgical training (ie. 3+ years as a surgical registrar in which at least 2 years is at a major tertiary institution).
Breast, abdominal, facial, reconstructive surgery should not be performed by just any medical graduate who deems themselves to be able to do the procedure. This is a huge "stain" on our profession.
Because 95%+ of anaesthetists recognise the inappropriateness of the so called "cosmetic surgeons" performing surgery, the anaesthetic for these procedures is frequently also provided by unsuitably trained doctors, creating additional risk.
Because 95%+ of hospital operators also recognise the inappropriateness of the so called "cosmetic surgeons" performing surgery, the procedures and the anaesthetic are also frequently performed in operating rooms, outside of hospitals, that are not at all suitable for such procedures.

This practice should be stopped immediately, pending further review.

Thank you,
Dr Jeremy Archer
VMO Anaesethetist
ANZCA, MBChB
Med registration number: MED0001200436

Submission to the Independent Review on Cosmetic Surgery

Cosmetic Practice
A Roadmap to better Regulation of the Industry

Professor Mark Ashton
Clinical Professor, University of Melbourne, Chair Plastic Surgery Epworth Freemasons Hospital
Past President, Australian Society of Plastic Surgeons

Professor Anand Deva
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Director, Integrated Specialist Healthcare Education and Research Foundation

APRIL 2022

Cosmetic Practice – A Roadmap to Better Regulation of the Industry

Historical context

Whilst reconstructive plastic surgical techniques have been described for centuries, the birth of modern cosmetic surgical practice has its origins in the treatment of facial trauma in the First World War. New techniques developed to treat the mutilating facial trauma encountered in returning soldiers from trench warfare were quickly realized to have an application in the wider public. In small private clinics, rich aristocrats and movie stars sought out the eminent surgeons proficient in these new techniques to alter their facial appearance[1]. Sir Harold Gillies, a New Zealander, is credited as one of the pioneers of this new and emerging specialty – Plastic Surgery - derived from Greek, *Plastikos,* to mould[2]. As time progressed, the demand for these procedures grew exponentially. However, they were not without risk and indeed, our very own Dame Nellie Melba was said to have suffered significant and ultimately fatal sepsis following a facelift[3].

Toward the end of our last century, an improved understanding of anatomy and refinements in reconstructive surgery techniques led to commensurate improved and predicable outcomes in cosmetic surgery. As an example, in the 1950s and 60s, advances in surgical anatomy, particularly vascular anatomy directly influenced techniques for breast reduction[4] and abdominoplasty (tummy tuck) [5]. The publication of large series of patients undergoing these procedures with improved outcomes have now established them as mainstream.
Later, the development of new implantable materials such as plastic and silicone allowed for the first time, a vast array of foreign devices to be used in medicine. In the 1960s, the manufacture of medical grade silicone allowed the development of breast implants[6]. While these novel implants heralded a new paradigm in cosmetic surgery when used for breast enlargement, they were not without controversy. From the very outset, the use of breast implants for augmentation has had a chequered regulatory history. Despite this, up until the recent impact of the COVID19 pandemic, breast augmentation using silicone breast implants was the number 1 cosmetic surgery procedure worldwide, and had been so for over a decade[6].

The use of liposuction to remove unwanted fat had its origins in the 1920s but was not well described until the 1980s, when better instrumentation and the use of a new type of regional anaesthesia called tumescent infiltration was described[7,8]. "Tumescent local anaesthetic infiltration" involves the preoperative infiltration of large volumes of a dilute local anaesthetic and adrenaline solution into the surgical area. It resulted in a significant decrease in blood loss, and for the first time, allowed the procedure to be performed as an ambulatory outpatient operation without the need for a general anaesthetic, making liposuction safer and more accessible.

In 1981, cosmetic soft tissue augmentation using the injection of bovine collagen was introduced. Because of allergic reactions to the bovine collagen, an alternative product was required, and now this augmentation is almost exclusively performed using a naturally occurring biological sugar called hyaluronic acid [9]. Simultaneously, research into botulinum toxin which was then being used to treat muscle spasm in patients with cerebral palsy[9], expanded its use into the cosmetic treatment of frown lines. Paralleling the translation of

reconstructive surgical techniques used to treat WW1 soldiers into the surgically treatment of facial ageing in the 1920's, the use of botulinum toxin has been similarly translated into the cosmetic treatment of naturally occurring facial ageing wrinkles.

These two procedures, the injection of hyaluronic acid for soft tissue augmentation, and the injection of botulinum toxin to reduce or eliminate naturally occurring frown lines, are now the most common cosmetic procedures performed world-wide. Because they can be performed without surgery, they have been marketed to the general public on a commercial mass scale, often without the regulatory checks and training required in traditional surgical practice.

Despite its very real, and well documented risk of instantaneous and permanent blindness[10], hyaluronic acid soft tissue augmentation is mostly performed in shopping centres or small cosmetic clinics by nursing staff, or medical practitioners with only a basic registration and with no, or at most, basic, knowledge of the critically important vascular anatomy. And people have gone blind, unaware of the risk. More than ever, the rapid proliferation of poorly trained practitioners performing this high-risk procedure in poorly equipped facilities highlights the pressures faced by regulators in keeping up with this rapidly changing environment and the to date, failure, of the existing regulations to adequately protect the public.

This new form of cosmetic practice, encompassing surgical and non-surgical interventions, has undergone rapid and exponential growth in demand over the last decade and is predicted to reach a total value of $66.96 billion by 2027 in the United States alone [11]. That is, in less than five years time.

This growth has been fueled by an increasing acceptance of these procedures in society, medical tourism, media fascination with body and facial transformation, availability of disposable income (and access to cheap finance) and the growth of competition and clinic chains that have lowered entry price and the translation of more aggressive commercially based sales and marketing strategies into medical care.

Cosmetic interventions - statistics

Table 1 lists the top 5 surgical and non-surgical cosmetic treatments in the United States in 2020.

Rank	Cosmetic Surgery	Cosmetic Treatment
1	Nose reshaping	Botulinum Toxin Type A
2	Eyelid surgery	Soft tissue fillers
3	Facelift	Laser resurfacing
4	Liposuction	Chemical Peel
5	Breast augmentation	Intense Pulsed Light

Commercial drivers and ethics in Cosmetic practice

The schism between what should be and what actually occurs in the marketplace in Cosmetic practice can be explained by the inherent tension between the pull of commercial forces and the need for the highest standards of ethical and safe practice[12]. In some instances, the two forces work together as patients become better informed to seek out practitioners and practices who practice with an appropriate level of skill and care. In some instances, however, the need to generate a profit, leads to unsubstantiated claims, underskilled and dangerous practice and poor outcomes, morbidity and in rare circumstances, mortality.

Ethical conflicts related to the discretionary, commercial and elective nature of cosmetic interventions have been well described[13]. In landmark essays on ethics and Plastic surgery, C.M. Ward concluded that ethical scenarios share one common theme – "the patient should have the final authority to decide"[14]. The four principles of medical ethics include 1. Respect for the autonomy of the patient 2. Beneficence or promoting what is best for the patient 3. Nonmaleficence – do no harm 4. Justice. Related to this are principles of disclosure and informed consent. It is easy to see how in cosmetic treatments, the promotion of a particular procedure or practitioner, downplaying of risks, use of suggestive images to entice patients, organising of cheap finance options and/or access to superannuation funds and failure to properly disclose financial or other conflicts of interest would breach these ethical principles on many levels.

As the regulator of all medical practice and practitioners, the Australian Health Practitioner Regulation Agency (AHPRA) should always ensure that patients interests, and safety are protected. The move of cosmetic practice out of the fringes of medicine into a more regulated and traditional practice of medicine, backed by good clinical evidence, will ultimately support a legitimate way toward improving the quality of patients' lives that can achieve safe, predictable and satisfactory outcomes in the majority of cases.

Table 2: key differences between Cosmetic Practice and Mainstream Medical Practice

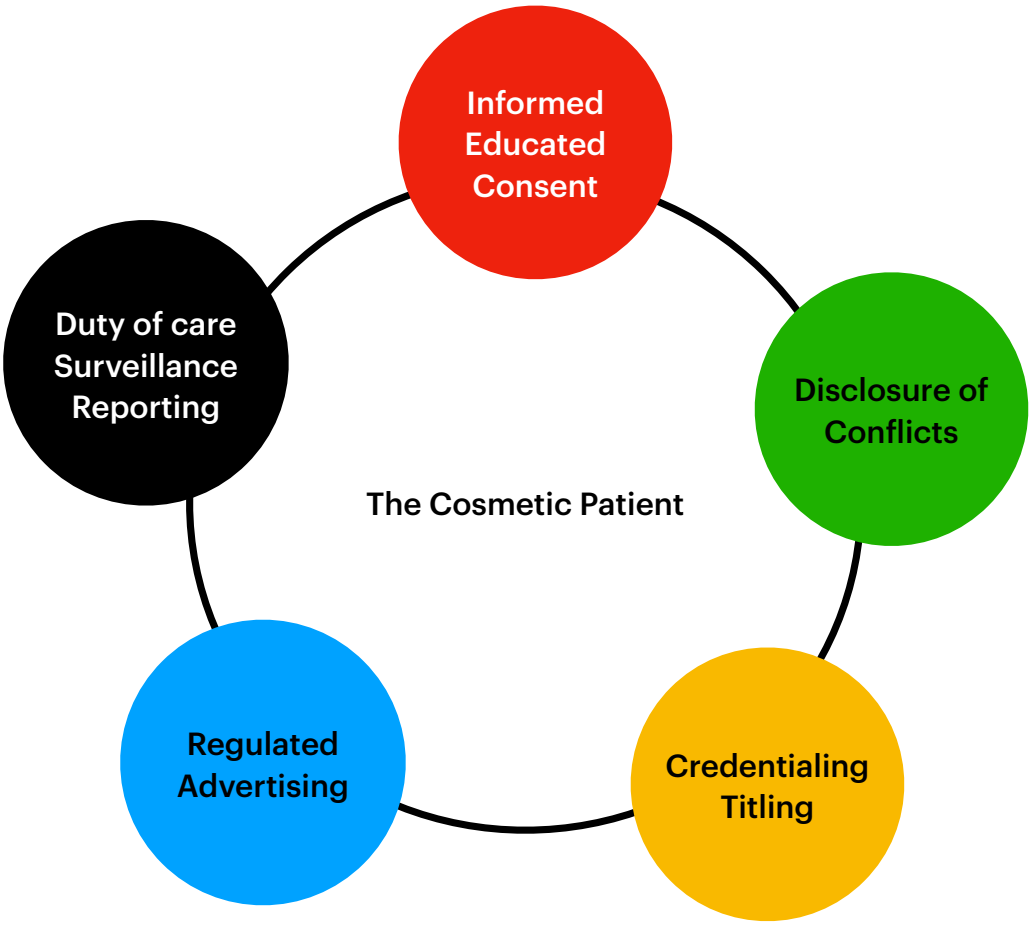
Cosmetic Practice	**Mainstream Medical Practice**
Market and sales driven	Outcome driven
Commercial gain	Patient gain
Discretionary	Needed to improve Quality of Life or treatment of life-threatening illness
Poor credentialing, regulation	Highly regulated, recognized credentialing
Poorly defined scope of practice, lack of audit and peer review	Well defined scope of practice, audit and peer review and quality control
Overlap with beauty and wellness industry e.g., medispa, conducted in variety of premises with lack of standardization of standards and licensing	Conducted in recognized health facilities, governed by strict standards and licensing

Roadmap to reform in Cosmetic Practice

The approach to reform in cosmetic practice requires five key areas to be addressed:

1. Informed (educated) consent
2. Declaration of Commercial Conflicts of Interest
3. Credentialing and Titling
4. Advertising in Cosmetic Practice
5. Ongoing duty of care, Surveillance, and Reporting of adverse events

Figure 1: the Roadmap to Reform in Cosmetic Practice



The context of each of these five areas will be summarised, outlining current deficiencies and propose suggested strategies to address these deficiencies in turn.

1. Informed Educated Consent

Every patient undergoing a medical or surgical intervention has to give their informed consent[15], which must be documented as part of the medical record. This is traditionally given during a pre-operative consultation after a discussion between proceduralist and patient and confirmed with a signature of patient (or proxy) and the clinician (or witness). The details of the procedure and risks that are explained to the patient are usually also documented in the patient's medical record. The ethically valid process of informed consent includes five elements : voluntarism, capacity, disclosure, understanding and decision[15]. Many studies have shown that whilst documentation of the process may be completed, the patient's knowledge of risk and benefit of a proposed medical treatment and the ability for the patient to withdraw consent for the intervention at any time was not well understood[16]. Ingelfinger wrote in 1972 that "the trouble with informed consent is that it is not educated consent"[17]. In cosmetic surgery and medicine, the stakes are raised higher, as the proposed treatments are both elective and discretionary.

The Agency for Clinical Innovation (NSWHealth) has recently released a toolkit for the management of breast implants, which outlines a specific process of clinical assessment and a proposed informed educated consent checklist for women who are considering cosmetic breast augmentation (see Appendix 1)[18].

Similar frameworks for the process of both informed and educated consent should be formalized and instituted for all areas of Cosmetic practice. Principles that would support the consent tool include;

1. Empowerment of patients and encouragement of shared and protected decision making with, where possible, multiple time points for discussion
2. Education of patients about risks, benefits, and alternatives for treatment. In the case of cosmetic treatments, the option of not proceeding with the elective and discretionary intervention should be discussed at multiple time points prior to surgery with a mandatory cooling off period prior to signing up for a treatment.
3. Management of patient uncertainty and anxiety
4. Providing options and choice for a variety of treatments
5. Outlining ongoing duty of care and post-operative surveillance

The use of customised checklists that are simple, easy to comprehend and are performed twice with the treating practitioner (as opposed to a proxy) would be a good first step and preferably this consultation would be performed face to face with the patient (rather than through telehealth). The use of a mandatory cooling off period between the first and second reading of this checklist, would ensure that patients are given the time and space to better understand a proposed cosmetic intervention and offered the opportunity to return to ask questions of the treating practitioner.

Proposed reform 1

Development of customised informed educated consent checklists for common cosmetic medical and surgical interventions to be discussed between patient and treating practitioner face to face at two separate consultations with an intervening mandatory cooling off period.

2. Declaration of Commercial Conflicts of Interest

There has been much written about potential conflicts of interest and the relationship between the medical profession and industry[19]. There is little doubt of the existence of a conflict of interest when the doctor derives a direct financial benefit (e.g., royalty payments, ownership of shares in a particular medical company) through recommending a particular medical product or treatment to a patient. A particular cosmetic treatment or device e.g., particular brand of breast implant, may be recommended over alternatives because of commercial arrangements between the supplier and the practice such as competitive pricing. A particular resurfacing device may be recommended over another because the practice has just acquired the device and has to justify the expenditure or lease of the equipment. There are also financial conflicts inherent in a for-profit private practice. Advice given to patients to encourage them to undergo a higher fee-paying procedure, discounts for early sign up for a procedure, failure to provide non-operative or alternative methods of achieving a particular outcome and minimising or omitting to discuss risks are other means of ensuring that the practitioner or practice secures higher revenue and return by recommending and proceeding with a particular cosmetic intervention.

Proposed reform 2

In the setting of a proposed cosmetic treatment, disclosures of financial conflicts of interest for both the practitioner and practice and beneficial commercial arrangements with a particular medical supplier or finance supplier should be disclosed to the patient in writing at the time of initial consultation and prior to patient consenting to undergo cosmetic treatment.

3. Credentialing and titling

In Australia, the Australian Health Practitioner Regulation Agency (AHPRA), records and regulates the registration and practice of appropriately qualified health professionals and also deems if a particular practitioner holds specialist registration in a defined and structured way in line with recognized credentialing for specialist medical or surgical practice. Additional "Specialist" registration beyond basic, or "General" medical training is certified by the relevant college responsible for delivering that advanced training, examination and certification of the practitioner to a pre-determined standard set by the independent Australian Medical Council (AMC). In order to maintain specialist registration, the practitioner needs to ensure that he/she maintains ongoing education and audit/peer review of his/her practice. The standard and scope of this *continuing professional development*, or CPD, is also set by the AMC. Specialist medical practitioners must adhere to their scope of practice, and

enforcement of this scope of practice is delivered by the relevant AMC Accredited College and by the individual hospital's Medical Board at which the medical practitioner operates.

As we stated above, many cosmetic surgical procedures can be performed in an ambulatory setting, outside licensed hospitals, in some jurisdictions. In such circumstances, the oversight and regulation of a medical practitioner's scope of practice, audit, credentialing and CPD is not subject to the same scrutiny and rigour that would ordinarily occur, should that practitioner have performed the exact same procedure inside a licensed hospital.

Cosmetic practice, as it operates in the grey zone between a doctor's office and a licensed hospital in some States, allows some practitioners to practice outside these regulatory frameworks, and to perform operations that would not be allowed had that practitioner attempted to perform the same operation in a licensed public or private hospital. As the recent Four Corners program "Cosmetic Cowboys" revealed, major cosmetic surgical procedures, such as large volume liposuction, can still be performed in a practitioner's day procedure centre with lax quality control, no formal oversight, and at a standard significantly below that which is both acceptable and safe.

All surgery has risk. Cosmetic surgery is no different. All surgical procedures that are invasive and carry inherent risks of both the procedure and associated anaesthetic require a pre-determined nationally consistent minimum standard of care and safety. Just as in all other areas of surgical practice, the performing of invasive procedures under anaesthetic or deep sedation also requires appropriate training, certification and credentialing of the anaestheist providing the anaesthesia required for the procedure to take place.

This training and the subsequent surgical (and anaesthetic) practice must be of the highest standard and should reflect current *best practice*. Accreditation, supervision and continued professional development of all surgical training must be underpinned by an objective nationally recognized pathway of selection, advanced training and certification of appropriate skills to the standard set by the AMC.

You could not perform neurosurgery, for example, unless you hold both a valid Fellowship of the Royal Australasian College of Surgeons detailing your surgical training in neurosurgery, with appropriate certification of that training from the Board of Training in Neurosurgery, and formal objective accreditation of your scope of practice and surgical training at the hospital at which you intend to operate. That is, in order to be appointed as a Neurosurgeon in either a public or a private hospital, you must present appropriate AMC accredited qualifications detailing your training and scope of practice, and valid AHPRA registration to the Hospital's Medical Board in order to be appointed and permitted to perform Neurosurgery at that hospital.

AHPRA should be aware of the existence of a number of organisations that do not have AMC recognition, yet still seek to claim legitimacy. Several attempts by these self-styled "cosmetic practitioners" to accredit their various training programs have been made to the AMC. All have been unsuccessful. Their training programs have not been recognized as being of a sufficient standard by the Australian Medical Council to meet their requirements.

It is these same practitioners, with no recognised AMC accredited specialist qualifications, that seek to obfuscate and denigrate the training, scope of practice and CPD of legitimate specialists who have been trained to the standard set by the AMC. For recognized specialists in surgery, the skill in performing these techniques, honed over many years of practice in surgical units, competitive selection into an advanced training program (ensuring the best candidates are chosen), a 5 year long advanced training program with hands-on supervised procedural instruction and final certification through a specialist surgical fellowship examination ensures that a properly qualified specialist surgeon does have the requisite skill set to practice safely and to an acceptable standard. All surgery has an intrinsic cosmetic element (a surgeon does not seek to deliberately create a poor aesthetic outcome), is integral to all congenital, trauma and cancer reconstruction, and as noted above –all cosmetic procedures have as their historical basis in Plastic & Reconstructive surgery.

It is recognized that for cosmetic surgery, the Board of Training of Plastic & Reconstructive Surgery, General Surgery, Ear Nose and Throat Surgery and Urology all include cosmetic surgical procedures as part of their formal curriculum and assessment of training. As such, a fellowship of the Royal Australasian College of Surgeons, or from one of the other AMC accredited training programs with a significant surgical component (Royal Australasian College of Obstetrics and Gynaecology, Royal Australasian College of Ophthalmologists and Oral and Maxillofacial Surgery) is the *only* objective and reproducible method to ensure a medical practitioner has the adequate skill, training and certification to perform surgery safely, and manage complications should they arise.

Attempts to bring these non AMC accredited “specialist” practitioners into line with standards of safe practice and recognized credentialing are met with claims that this is a “turf war” and an unfair fight to protect access to the lucrative cosmetic surgical and medical dollar. Whilst these claims do make the news, they are designed to confuse an unknowing and medically illiterate public and detract from the real aim – which is to ensure that practitioners in this area are properly credentialed, have the requisite skills and are safe. By continuing to allow this regulatory blind spot, AHPRA has failed to adequately protect the unsuspecting cosmetic patient from unsafe practice and from harm from the undertrained and sometimes unscrupulous practitioner.

Unfortunately, in Australia in 2022, what we call “cosmetic” surgical practice is currently being delivered by a disparate group of practitioners, some of which have undergone appropriate selection, training, certification and registration as specialists and some of which have not. In NSW and Victoria, recent changes to the legislation have mandated that invasive cosmetic surgical procedures are now only permitted in licensed private hospitals, most of which require appropriate specialist credentialing and require oversight by the individual hospital’s medical board. This, however, is not uniform, nor is it nationwide. Performing invasive surgery in a licensed facility with oversight by the hospitals medical board would ensure that standards of surgical safety with respect to infection control, anaesthesia/sedation and patient monitoring are satisfied.

The title “Cosmetic Surgeon” and the recent public push to create a new specialty of “Cosmetic Surgery” has added to further confuse a vulnerable public and is another important factor in preventing proper regulation, patient protection, and establishment of minimum

standards of safety and quality in this space. The title "*Cosmetic Surgeon*" is not AMC accredited nor is it backed by the rigorous selection, training and attaining of competence that is mandatory of all other areas of surgical practice. Naively and falsely, many patients believe a practitioner calling themselves a "*Cosmetic Surgeon*" is better trained and has more experience than any other practitioner in any operation with a significant cosmetic component. This misconception is not accidental, and its messaging has been deliberately crafted.

Right now, any doctor with a basic medical degree and no formal training in surgery could insert a breast implant, perform major liposuction, or perform an abdominoplasty. All these operations are major surgical procedures and carry a significant and very real risk of injury, infection, and death. Up until recently, any doctor could perform this procedure in his/her back office in any part of Australia. In NSW and Victoria at least, this has now been made illegal.

It is vital that any patient undergoing any invasive surgical procedure has the assurance that the doctor performing that procedure has the recognized and sufficient level of skill to carry out the procedure safely and appropriately, to treat the intra or post-operative complications should they arise, to provide the aftercare to an accepted standard and that such an invasive procedure be performed in a licensed and accredited facility. This assurance needs to be transparently and readily available. Further, patients need to be able to easily and reliably double check the claims made by an individual about their surgical training and compare the standard of that training against a nationwide, objective independent easily understandable benchmark before undertaking surgery. It would make sense that this benchmark is set by the AMC.

Ultimately, clarity and restrictions around training, titling and certification will enable patients to be confident that the doctor performing their procedure has the skillset to achieve the best outcomes, as well as keeping them safe before, during and after their operation.

Proposed Reforms 3a-e

3a. Jurisdictional and/or National legislation to ensure that all invasive Cosmetic Surgery in Australia is performed in an appropriately licensed medical facility. These facilities must be licensed to acceptable standards by the Jurisdictional and/or National health regulators and must be able to provide an audit of safety standards and patient outcomes.

3b. Protect the use of the title 'Surgeon' to appropriately credentialed and qualified specialist registered practitioners with appropriate Surgical training and qualification to a predetermined, independent, objective benchmark. We would suggest this is to the standard set by the AMC.

3c. Restrict the use of the medical practitioners' titles and post nominals to only those formally approved by AHPRA. Fabricated titles (such as the term "Cosmetic Surgeon") lack uniformity and are not necessarily linked to recognised skill, credentialing and certification. These titles have the potential to mislead the general public and make it difficult for a prospective patient to accurately and transparently assess the practitioner's level of skill and training. Patients are therefore potentially put at risk of harm.

3d. AHPRA and AMC work towards formalising standards of certification and training in Cosmetic Practice with AMC recognized Colleges and training programs. For any major invasive surgery, the minimum standard should be a fellowship of an AMC Accredited College with a significant surgical scope of practice, that is, the Royal Australasian College of Surgeons, The Royal Australasian College of Ophthalmologists, The Royal Australasian College of Obstetrics and Gynaecology and Oral and Maxillofacial Surgery.

3e. Consider the development of post fellowship training pathways for excellence in Cosmetic Practice

4. Advertising in Cosmetic Practice

Historically, advertising of medical or surgical services by doctors in Australia was heavily restricted. When Anand's father began practicing as a GP in the 1970s, he was only allowed to have a single line entry in the White Pages listing his name, address, and telephone number.

In 1994 the Australian Competition and Consumer Commission (ACCC) allowed doctors to advertise their services, initially through print in the yellow pages and then subsequently onto other media platforms such as radio and television and more recently social media. This led to an explosion in both the amount and extent of medical advertising that targets consumers directly.

As outlined by current AHPRA guidelines, advertising for any health service must **not**

Be false, misleading, or deceptive
Offer a gift, discount, or other inducement
Use testimonials or purported testimonials
Create an unreasonable expectation of beneficial treatment
Encourage the indiscriminate or unnecessary use of regulated health services

For cosmetic practice, advertising an elective or discretionary intervention could potentially involve breaching any of all of the above principles.

a. Patient images used for advertising Cosmetic practice

Images of patients before and after undergoing cosmetic interventions are widely utilised in advertising for Cosmetic Practice. The use of before and after photos has an important role in educating patients about the likely outcomes of a cosmetic intervention. There are standards that have been described to properly document the effect of a cosmetic surgical intervention[20]. Images can also be misleading and used to try to entice patients to sign up for treatments. The images that are displayed on websites, social media and marketing materials are highly curated and capture a single time point during the patient's journey, usually taken at the time when the patient looks their best.

The use of lighting, make up, varied angles to improve contour, facial expression and clothing may also provide an unrealistic and misleading image of the results of a cosmetic intervention.

Examples of where the use of imagery may be misleading or enticing include:

1. The use of glamorous, sexualised and posed images, lifestyle shots accompanied by captions that minimise the risk or complexity of a procedure can be considered potentially false, misleading, and deceptive.
2. The tagging or naming of a particular patient, especially one with a large following on social media platforms ("influencers") may constitute a surrogate testimonial.
3. Claims relating to likely outcomes as a result of a cosmetic surgical procedure e.g., "cutest person in the world", "looking great" may create an unreasonable benefit or expectation of a proposed treatment or procedure

Proposed reforms 4a-e: Images used for Cosmetic practice

4a. Should be standardised i.e., Taken at the same angle, with the same lighting and background both before and after the intervention

4b. The after image should clearly state the time in days, months or years following the intervention.

4c. Should not name individual patients or link to individual patients' social media or digital media accounts

4d. Should not be accompanied by testimonials and/or subjective description(s) of the benefit or apparent result of the procedure

b. Financial incentives to entice patients

The use of financial incentives such as discounts and time sensitive "specials" to entice a patient to undergo a cosmetic intervention is an area that requires careful scrutiny.

Examples of financial incentives to entice patients include

1. Giving a fee discount if the patient undergoes the surgery before a certain date
2. Offering other benefits, such as discounted airfares, accommodation, spa treatment as part of a treatment package etc.
3. Offering a gift or prize for promoting a particular cosmetic practitioner or practice
4. Entering into any arrangements with patients to assist them in obtaining finance to pay for a procedure, or offering financing schemes to patients, either directly or through a third party

Supplying services by a practitioner to a patient for free or for a reduced fee in exchange for some benefit, including the endorsement of the practitioner through media and social media can be construed as a breach of AHPRA advertising guidelines. This practice is termed influencer marketing. This involves endorsement of a product or service by a person with a large following or a high public profile in exchange for reduced or no cost access to a cosmetic intervention. Recent moves to delineate sponsored content have been introduced but there is sufficient opacity here so that many incentives remain hidden. This type of marketing is often successful because it appears to be organic and may seem to reflect the influencer's genuine assessment of the service they received. The strategy has been employed widely by most sales driven industries but is now also being employed to promote cosmetic practice, with social media personalities flaunting the results of procedures they have undergone and publicly crediting the doctors who performed them.

These arrangements may be informal, verbal or written and may be obfuscated through false receipts and invoices. In many cases, the influencer has no intention of disclosing these arrangements and may be inappropriately bound by non-disclosure agreements.

Proposed reform 5

Consider banning the naming of any individual patients or conversely the naming or tagging of a practitioner or practice in relation to a cosmetic treatment through media/social media

c. False claims of efficacy and expertise

Review of the advertising material for both cosmetic practitioners and cosmetic interventions reveal a large number of potentially unsubstantiated claims of efficacy. While there have been a number of attempts to reign in content and appropriateness through, there is little evidence that these are adhered to[21]. A recent study in the UK found only 41 per cent of medical websites complied with published guidelines, with 34 per cent of advertisements for breast augmentation containing (deliberately) false and/or misleading information including minimising risk and down time after surgery[22]. The study also noted frequent exaggerated claims such as "a true artist", "one of the top doctors", "prescribing the power to be beautiful", "kissable lips, just a click away"[22].

Recently the TGA has introduced penalties for claims that are in breach of regulatory approval and/or unsubstantiated benefits not backed by evidence. These penalties apply to both the practitioner making these claims or by individuals promoting such treatments. There is a real danger that an unproven treatment or medical device utilised outside of regulatory approval place patients at risk of adverse events from a particular intervention or device.

Additionally, we have seen many claims made by cosmetic practitioners to be true pioneers and innovators in their field, being the first or only surgeon to practice a certain technique in Australia including eponymous "lifts" and "smart" techniques. Innovation is important in medicine, but the real risk is that self-styled "new" techniques have not been properly evaluated by scientifically valid comparative studies or published in peer reviewed journals and simply do not have good evidence to back their claims.

Proposed reform 6a-c

6a. Claims of innovation be backed by published, peer reviewed articles
6b. Claims and use of medical interventions and devices are in line with TGA approved usage and breaches of this are to be reported to the TGA.
6c. Claims of efficacy of any new product or intervention be backed

d. Social media has changed the game – the regulator needs to catch up

The advent of social media, more recently, has turbo-charged the use of sales and marketing tactics and opened up a wide range of opportunities to specifically target individuals and build brand awareness in the cosmetic surgery industry[23]. There is increasing evidence, however, that the images and strategies used to target individuals may worsen feelings of low self-esteem and body image[24,25]. The use of operative videos on some social medial platforms has

also gained popularity. Ethical challenges with posting such material has been raised in the literature[26]. The posting of videos of surgery are designed to legitimise the "expertise" of the practitioner, whilst also giving the patient an opportunity for fame. Some patients seek out high profile surgeons offering to have their video and testimonials posted on either the practice or their personal social medial platforms to enhance each other's reputations. There are also risk in breaching confidentiality when videos are posted without consent and images and videos, once released may be copied, manipulated, and redistributed. More recent platforms such as Snapchat have transient posts, thereby making it more difficult for authorities to review and assess appropriateness of content.

Increasingly patients rely on social media to find their "ideal" cosmetic practitioner, often looking to online reviews to make their selection. It is a dangerous and unregulated area and borrows on the wider commercial drivers common to other sales-driven industries. Recent reports of deliberate censoring of poor reviews, paying patients and/or staff to post glowing endorsements and paying third party "cosmetic surgery forums" to promote a particular practice casts doubt over the independence and veracity of online information that patients use in good faith to make their choice.

Unlike traditional media, such as television, print and radio, social media lacks the checks and balances and vetting by journalists and broadcasters who moderate and sense-check what gets promoted to the public. A quick look through brand building manuals shows that much of what is displayed seeks to build a cult of celebrity, followers, and pre-eminence through flooding these platforms with highly sexualized images, music videos and luxury products.

A recent survey by the British Association of Plastic Surgeons (Think before you make over) showed that patients relying on social media for their information were not aware of the risks of their intended procedure (21%), are not clear on the likely outcomes of a procedure (27%) with 59% undergoing a cosmetic intervention within 2 weeks of first contact with a practice on social media[27]. Just over half of these patients (53%) sought to find the cheapest option for their intended procedure. These worrying statistics point to a targeted demographic of vulnerable and impressionable patients who are easy prey to marketing, pricing and sales tactics[27].

Proposed reform 7
Consider the establishment of a social media monitoring authority to study the content and report any potential or direct breaches to AHPRA

5. Ongoing duty of care, surveillance, and reporting of adverse events

All patients undergoing cosmetic interventions should have arrangements to receive appropriate post intervention care and follow up. It is also important that any adverse events of cosmetic interventions be properly documented and reported to a formal national register overseen by the respective jurisdictional Health authorities and to AHPRA.
Patients coming from interstate or regional parts of the State should be encouraged to remain close to the practice for a reasonable time-period after surgery, so that any early postoperative complications can be identified early and treated.

For breast implant surgery
Patients undergoing breast implant surgery should be given a postoperative surveillance plan and information relating to medium to long term risks of these devices (see Appendix 1). The breast implant must be registered with the Australian Breast Device Registry and the patient should be also informed of the need to report any future adverse events to both the registry and the Therapeutic Goods Association (TGA).

Proposed reform 8a-c

8a. Standardised post intervention care and surveillance plans be instituted and communicated
8b. Wider education of general practitioners on the risks and adverse events associated with cosmetic interventions
8c. Consider the development of a patient adverse event reporting line or portal to capture true risks and outcomes following cosmetic interventions

A history of regulatory failure

In 1999, the NSW health minister established an enquiry into the cosmetic medical industry with a report tabled by the Commissioner, Merrilyn Walton.

The key findings tabled were

1. Little published research on clinical standards and skills required to perform cosmetic surgery procedures
2. Little information on adverse outcomes but no disproportionate level of complaints or legal claims in the cosmetic surgery industry
3. A proliferation of professional and industry organisations responsible for training and representation of cosmetic surgery providers, with some providers who are not members of any such specialist groups
4. No uniform standards for information to consumers
5. Little understanding of the regulations governing promotional activity

The report provided an in-depth analysis of the industry and its failures. It called for a Cosmetic Surgery Credentialing Council (CSCC) to be established for all registered providers of cosmetic surgery to ensure that there was provision of reliable information for consumers and effective sanctions for those that fail to comply with standards of safe and ethical practice. It also called for an amendment to the Private hospitals and Day Procedure Centres Act and the Day Procedure Regulation to ensure that facilities who provided cosmetic surgery procedures adhered to safety standards to ensure that procedures were performed in properly licensed facilities.
The majority view was that medical practitioners performing invasive cosmetic surgery procedures should have a fellowship of the Royal Australasian College of Surgeons.

In March 2017, The Private Hospital and Day Surgery Act was amended in NSW response to the public outcry following the reporting of a number of patients who suffered local

anaesthetic toxicity at an unlicensed breast augmentation clinic (The Cosmetic Institute). Other recommendations from this report remain to be enacted and closely echo our recommendations.

Proposal 9

Establishment of an AHPRA cosmetic practice authority to monitor and investigate any breach of advertising claims and guidelines (this was originally proposed in NSW 1999 submission)

This authority has the power to call for urgent s150 hearings to question practitioners and/or practices that are potentially in breach

Make clear that the consequence of multiple and/or significant breaches of advertising guidelines could result in restriction of medical practice.

Conclusions

This enquiry brings with it the real opportunity for AHPRA to establish a framework for better regulation of cosmetic practice. We have proposed a number of strategies for you to consider and a roadmap to real reform in cosmetic medical and surgical practice. Lasting reform should rightly be focused on patients and educating them on how best to navigate this complex space. It is, after all, the choice and power of an informed and educated patient that will ultimately drive better standards of care and call poor practice to account.

There are those within this industry that have repeatedly called for reform and for protection of the patient[28,29]. Both our practices are now seeing an increasing number of patients, mainly women, who have been harmed physically, psychologically, emotionally, and financially by the consequences of their engagement with the industry. We have witnessed the growing divide between aggressive sales and marketing tactics and profit seeking and the need for the highest standards of clinical skill, patient informed educated consent, clinical assessment, and treatment. The advent of social media, enticing imagery, celebrity and influencer marketing are moving the industry ever further away from the profession of medicine into a highly geared commercial enterprise, aimed at preying on the vulnerable and commoditising medical interventions. It has been 23 years since the NSW Health Minister commissioned the first enquiry into cosmetic surgery. The problems that existed then still exist today, albeit now scaled to a level that was unimaginable at that time. We call on AHPRA to consider our proposals and to engage with those of us that are committed to bringing change and to better regulate cosmetic practice. Rather than be reactive and respond when stories of patient harm are aired in the media, let us be proactive to deliver real and meaningful reform to ultimately prevent patients from being harmed in the first place and to ensure that cosmetic practice delivers safe and effective treatments with the power to improve the quality of life of our patients.

Mark Ashton & Anand Deva April 2022

Summary of Proposed Reforms to Cosmetic Surgery Practice

Proposed reform 1

Development of customised informed educated consent checklists for common cosmetic medical and surgical interventions to be discussed between patient and treating practitioner face to face at two separate consultations with an intervening mandatory cooling off period.

Proposed reform 2

In the setting of a proposed cosmetic treatment, disclosures of financial conflicts of interest for both the practitioner and practice and beneficial commercial arrangements with a particular medical supplier or finance supplier should be disclosed to the patient in writing at the time of initial consultation and prior to patient consenting to undergo cosmetic treatment.

Proposed Reforms 3a-e

3a. Jurisdictional and/or National legislation to ensure that all invasive Cosmetic Surgery in Australia is performed in an appropriately licensed medical facility. These facilities must be licensed to acceptable standards by the Jurisdictional and/or National health regulators and must be able to provide an audit of safety standards and patient outcomes.

3b. Protect the use of the title 'Surgeon' to appropriately credentialed and qualified specialist registered practitioners with appropriate Surgical training and qualification to a predetermined, independent, objective benchmark. We would suggest this is to the standard set by the AMC.

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3d. AHPRA and AMC work towards formalising standards of certification and training in Cosmetic Practice with AMC recognized Colleges and training programs. For any major invasive surgery, the minimum standard should be a fellowship of an AMC Accredited College with a significant surgical scope of practice, that is, the Royal Australasian College of Surgeons, The Royal Australasian College of Ophthalmologists, The Royal Australasian College of Obstetrics and Gynaecology and Oral and Maxillofacial Surgery.

3e. Consider the development of post fellowship training pathways for excellence in Cosmetic Practice

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Make clear that the consequence of multiple and/or significant breaches of advertising guidelines could result in restriction of medical practice.

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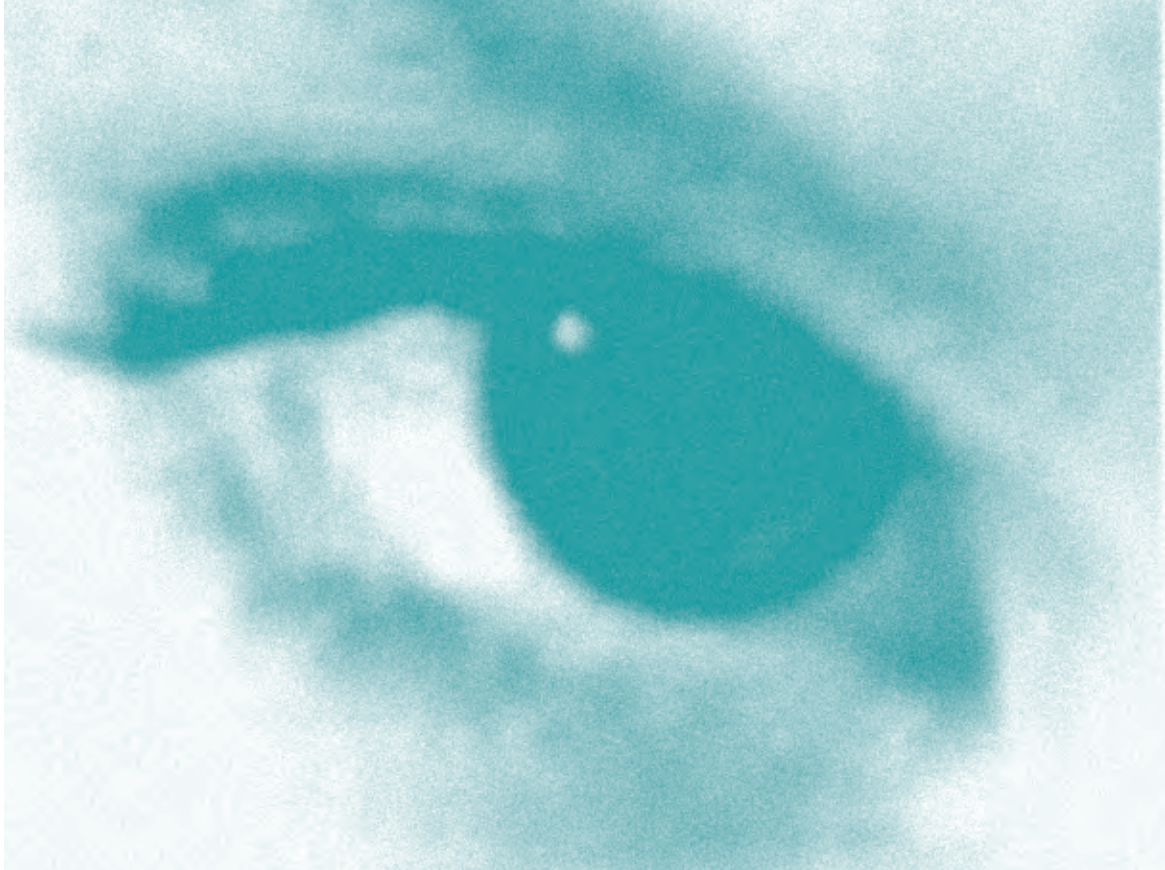
Appendix 1: Toolkit for the management of breast implants

Appendix 2: The Cosmetic Surgery Report – Report to the NSW Minister for Health October 1999



THE COSMETIC SURGERY REPORT

REPORT TO THE NSW MINISTER FOR HEALTH • OCTOBER 1999

THE COSMETIC SURGERY REPORT

Report to the NSW Minister for Health

October 1999

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The Committee was assisted by Executive Officer, Amanda Cornwall, who prepared this report. Sue Russell provided clerical support to the Committee.

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HCCC
HEALTH CARE COMPLAINTS COMMISSION

The Hon Craig Knowles
Minister for Health
Level 33, GMT
1 Farrer Place
Sydney NSW 2000

Dear Mr Knowles,

It is with pleasure that I present the report of the Committee appointed under the *Health Administration Act 1982* to inquire into cosmetic surgery in New South Wales.

The Committee advertised and consulted widely seeking information through submissions and public hearings, and advice from four subcommittees. It was assisted by a review of the published literature, a survey of consumers of cosmetic surgery and a survey on the use of lasers in cosmetic procedures. The Committee found:

- little published research on clinical standards and the skills required to perform cosmetic surgery procedures;
- little information about adverse outcomes, but no disproportionate level of complaints or legal claims in the cosmetic surgery industry;
- a proliferation of professional and industry organisations responsible for training and representation of cosmetic surgery providers, and some providers who are not members of any such specialist groups;
- no uniform standards for information to consumers;
- little understanding of the regulations governing promotional activity.

The Committee recommends these issue are addressed through a combination of industry initiatives, guidance from regulators and some regulatory measures.

Cosmetic surgery is mainly performed outside organised medicine where the traditional protections provide patients with a safety net. This report recommends a new structure for the delivery of cosmetic surgery, which focuses on consumer choice and patient safety. The inquiry has already had a significant impact on the cosmetic surgery industry by promoting informed public debate about appropriate standards for training and information to consumers. This dialogue should continue through the measures we have recommended.

I commend this report to you and urge you to implement the recommendations concerning government action and to support those concerning the industry.

Yours sincerely,

Merrilyn Walton

Commissioner
Health Care Complaints Commission and
Chairperson
Cosmetic Surgery Inquiry

SUMMARY OF RECOMMENDATIONS

General safety and quality issues

Cosmetic surgery credentialling

1a. A Cosmetic Surgery Credentialling Council (CSCC) be established for all registered providers of cosmetic surgery procedures to provide independent and accountable verification of qualifications and training. The Council would have the following features:

- provision of reliable information for consumers;
- peer review, but independent of any particular guild or registration body;
- industry funding, based on membership fees or subscriptions;
- voluntary membership, not affecting practitioners' rights to practice;
- effective sanctions for members who fail to comply with credentialling requirements, including loss of credentials and publishing the provider's name where appropriate.

1b. The CSCC expand membership to include unregistered providers of cosmetic surgery procedures within two years.

2a. The CSCC establish credentialling committees of peers to make credentialling decisions. The credentialling process would be based on the following principles:

- peer responsibility for credentialling on a non-discriminatory basis that requires the same standards for all providers, regardless of background training or speciality;
- published requirements for credentialling;
- procedural fairness, including an appeal process for review of unfavourable decisions and a procedure for resolving conflicts of interest.

2b. Credentials will be renewed regularly (two to three years) and will require:

- demonstration of continuing professional indemnity insurance;
- compliance with codes of conduct on advertising, informed consent, appropriate patient/client selection, and financial disclosures; and
- satisfactory participation in a systematic audit process for activity and outcomes.

3a. The Department of Health sponsor and set up the Cosmetic Surgery Credentialling Council.

3b. The structure and membership of the CSCC be representative and accountable to all stakeholders in the industry.

Licensing of doctors' rooms

4a. Amend the *Private Hospitals and Day Procedure Centres Act* and the *Day Procedure Centre Regulation* to require licensing for facilities where medical procedures are performed using local anaesthetic and sedation. New risk factors should be recognised under the Act including level of drugs and drug combinations, patient assessment and selection, adequate provision for recovery and discharge, and risks associated with lasers. (majority view)

4b. The licence should be conditional on certification by a third party accreditation body, provided on a fee-for-service basis.

4c. Consistent with the *Private Hospitals and Day Procedure Centres Act* and regulations, medical practitioners with licenced facilities should be required to:

- maintain records of surgical procedures and drugs administered including, type of procedure, duration, adverse events and post-operative care; and
- notify NSW Health if the procedure results in death or removal to a hospital within 72 hours of cosmetic surgery or a cosmetic medical procedure.

4d. Amend the *Medical Practice Act, Nurses Registration Act* and *Dentists Act* to deem non-compliance with licensing and reporting requirements unsatisfactory professional conduct.

Information about cosmetic surgery

5a. The Cosmetic Surgery Credentialling Council collect data on the number and type of cosmetic procedures in NSW, and outcomes (morbidity and mortality), and publish it annually.

5b. United Medical Protection should publish annual statistics on the number and types of cosmetic surgery procedures for which notifications and claims are made, and the basis for the claims.

Surgical qualifications

6. Medical practitioners performing invasive cosmetic surgical procedures should have adequate surgical training, being that required for Fellows of the Royal Australasian College of Surgeons, or equivalent. (majority view)

Safe use of lasers

7a. Prescribe the use of class 3B and class 4 lasers for health related and cosmetic purposes under the *Radiation Control Act* so that users are required to be licenced and prescribe laser equipment used for those purposes so that it must be registered under the Act. (majority view)

7b. The Cosmetic Surgery Credentialling Council facilitate development of guidelines and accreditation of training programs for the use of lasers by registered cosmetic surgery providers.

Breast implants

8a. The National Health and Medical Research Council fund research on the main adverse outcomes of augmentation mammoplasty in Australia, particularly capsular contracture.

8b. The Therapeutic Goods Administration be given legislative authority to establish a mandatory device-tracking register for current and future recipients of breast implants.

Liposuction

9. The relevant medical colleges and professional associations, in conjunction with the Cosmetic Surgery Credentialling Council develop guidelines for liposuction addressing qualifications of medical practitioners, limits on drug use, fluid management, and patient selection.

Patient satisfaction

10. The Cosmetic Surgery Credentialling Council conduct regular patient satisfaction surveys to improve understanding of consumer experiences of cosmetic surgery. The *Consumer Survey* conducted for this Inquiry provides a model.

Consumer issues

Information about providers

11a. The Cosmetic Surgery Credentialling Council provide the following information to the public about credentialled providers to address consumer uncertainty about the level of skill and qualifications of cosmetic surgery providers:

- the provider's relevant qualifications and whether or not currently credentialled with the Council;
- the provider's relevant training (as assessed by the Council);
- the extent of the provider's experience and clinical outcomes.

The information should be made publicly available by the Council via telephone, website and other appropriate methods.

11b. Cosmetic surgery providers should give consumers the following information:

- their qualifications, credentials, and training;
- their experience in performing the procedure(s);
- the number of times they have performed the procedure recently;
- their clinical outcomes, and number of adverse events.

Communicating information about procedures

12a. Cosmetic surgery providers should use information brochures during the consultation to help consumers understand the nature of the procedure(s) and the risks of complications.

12b. Visual aids, such as appropriate 'before and after' photos, should be used during the consultation to help provide consumers with realistic expectations of outcomes, including a photo of a common complication.

13a. Effective communication between doctors and patients requires:

- at least one face to face meeting between the patient and the treating doctor at which a full medical consultation occurs and written information about the procedure(s) is provided and discussed;
- a cooling-off period of at least five working days between the first consultation and providing the treatment.

13b. Cosmetic surgery providers should use well designed consent forms to help structure and record communication between the doctor and patient, signed and retained by both parties.

13c. The Cosmetic Surgery Credentialling Council should prepare a *Code of Conduct on Communicating with Patients and Informed Consent*. It should be widely promoted to providers and consumers.

14. The HCCC and NSW Department of Fair Trading prepare consumer information guides to assist consumers to identify factual information about cosmetic surgery.

15. To address gaps in the information provided to consumers cosmetic surgery providers should:

- provide a disclosure notice setting out relevant financial interests and information about alternative providers if a conflict of interest exists;
- provide a statement of the cost of all relevant services;
- advise consumers if a drug is used in a manner different to the indications for use given by the Therapeutic Goods Administration.

Provision for aftercare

16a. Providers of cosmetic surgery give undertakings to consumers as to what they will do if there are complications or the consumer is not satisfied.

16b. Providers of cosmetic surgery make adequate provision for aftercare of consumers. As a minimum this would include:

- the doctor's contact details if questions or complications arise;
- if the treating doctor is not available, the contact details of an appropriately qualified medical practitioner with whom the provider has a prior arrangement;
- the hospital to attend in an emergency, the hospital being a facility with which the medical practitioner has a prior arrangement;
- appropriate discharge procedures and information to the patient about recovery;
- appropriate instructions for medication and other aftercare procedures that the consumer needs to follow;
- details of the date and time of the follow-up visit.

17. The NSW Medical Board inform cosmetic surgery providers of their obligations to give consumers objective information about the risks and benefits of alternative treatment options, including treatment options for complications. The information should follow a full medical examination and assessment of the treatment options most suitable for the consumer.

Patient selection

18. The Cosmetic Surgery Credentialling Council develop a *Code of Ethics on Appropriate Patient Selection*. The Code should incorporate:

- an evaluation of the physical condition of patients and potential risks associated with treatment options;
- a discussion with patients about their expectations in terms of self-esteem. This should include an explanation that determinants of self-esteem are multifactorial and cosmetic surgery is only one aspect of improved self-esteem;
- an evaluation of whether the patient's expectations are realistic. This should include consideration of deleterious psychological or emotional outcomes that may eventuate if an adverse surgical outcome occurs.

Promotion of cosmetic surgery

Advertising and promotions

19a. The ACCC and HCCC develop a guide on the application of fair trading laws to the promotion of health services.

19b. The impact of the guide be monitored and a report on its impact and an assessment of the need for a mandatory industry code be made within 18 months of release of the guide.

Financial relationships

20a. Amend the *Medical Practice Act* to prohibit doctors from entering into financial arrangements with agents who refer patients.

20b. Amend the *Medical Practice Act* so that 'unsatisfactory professional conduct' includes failure to disclose to patients their financial interests in treatments offered or recommended.

20c. The Department of Health, the NSW Medical Board, and professional organisations educate doctors and consumers about financial conflicts of interest in the health services sector.

20d. The Cosmetic Surgery Credentialling Council develop a *Code of Ethics on Financial Conflicts of Interest*. Compliance with the Code should be a condition of credentialling and re-credentialling.

Cosmetic surgery as a prize

21. The NSW Government not grant permits for competitions offering cosmetic surgery procedures and products as prizes, and amend the *Lotteries and Art Unions Act* (NSW) to prohibit competitions offering cosmetic surgery as a prize.

Patenting surgical procedures

22. The public policy issues arising from patents on surgical procedures should be referred to the Australian Health Ethics Committee for their consideration.

EXECUTIVE SUMMARY

The Committee was appointed to examine cosmetic surgery in NSW. This included ascertaining the adequacy of consumer safeguards, the quality of consumer information, and the problems with promotion. The Committee was also asked to make recommendations on the need for additional safeguards.

The Committee defined cosmetic surgery as a procedure performed to reshape normal structures of the body, or to adorn the body, with the aim of improving the consumer's appearance and self-esteem. It excluded gender reassignment and the link between silicone breast implants and connective tissue diseases.

The environment

Cosmetic surgery has the following characteristics:

- medical practitioners performing cosmetic surgery include plastic surgeons, cosmetic surgeons, cosmetic physicians, general practitioners (GPs), dermatologists, ophthalmologists (eye surgeons), otolaryngologists (ear, nose and throat specialists);
- there are about 350 doctors in Australia who substantially perform cosmetic surgical procedures, and about 150 doctors and 50 nurses providing cosmetic medicine;
- these doctors are trained, accredited and represented by 10 specialist colleges and professional associations, some of which are less than 12 months old.

It is generally accepted that the industry has doubled in the past five years. The Committee estimates in 1998 there were about 50,000 cosmetic surgical procedures and possibly as many as 200,000 cosmetic medical procedures performed in Australia. The most popular surgical procedures are liposuction and breast enlargement, followed by rhinoplasty (nose surgery) and facelift.

A Consumer Survey commissioned by the Committee found that consumers of cosmetic surgery in NSW come from a wide range of geographic, income and age groups. Almost half the respondents indicated previous cosmetic surgery. A large proportion first heard about the procedure they had from the media or advertising. While most paid for the procedure from savings, 23% paid by credit card or bank loan. Over a quarter of respondents had their procedure paid for by Medicare, and almost as many had all or part of the procedure covered by private health insurance.

Consumer safeguards

The cosmetic surgery industry operates outside the framework of organised medicine:

- it does not come under the auspices of any particular specialist medical college or professional body that can establish competency standards and appropriate training;
- cosmetic surgery is now frequently performed in doctors' rooms where there is no regulation of safety, no independent peer review, and no reporting of complications.
- cosmetic surgery is not covered by Medicare, so there is no protection through screening patients by GP referral.

Adequacy of consumer safeguards

Little information exists on the effectiveness of consumer safeguards. According to medical indemnity insurers and health complaints bodies the number of legal claims and complaints about cosmetic surgery are not disproportionate to other areas of medicine. However, they regard it as a high risk area of practice because the complaints are primarily about clinical outcomes, and certain characteristics of the industry i.e. the different nature of the doctor/patient relationship and the financial arrangements in the industry. The largest number of complaints and legal claims are about breast surgery, followed by liposuction. Blepharoplasty (eyelid surgery), rhinoplasty (nose surgery) and facelifts are also the source of a substantial proportion of complaints.

Cosmetic surgery generally receives high satisfaction ratings from consumers. However, most of the studies in the literature should be viewed with caution because of methodological weaknesses. The Consumer Survey conducted for the Committee reported a high satisfaction rating by 80% of respondents.

General quality and safety

A *Review of the published literature* commissioned by the Committee found little useful research on the safety, appropriateness and effectiveness of most procedures, or on the level of training required to safely and effectively perform cosmetic surgery procedures. Cosmetic surgery is very competitive and providers have not been prepared to share information about their sometimes unconventional treatments with their peers.

Any medical practitioner can practice cosmetic surgery in Australia. The only information available to consumers to assess competence is membership of medical colleges and professional associations, but this provides no guarantee of skill and experience in cosmetic surgery. Many submissions support a process that would give the public reasonable confidence that a person claiming to be a cosmetic surgeon meets minimum standards of competence and quality. The Committee recommends a credentialling process to verify a practitioner's training and qualifications in cosmetic surgery.

The Committee recommends a Cosmetic Surgery Credentialling Council be established to provide consumers with independent information about the qualifications and training of registered health professionals providing cosmetic surgery. The proposed Council would be made up of stakeholders, but would be independent of any one particular professional interest group. It will be voluntary, and industry-funded. The credentialling process will be based on principles of peer review, procedural fairness and openness. The Committee recommends the Council should be set up by the NSW Department of Health initially.

An important role of the Council will be to collect data on cosmetic surgery outcomes (morbidty and mortality), on patient satisfaction, and complaints about members. It will also ensure credentialled providers collect information on their own clinical outcomes.

Specific safety issues

The Committee noted a large proportion of cosmetic procedures are performed in doctors' rooms using minor sedation and local anaesthetic. These facilities do not require a licence so there is no regulation of minimum staffing, drug combinations, emergency equipment, quality assurance, recording details of patient treatments and reporting deaths. Once again a lack of information made it difficult to gauge the actual level of harm to patients. The Committee concluded that the risks are sufficiently serious to require facilities to be licenced where medical procedures are performed using sedation and local anaesthetic. It recommends a licencing requirement under the *Private Hospitals and Day Procedure Centres Act* based on third party accreditation. The representative of the Australian Medical Association dissented from the Committee view.

The Committee also heard of the substantial risks to consumers posed by unskilled operators of lasers in cosmetic procedures. These risks include infection, hypo-pigmentation and scarring. A majority of submissions to the Committee on *Use of lasers for cosmetic procedures* supported licensing of people using lasers, focusing on the adequacy of training. The Committee agreed. The representative of the Australian Medical Association dissented from the Committee view.

There is no requirement to have a particular set of specialised skills and knowledge to claim to be a 'cosmetic surgeon'. The Committee recommends that medical practitioners performing invasive cosmetic surgical procedures should have adequate training in surgery, being that required for Fellows of the Royal Australasian College of Surgeons, or equivalent. The representative of the Australian College of Cosmetic Surgery dissented from this view.

The *Review of the published literature* highlights high complication rates with breast implants, but there is no Australian research on the topic. The Committee recommends that the National Health and Medical Research Council fund research on complications of breast implants in Australia and the Therapeutic Goods Administration establish a mandatory device tracking register for breast implants.

Consumer information

Cosmetic surgery providers have a greater legal obligation to inform consumers of risks, benefits and alternative treatments because the procedure is truly elective. The courts have assumed in some cases

that consumers would not choose to have a cosmetic procedure if they are informed of even minimal risks. To address these obligations, and ensure that consumers have reasonable expectations of the service provided, the Committee recommends that providers:

- give consumers detailed information about their skills, experience and clinical outcomes;
- use information brochures, and visual aids such as 'before and after' photos and videos during the consultation;
- keep a record of the information discussed in a well designed informed consent form;
- ensure there is at least one face to face meeting between the patient and the treating doctor before any surgery is performed at which a full medical examination and patient assessment is conducted, and the proposed procedure is discussed;
- provide objective information on the risks and benefits of alternative treatment options;
- allow a cooling-off period of at least five working days between the first consultation and providing treatment;
- disclose any financial interests that might affect patient care;
- provide a statement of charges and fees for all relevant services;
- give notice if a drug is used in a manner different to the use indicated by the ARTG;
- make adequate provision for aftercare of patients; and
- provide undertakings of what they will do if there are complications or a procedure is not successful.

The Committee recommends the Council produce Codes of Conduct on *Communicating with patients and informed consent* and *Appropriate patient assessment and patient selection.*

Promotion

The Committee found a number of problems with cosmetic surgery promotions, particularly 'before and after' photos used in advertising. Many claims may be misleading and deceptive. The Committee concluded that regulators need to promote improved understanding and enforcement of the existing laws. A guide to complying with fair trading laws in the promotion of health services by the ACCC and HCCC is a first step.

The Committee identified some potential problems with commercial agreements between doctors and others involved in the promotion of cosmetic surgery procedures and products. It was particularly concerned about people with no medical training providing consumers with referrals to doctors and making judgements about preferred procedures. Another problem relates to agents providing consumers with referrals to doctors where there is an undisclosed financial arrangement between the agent and the doctor.

The Committee concludes that more work is required to understand the business side of cosmetic surgery and its impact on patient care. It recommends that doctors be prohibited from entering into financial arrangements with agents that provide referrals, and amendment of the *Medical Practice Act* so that 'unsatisfactory professional conduct' includes failure to disclose to patient financial interests in treatments offered. It also recommends the Cosmetic Surgery Credentialling Council develop a Code of Ethics on *Financial conflicts of interest.*

Three separate competitions offered cosmetic surgery as a prize during the course of the Inquiry. This is dangerous because it trivialises surgical procedures and encourages people to diagnose themselves as an appropriate candidate for surgery. The Committee recommends that permits under the *Lotteries and Art Unions Act* should not be granted for competitions offering cosmetic surgery as a prize, and the Act be amended pt prohibit such prizes.

The Committee found that some cosmetic surgery procedures are subject to patents. It recommends the public policy issues arising from patents on surgical procedures be considered by the Australian Health Ethics Committee.

GLOSSARY

Accreditation A formal system to evaluate a doctor's competence necessary to perform safely and effectively within the scope of the doctor's practice, assessed against specific criteria.

Advanced Beauty Therapists Association An association that represents beauty therapists and aestheticians in NSW.

Australasian Society for Aesthetic Plastic Surgery A Society formed to promote research and dissemination of information on aesthetic surgery in plastic surgery.

Australasian College of Dermatologists The specialist medical college responsible for training and accrediting skin specialists. Most dermatologists do some cosmetic skin procedures. Those who actively provide cosmetic surgery procedures are known as cosmetic surgery dermatologists.

Australasian Academy of Facial Plastic Surgery The Academy provides education in the field of facial cosmetic surgery to its specialist members comprised of otolaryngologists, ophthalmologists and dermatologists.

Australian College of Cosmetic Surgery The College provides accreditation and plans to provide training for cosmetic physicians and cosmetic surgeons.

Australian Competition and Consumer Commission (ACCC) A Commonwealth body established under the *Trade Practices Act 1974* to regulate the conduct of corporations in providing goods and services to the public.

Australian Medical Association (AMA) The largest medico-political organisation representing medical practitioners in Australia through voluntary membership.

Australian Register of Therapeutic Goods (ARTG) A register of therapeutic drugs and devices approved for therapeutic purposes in Australia by the Therapeutic Goods Administration.

Australian Society of Otolaryngology/head and Neck Surgery The Society forms the Surgical Board in Otolaryngology/head and neck surgery jointly with the Royal Australasian College of Surgeons.

Australian Society of Plastic Surgeons The Society provides training in plastic and reconstructive surgery and cosmetic surgery, publishes guidelines for standards of practice and research. All plastic surgeons are accredited by the Board of Plastic and Reconstructive Surgery of the Royal Australasian College of Surgeons.

Competence Possessing the requisite obligations and qualities (cognitive, non-cognitive and communicational) to perform effectively in the scope of the practitioner's practice while adhering to professional ethical standards.

Cosmetic medicine A range of cosmetic procedures including injections of collagen and similar products, chemical peels, dermabrasion and laser resurfacing.

Cosmetic Nurses Association A national organisation that provides a forum for discussion and education for nurses in the cosmetic surgery industry.

Cosmetic and Plastic Surgery Nurses Association The Association represents nurses in the cosmetic surgery industry in NSW.

Cosmetic Physicians Society of Australia The Society provides education and accreditation for its members who must be medical practitioners who have practised in at least one area of cosmetic procedures for 12 months.

Credentialling A process involving a group of peers ratifying the general ability of a practitioner to perform particular types of procedures, usually relying on information provided by the practitioner, such as curriculum vitae, qualifications or college fellowship, a log of procedures or treatments, evidence of continuing medical education and supervised assessment, where appropriate.

Health Care Complaints Commission (HCCC) A statutory organisation established to assess, conciliate and investigate complaints about health services and health practitioners in NSW. In appropriate cases complaints are prosecuted before disciplinary committees and tribunals.

NSW Medical Board The Board registers all medical practitioners in NSW and is responsible for

maintaining professional standards prescribed under the *Medical Practice Act 1992* and regulations.

Physician A recognised speciality in Australia, physicians are members of the Royal Australasian College of Physicians. The American usage of the term, which refers generally to medical practitioners, is often used in the cosmetic surgery industry in Australia.

Privileges Credentialling committees provide advice on the competence of medical staff to perform particular roles within the facility. These are referred to as privileges. Privileges delineate the role a practitioner is allowed to perform in the facility. The privileges may be broad, allowing general surgical work up to a certain level, or may be specific to treatments or procedures that are part of the practitioner's training.

NSW College of Nursing The College trains and accredits nurses in NSW.

Royal Australian College of General Practitioners A national organisation concerned with the development and maintenance of standards for general medical practice and the training and education of general practitioners.

Royal Australian College of Ophthalmologists The College trains and accredits specialist eye surgeons who are uniquely trained in dealing with the structure of the eye, vision and diseases of the eye. Most ophthalmologists perform some cosmetic surgery. There is sub-specialty training in ocular plastic surgery.

Sclerotherapy Society of Australia The Society represents and trains doctors, who are mostly general practitioners, in sclerotherapy.

Therapeutic Goods Administration (TGA) The Commonwealth body that regulates the import and marketing of therapeutic medications and devices in Australia.

Common procedures used in cosmetic surgery

abdominoplasty (tummy tuck): a surgical procedure to remove excess skin and fat from the abdomen and to tighten the muscles of the abdominal wall.

augmentation phalloplasty (penile enlargement): a relatively new procedure in cosmetic surgery to enhance the form and function of the penis. Although most phalloplastic operations are performed for aesthetic purposes, some are for functional reasons.

blepharoplasty (eyelid surgery): a surgical procedure performed for correction of heavy upper or lower eyelids with excess skin. The surgery requires an incision in the skin fold. An ellipse of skin is excised, along with a strip of underlying muscle. It often involves the removal of excess fat as well.

botox therapy: botox, purified neurotoxin complex, is a protein produced by the bacterium *Clostridium botulinum*. The toxin is used to treat creases formed by the two horizontal muscles of the forehead located between the eyebrows. The botulinum can be injected into these muscles causing them to 'go to sleep' for a period of up to six months. It has been used to treat ophthalmologic problems for nearly 20 years.

breast reduction (breast reconstruction, reduction mammoplasty): a surgical procedure to reduce the size of the breast or to correct asymmetry.

breast augmentation (augmentation mammoplasty): a surgical procedure for increasing the size of the breast by the insertion of a synthetic implant either behind the natural breast or behind the pectoral muscle.

chemical peel: a procedure to remove top layers of skin to achieve a similar result to dermabrasion. The most popular peeling agent now is trichloroacetic acid which produces a controlled chemical burn.

collagen/fat injection: a treatment that literally 'fills in' facial lines and wrinkles. The most common areas treated are lips, smile lines, crow's feet and sleep lines. Other products are used in injection procedures, including Restylane, a non-animal product.

dermabrasion: a procedure that removes the top layers of skin mechanically by use of a wire brush, and can be used either superficially to remove skin blemishes, or more deeply, for removing scars, especially acne scars.

facelift (rhytidectomy): a surgical procedure involving muscle modification combined with limited skin undermining. It aims to remove excess skin that is loose and sagging on the face and neck and to tighten the underlying tissue.

laser resurfacing: a treatment using resurfacing lasers for vapourising layers of skin to treat sun damage, acne scars, wrinkles, remove tattoos, spider veins, etc. Resurfacing lasers are also used to cut the skin, with laser blepharoplasty (eyelid surgery) being the most common.

liposuction: a procedure for the removal of localised fat deposits by aspirating fat using a cannula attached to a suction machine (a vacuum source or a syringe). It is also known as liposculpture, lipoplasty, lipo-aspiration, suction lipectomy, and suction-assisted lipectomy. The procedure is used to remove fatty deposits from the hips, outer thighs, abdomen, buttocks, front of the neck, waist, knees, calves and ankles. It can also be used for breast reduction (usually in conjunction with conventional surgery), including the treatment of gynaecomastia (excessive breast tissue development) in males.

otoplasty (surgery of the ear): a surgical procedure to reshape the ears by either removing a wedge section of cartilage from behind the ear, causing the ear to sit closer to the head, or by removing skin from the lobe or tip of the ear to reshape and mould the ear.

rhinoplasty (nose surgery): a surgical procedure for altering the contour of the nose by altering the supporting anatomy. The underlying structure of the nose, nasal bones and nasal cartilage are modified to produce a more pleasing shape or to improve breathing.

sclerotherapy: a procedure used to treat the majority of varicose and spider veins.

THE COSMETIC SURGERY REPORT

1. ABOUT THE INQUIRY

1.1 Background

The NSW Minister for Health appointed a Committee of Inquiry into Cosmetic Surgery in October 1998. The Inquiry was prompted by concerns about the way cosmetic surgery procedures are promoted and the quality and safety of those procedures raised by health professionals, the NSW Health Department, the NSW Medical Board, the Health Care Complaints Commission and professional bodies.

The Committee was to investigate cosmetic surgery and recommend what should be done to fix any problems. Its terms of reference were:

- To identify the extent and type of problems associated with the promotion of cosmetic surgery;
- To identify and review the adequacy and limitations of existing consumer safeguards including those relating to regulatory and professional registration processes;
- To identify the quality and accessibility of sources of current consumer information on cosmetic processes;
- To make recommendations to the Minister for Health on the need for and options for additional safeguards for consumers.

1.2 Scope

To ensure that no procedures were arbitrarily excluded from the scope of the Inquiry the Committee defined 'cosmetic surgery' in the following terms:

> Cosmetic surgery is a procedure performed to reshape normal structures of the body, or to adorn parts of the body, with the aim of improving the consumer's appearance and self-esteem.
>
> The Committee notes that:
>
> - the notion of 'improvement' of appearance is a subjective one, defined by the consumer;
> - cosmetic surgery is initiated by the consumer, not medical need;
> - cosmetic surgery includes any cosmetic treatment, including cosmetic surgery, cosmetic injections, or other cosmetic procedures.
>
> 'Cosmetic surgery' excludes reconstructive surgery, being surgery which is performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumours or disease. It is generally performed to improve functions, but may also be done to approximate a normal appearance.
>
> For the purpose of the Inquiry the Committee excluded:
>
> - gender reassignment; and
> - the link between implantation of silicone breast implants and connective tissue diseases.
>
> Gender reassignment was excluded because of the complex clinical issues involved. The link between silicone breast implants and connective tissue diseases was excluded because the Committee could not add to the medical research on the issue.

1.3 Methodology

The Inquiry was conducted by a Ministerial Committee appointed under the *Health Administration Act* (NSW). The Committee was chaired by Commissioner Merrilyn Walton, Health Care Complaints Commission. The members of the Committee are as follows:

- Chairperson: Commissioner Merrilyn Walton, Health Care Complaints Commission, and Adjunct Assoc. Professor, Department of Psychological Medicine, University of Sydney;
- Mr Richard Barnett, President, Australian Society of Plastic Surgeons, NSW;
- Professor John Horvath, President, NSW Medical Board;
- Dr Martyn Mendelsohn, Australian Medical Association;

- Dr Colin Moore, Australian Association of Cosmetic Surgery;
- Mr Kel Nash, Department of Fair Trading;
- Professor Thomas Reeve, General Surgeon;
- Ms Susan Sharpe, Australian Consumers Association;
- Dr Simon Willcock, Royal Australian College of General Practitioners;
- Dr Andrew Wilson, Chief Health Officer, NSW Health Department;
- Dr Ross Wilson, Chairperson, NSW Ministerial Committee on Quality in Healthcare.

The Committee met six times between January and August 1999, in addition to the five days of public hearings and meetings of the subcommittees. To ensure that the Committee was inclusive of all the stakeholders, four subcommittees were convened to provide advice on:

- Consumer Issues
- Clinical Issues
- Training and Accreditation Issues
- Commercial and Regulatory Issues.

Members of the subcommittees included members of the Ministerial Committee, consumer representatives, lawyers, representatives from medical specialities that were not represented on the Ministerial Committee, regulators and other experts (see Appendix 1). The subcommittees met five times during May and June 1999.

The Committee called for written submissions through advertisements in statewide and national newspapers in November 1998. There were 98 written submissions received, as well as hundreds of inquiries, letters and emails (see Appendix 2).

Public hearings were held in Sydney on 18 and 19 March and on 8, 9 and 12 April 1999. The hearings gave the Committee an opportunity to meet with people who had provided written submissions and to ask them questions. It was also an opportunity for members of the public to see the Committee in action. Over 40 individuals and organisations appeared before the Committee during the public hearings (see Appendix 3).

During the course of the Inquiry four discussion papers were prepared by the Committee secretariat for the benefit of the Committee and subcommittees. A *Discussion paper: Use of lasers for cosmetic procedures* was prepared in June 1999 to seek the views of stakeholders on the nature and risks of lasers and the merits of regulating the use of lasers. Twenty six submissions were received in response (see Appendix 4).

The Committee benefited from experiences in the USA and England through submissions and information provided by cosmetic surgery practitioners and regulators in those countries. Commissioner Merrilyn Walton met with a number of these groups during a visit to the USA and England in April 1999.

1.4 Consumer Survey and Review of the Literature

A *Review of the published literature on the effectiveness of selected cosmetic surgery procedures* was prepared for the Committee by the Centre for Effective Health Care, University of Sydney. The *Review* provided information about the level and type of medical research available on: liposuction, laser resurfacing, rhinoplasty, phalloplasty, breast augmentation and breast reduction. It included a search of electronic databases indexing the scientific literature in health and medicine and included Medline over the period 1966 to the present, Embase 1988 to the present, The Cochrane Library Issue 1, 1999 and Best Evidence 1991-1998. It collected and appraised relevant English-language publications from this search and collected and appraised relevant articles cited in these publications.

For each procedure the researchers were requested to answer the following questions:

- what is the procedure and what is its main use?
- what are its intended outcomes?

- what techniques are in use?
- what does the published literature tell us about its safety and effectiveness?
- what are the gaps in knowledge about its safety and effectiveness?
- what conclusions and recommendations can be drawn?

The Committee also commissioned social research consultants, Community Solutions, to conduct a survey of consumer experiences of cosmetic surgery in NSW. The report of the *Survey of Consumers of Cosmetic Surgery* (Consumer Survey) documents the experiences of 280 people in NSW who have undergone a cosmetic surgery procedure in the past two years. It sets out the respondents' reasons for choosing to have cosmetic surgery, how they chose the particular procedure, how they chose the person who provided the procedure, whether enough information was provided, whether they were satisfied with the results, and whether the cost was reasonable. The respondents to the survey are anonymous. The *Review of the published literature* and the *Consumer Survey* are available for a fee from the Health Care Complaints Commission.

2. THE SIZE AND SHAPE OF THE INDUSTRY

2.1 What is cosmetic surgery?

While cosmetic surgery is difficult to define precisely, it has a number of key characteristics. It involves reshaping normal structures of the body using surgical and non-surgical techniques. It frequently involves using new and untested technology and techniques that are rapidly changing. New procedures are using less invasive surgical techniques and minimal use of sedation and anaesthesia.

A central characteristic of cosmetic surgery is that it is initiated by the consumer to improve their appearance and self-esteem. Other medical procedures are performed for therapeutic reasons, as a result of medical need. However, delineating procedures performed for therapeutic reasons from those that are performed for cosmetic reasons is difficult. Another important feature is the subjective nature of judgements about improvement in appearance.

Cosmetic surgery covers a range of procedures, including surgical procedures, non-surgical procedures and dental procedures. Surgical procedures include breast enlargement, rhinoplasty (nose surgery), surgical face-lifts, abdominoplasty (tummy tuck) and liposuction. Procedures such as chemical peels, collagen injections, laser skin resurfacing, vein removal, and laser hair removal are collectively referred to as cosmetic medicine. Cosmetic dentistry is another category of procedures that are regarded as part of cosmetic surgery. However, the Committee did not receive any information about cosmetic dentistry. Procedures such as tattoos, body piercing and lasik eye surgery tend not to be regarded as cosmetic surgery. Although the Committee did not exclude them from its investigations, there were no submissions on those topics, and as a result they are not dealt with substantively in this report.

2.2 Who provides cosmetic surgery?

Cosmetic surgery is very competitive with doctors competing to establish themselves as the leading provider.

The industry

The first task for the Committee was to understand the cosmetic surgery industry. This was difficult because no data exists on who is providing cosmetic surgery, how much is being provided and where it is being provided. The information presented in this report is based on 'guesstimates' from the industry.

Cosmetic surgery procedures are mostly performed by doctors with a wide range of qualifications, but dentists, nurses and beauty therapists are also represented. The medical practitioners performing cosmetic surgery include plastic surgeons, cosmetic surgeons, cosmetic physicians, general practitioners (GPs), dermatologists, ophthalmologists (eye surgeons), otolaryngologists (ear, nose and throat specialists) and to a lesser extent oral and maxillofacial surgeons. Plastic surgeons have specialist surgical training and experience in plastic and reconstructive procedures, and perform cosmetic surgery. Cosmetic surgeons do not necessarily have specialist surgical qualifications, and tend to be specifically trained in cosmetic procedures, usually in the USA. Dermatologists have specialist training and experience in the skin, and may perform dermabrasion, injections, peels, and laser resurfacing, in combination with liposuction, cheek implants and other surgical procedures. Ophthalmologists have specialist training in eye surgery, and most perform blepharoplasty (eyelid surgery), eye lifts and some brow lifts. Otolaryngologists have specialist training and experience in the ear, nose and throat, and they perform facelifts, brow lifts and rhinoplasty (nose surgery) and laser skin treatments. GPs performing cosmetic medicine may provide collagen and other injections, peels, laser skin treatments and dermabrasion. In the USA other specialities, particularly gynaecology and oral surgery, have a significant profile in the cosmetic surgery industry.

Nurses also play a significant role in the cosmetic surgery industry. In addition to their traditional roles, nurses also perform some cosmetic procedures and provide patient counselling in some plastic and cosmetic surgery clinics. A large number of practitioners who use injections in cosmetic medicine are nurses, constituting about 35% of injectors of collagen in Australia. In the UK nurses make up 80% of injectors.[1] They also provide some laser skin treatments, dermabrasion and peels, mostly under supervision of medical practitioners.

Beauty therapists are a third industry group, providing removal of unwanted hair and facials. The techniques used by beauty therapists have changed in recent years with the use of new equipment and techniques used in cosmetic medicine, such as lasers for removal of unwanted hair.

How are they organised?

Cosmetic surgery is very competitive with doctors competing to establish themselves as the leading provider. Twelve specialist colleges and professional associations made submissions to the Committee on behalf of an estimated 500 doctors performing cosmetic procedures in Australia.[2] Many of these groups are new, some less than 12 months old. Some doctors in the industry do not belong to any of these organisations. The main professional groups representing doctors are as follows.

Australian Society of Plastic Surgeons (ASPS): The Society has 217 members nationally, with about 190 performing cosmetic surgery procedures such as breast augmentation, facelifts and liposuction.[3] The Society provides training in plastic and reconstructive surgery and cosmetic surgery, and publishes guidelines for standards of practice, and research. In doing so it works closely with the **Board of Plastic and Reconstructive Surgery** of the Royal Australasian College of Surgeons, which is responsible for selection, training and supervision of plastic surgeons. ASPS promotes public education about plastic and cosmetic surgery procedures. It provides a public information telephone service and a website with information about members and procedures.[4] ASPS members are Fellows of the Royal Australasian College of Surgeons (FRACS) in the speciality of plastic and reconstructive surgery, which requires a minimum of eight years training after medical graduation.

Australian College of Cosmetic Surgery: The College is new, being formed in 1999 during the course of the Inquiry. It has 49 Members and Fellows, of whom 15 are cosmetic physicians (not surgeons), and at least five are dermatologists or ENT specialists.[5] The Australian Association of Cosmetic Surgery, established in 1992, was taken over by the College. The College is planning to provide training and has commenced accrediting Members and Fellows. College Fellows (cosmetic surgeons) must have three years basic surgical training, and a minimum of two years specific cosmetic surgery training, which may include training with cosmetic surgery colleges in the USA and Europe.[6] The College has a telephone information service number that provides names and contacts of College members.

Cosmetic Physicians Society of Australia: The Society was formed in 1998 with the aim of providing standards for education and accreditation for its members. It has 130 members nationally, and 51 in NSW in August 1999. Members must be medical practitioners and must have practised in at least one area of cosmetic procedure for at least 12 months. Some members include surgeons and other specialists, but most are general practitioners. All full members must have completed 12 months preceptorship with a suitable member of the Society to obtain ordinary membership (this excludes workshops, seminars and conferences). It has conducted seminars and its first national conference was held in May 1999. The Society has a website with consumer information about the procedures commonly carried out by cosmetic physicians, and names and contacts for members. [7]

Australasian Society for Aesthetic Plastic Surgery: The Society was formed more than 20 years ago to promote research and dissemination of information on aesthetic surgery in plastic surgery. It conducts an annual scientific conference in Australia and two or three training meetings each year.[8]

Australasian Academy of Facial Plastic Surgery: The Academy told the Committee that it has 60 members. It was formed in 1990 to provide education to its specialist members in the field of facial cosmetic surgery. The membership is comprised of otolaryngologists, ophthalmologists and dermatologists.[9]

Australian Society of Otolaryngology/head and Neck Surgery: The Society has 300 members nationally, with 100 members in NSW. It forms the Surgical Board in Otolaryngology/head and neck surgery jointly with the Royal Australasian College of Surgeons. There is a long tradition of facial plastic surgery being performing by otolaryngologists and it is included in the curriculum and examined by the Board. This is particularly so for rhinoplasty (nose surgery) and otoplasty (ear surgery), as well as blepharoplasty and facelift.[10]

Australasian College of Dermatologists: The College has 300 practising members Australia-wide and 120 members in NSW. It trains and accredits specialists with primary expertise in the skin.

Education and training involves a period of at least two years of basic training in the specific technical skills of the speciality, two years training in a teaching hospital, followed by successful completion of advanced clinical training for four years and examination. There are also active continuing medical education requirements. While most dermatologists do some cosmetic skin procedures, about 60 to 80 dermatologists nationally are estimated to be performing cosmetic surgery procedures regularly (known as cosmetic surgery dermatologists).[11]

Royal Australian College of Ophthalmologists: The College has 582 practising Fellows in Australia. It trains and accredits specialist eye surgeons who are uniquely trained in dealing with the structure of the eye, vision and diseases of the eye. Education and training involves a period of at least two years of basic training in the specific technical skills of the speciality followed by successful completion of advanced clinical training for four years. There are also active continuing medical education requirements. Some ophthalmologists complete two years training for the sub-speciality of ocular plastic surgery. The College told the Committee that most ophthalmologists are performing some cosmetic surgery – blepharoplasty (surgery of the eye), eye lifts and some brow lifts. Complementary surgery such as rhinoplasty and facelifts is usually performed in collaboration with other surgeons.[12]

Sclerotherapy Society of Australia: The Society was established in 1993 to offer training in sclerotherapy for its members, mostly GPs. It told the Committee that it has over 100 members, some of whom are also members of the Cosmetic Physicians Society. The Society holds annual conferences.[13]

Nurses working in the industry were not well represented in the Inquiry. The NSW College of Nursing and the Nurses Association (NSW) told the Committee that they do not have knowledge of nurses who provide cosmetic procedures.[14] The Cosmetic Nurses Association is a national organisation that provides a forum for discussion and education for nurses in the industry but only in the traditional nursing roles, not as injectors or providers of laser treatments. It is based in Melbourne, with about 150 to 180 members. It has held a number of national conferences since it formed in 1995. The Cosmetic and Plastic Surgery Nurses Association also covers nurses in the industry in NSW.

Beauty therapists and aestheticians are represented in NSW by the Advanced Beauty Therapists Association (ABTA) and the Association of Professional Aestheticians of Australia. The ABTA did not respond to an invitation to make a submission. However, the Victorian-based Hairdressers and Beauty Therapists Association provided a submission in response to the *Discussion paper: Use of lasers for cosmetic procedures*.

Manufacturers and distributors of devices

Manufacturers and distributors of devices used in cosmetic surgery, such as implants, injection products, and laser machines, play a major role in quality control and marketing. Manufacturers of injection products such as *Collagen Aesthetics Australia* and *Restylane* advertise their products, provide referrals to doctors who use their products through telephone helplines, and provide consumer information packages. *Collagen Aesthetics Australia* told the Committee that they provide training support to doctors and nurses prior to supplying their product, and follow-up training six weeks later, followed by refresher workshops.[15] They withdraw their product and offer retraining if a provider is the subject of more than three complaints from consumers. The companies distributing medical laser machines limit the types of machines made available to different providers – doctors, nurses and beauty therapists. They provide some training, such as weekend seminars and provide consumer information through providers, including 'before and after' photographs.[16] The suppliers of breast implants in Australia do not promote the product directly to the public.[17]

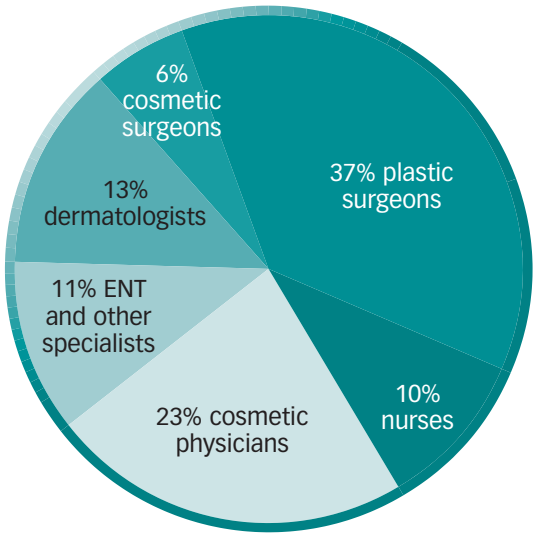
How many providers?

Information provided to the Committee shows there are approximately 350 doctors with a substantial practice in cosmetic surgical procedures in Australia – 190 plastic surgeons, 30 cosmetic surgeons, 70 cosmetic surgery dermatologists, and about 60 otolaryngologists and ophthalmologists.[18] This is consistent with figures provided by United Medical Protection, which estimates there are about 90 plastic and cosmetic surgeons in NSW, excluding the other specialities and GPs providing cosmetic medicine procedures.[19] The number of doctor and nurse providers of cosmetic medical procedures in Australia is more difficult to assess. However, the Committee estimates there are about 150 doctors and at least 50 nurses providing cosmetic medicine procedures in Australia.

A laser manufacturer told the Committee that 200 doctors have laser equipment for skin resurfacing (100 using CO2 lasers and 50 using Erbium lasers) and 50 have equipment for vascular treatments. A further 100 lasers are being used for hair removal.[20] This suggests that at least 200 doctors and nurses are offering laser treatments, assuming laser skin and vein treatments are mostly offered by the same providers. The Cosmetic Physicians Society claim half these medical lasers are being used by cosmetic physicians, 10% are being used by dermatologists and the remaining 40% by plastic and cosmetic surgeons.[21] This means about 100 cosmetic physicians Australia-wide are using lasers, and an unknown number of nurses are providing cosmetic laser treatments either within medical practices or from their own clinics.

Collagen Aesthetics Australia, the main supplier of collagen and similar products in Australia, told the Committee they estimate there are about 120 doctors and nurses actively providing collagen and similar injectable products on a regular basis Australia-wide. A further 200 are estimated to do so on an infrequent basis. A third of Collagen Aesthetics Australia's business is in NSW. They estimate that 35% of the injectors are nurses, and most injectors in plastic and cosmetic surgeons' practices are nurses.[22] This information suggests there are about 150 doctors providing cosmetic medical procedures in Australia, not including dermatologists, and about 50 nurses.[23] Figure 1 gives a profile of the qualifications of doctors and nurses providing cosmetic surgery procedures in Australia.

Figure 1 - the cosmetic surgery pie



Source: Estimates provided to the Committee by professional organisations and product distributors

2.3 The extent of cosmetic surgery

No-one knows exactly how much cosmetic surgery is being performed in Australia, but it is generally accepted that the industry has doubled in the past five years. The Committee estimates that about 50,000 cosmetic surgical procedures (including liposuction) were performed last year, and about 250,000 cosmetic medical procedures undertaken for the same period.

The estimated 350 medical practitioners providing cosmetic surgical procedures in Australia are estimated to perform an average of 150 cosmetic surgical procedures per year. If that is the case, there would be 52,500 cosmetic surgical procedures per year.[24] It is estimated that between 4,500 and 6,000 breast implants are currently performed for cosmetic reasons each year. One cosmetic surgeon estimates 10,000 liposuction procedures, 3,000 facelifts and 3,000 blepharoplasty procedures are now performed annually.[25] Figures available from Medicare and the *Consumer Survey* suggest that rhinoplasty (nose surgery) is also very popular. Just under 5,000 rhinoplasty procedures (nose surgery) were performed as a therapeutic procedure in the past year, and 6,000 a year in the previous two years (see section 2.5). Nose surgery made up 10% of the procedures performed in the *Consumer Survey* (see section 2.7). The Committee was told that about 10%-15% of cosmetic surgery procedures involve laser treatments used as part of facelifts and blepharoplasty (eyelid surgery), or for laser resurfacing.[26]

The number of cosmetic medical procedures provided is harder to estimate. Providers in this category have not been organised into professional associations until recently, and some provide

cosmetic procedures on a part-time basis. Another factor is that some of the procedures, such as chemical peels and injections, are relatively quick (30 to 60 minutes) and have a temporary affect (3 to 6 months). A Sydney cosmetic physician estimated that a cosmetic physician with a full-time specialised practice in this area is likely to be performing an average of 45 cosmetic procedures a week, or 2,000 per year.[27] If this is the case for the 130 members of the Cosmetic Physicians Society, they would be performing a total of 260,000 cosmetic medicine procedures a year.

The USA, being the leader in cosmetic surgery developments, can provide Australia with some insights and useful comparisons. Four major professional groups in the cosmetic surgery industry in the US provide annual statistics on the number of procedures performed by their members – the American Society of Plastic and Reconstructive Surgery, American Academy of Facial Plastic Surgeons, American Academy of Cosmetic Surgery and American Society of Aesthetic Plastic Surgery. The figures published by these organisations for 1996 and 1997 were compiled into a report in 1999 by the American Society of Plastic and Reconstructive Surgery. It gives some indication of the number of procedures performed.[30] However, the figures are difficult to compare, and do not provide a precise picture of the industry.

Most popular cosmetic surgery in the USA in 1996/97

Surgical procedures	
liposuction	600,000
breast augmentation	300,000
blepharoplasty (eye lid surgery)	380,000
rhinoplasty (nose surgery)	275,000
facelift	229,000
breast reduction	120,000[1]

Cosmetic medicine	
chemical peels	1,080,000
collagen injections	635,000
hair transplants	300,000
laser skin resurfacing	200,000
dermabrasion	120,000
botox injections	65,000

Source: 'The cosmetic surgery pie: What piece do plastic surgeons have?', Plastic surgery news, American Society of Plastic and Reconstructive Surgeons Inc, February 1999, pp. 1, 24, 25. All figures are from 1996 and 1997. All figures have been rounded to the nearest 10,000.

2.4 Where is cosmetic surgery performed?

Cosmetic surgery procedures are increasingly performed in doctors' rooms rather than in licenced day procedure centres or hospitals. The more recently developed cosmetic surgery procedures such as liposuction, laser skin treatments and sclerotherapy provide alternatives to the traditional surgical procedures. They are commonly performed in doctors' rooms under light sedation or using combination drug therapies, local anaesthesia and minor nerve blocks. Chemical peels, injections, dermabrasion and laser hair removal are also likely to be performed in doctors' rooms, clinics or in the case of hair removal, in beauty salons (see section 4.6).

2.5 Medicare figures

Figures available from the Health Insurance Commission on the reconstructive or therapeutic procedures commonly used in cosmetic surgery, such as rhinoplasty (nose surgery), breast reconstruction, and varicose vein removal, help to provide a picture of the industry. Medicare provides financial benefits for professional services that are necessary for the appropriate treatment of the patient.[28] However, a grey area exists in relation to doctors' interpretations of 'necessary'. For example, under 'dermatology' the eligible procedures include laser photocoagulation for the treatment of severely disfiguring vascular lesions to head or neck (visible from four metres). 'Severely disfiguring vascular lesions' can mean spider veins, the removal of which many people might regard as cosmetic.

The extent of the overlap is illustrated in the *Consumer Survey*, which found 26% of respondents had their procedure paid for in full or in part by Medicare. However, the results may not be reliable as the doctors who distributed the survey randomly selected patient names from their records, and they may not have distinguished between cosmetic and therapeutic procedures.

The Health Insurance Commission told the Committee it has a range of strategies to monitor appropriate use of Medicare benefits, particularly in regard to cosmetic procedures. The primary method is regular random and targeted audits. Also, a National Information Register was established

in July 1996 where complaints (internal and external) of inappropriate procedures and practices resulting in leakage of Medicare benefits can be listed for action. The Medicare Benefits Schedule is monitored routinely to identify exceptional performance of particular items in the Schedule or sudden changes in their utilisation, using traditional statistical methods of analysis. It also utilises neural networks technology (artificial intelligence), which mirrors the reasoning processes of the human brain, to detect abnormal patterns of billing behaviour.[29]

The table below sets out the number of therapeutic procedures performed over the past three years for procedures commonly used in cosmetic surgery. Breast prosthesis removal and replacement of breast prostheses have accounted for about 3,000 procedures per year over the past three years. The large number of rhinoplasties (nose surgery) is also notable, with 6,000 to 5,000 a year. There appear to be a large number of varicose vein treatments (about 65,000 a year), and an increase in the number of dermatology treatments. The trend in impotency treatments is notable. There has been a marked decrease over the past three years in the number of penile injections for investigation and treatment for impotency, which coincides with a NSW Inquiry into Impotency Treatment Services in NSW in 1998 and the release of Viagra onto the market.

Procedures provided under Medicare 1996-1999

DESCRIPTION OF PROCEDURE	1996/97	1997/98	1998/99
Dermatology - photocoagulation for severely disfiguring vascular lesions, wine stains (selected items)	8,190	10,381	11,715
Tumor, cyst, ulcer or scar removal by surgical excision	391,102	595,754	570,690
Varicose veins removal or injections	63,739	67,048	65,526
Laser eye surgery - includes laser trabeculoplasty, laser iridotomy, laser capsulotomy, laser vitreolysis or corticolysis of lens material, laser division of suture, laser coagulation of corneal or scleral blood vessels	52,501	50,140	49,409
Mammaplasty augmentation - for significant breast asymmetry, following mastectomy, or where it can be demonstrated that surgery is indicated because of disease, trauma or congenital malformation	264	257	457
Breast reconstruction and reduction - by using latissimus dorsi or other large muscle, or breast sharing technique (first stage and second stage), and following mastectomy using tissue expansion	600	665	843
Removal of breast prosthesis - as independent procedure, or with complete removal excision of fibrous capsule, or with excision of capsuleand replacement of prosthesis	1,323	1,070	1,246
Replacement breast prosthesis following medical complications - such asrupture, migration of prosthetic material or capsule formation	1,446	1,515	1,821
Hair transplant - for treatment of alopecia of congenital or traumatic origin, excludes male baldness	95	98	82
Liposuction - for treatment of post traumatic pseudolipoma, or where it can be demonstrated that the treatment is for pathological lipodystrophy of thigh, hip, buttock, lower legs	145	128	172
Meloplasty (cheek implant) - for facial asymmetry	80	100	84
Eye lid correction	5,242	5,291	6,190
Impotence - **injection** of penis for investigation and treatment of impotence	58,563	45,276	16,980
other impotence treatments and penis lengthening surgery	1,060	1,080	827
Rhinoplasty (nose surgery)	6,055	5,846	4,847

Note: Figures provided by HIC against item numbers for the type of procedures described in the current Medicare Benefits Schedule. Only current item numbers have been used. Figures showing significant changes from one year to the next may be the result of changes to item numbers.

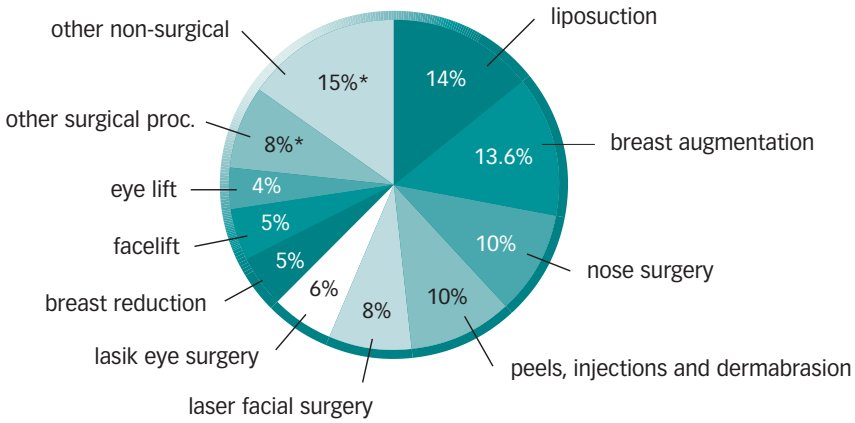
2.6 Who are the consumers?

To obtain a cross-section of the experiences of consumers of cosmetic surgery the Committee commissioned a survey of cosmetic surgery consumers in NSW. Over 1,500 surveys were distributed through 22 cosmetic surgery providers, including some plastic surgeons, cosmetic surgeons, cosmetic physicians, ENT specialists, dermatologists, nurses and beauticians. The providers were asked to randomly select patients who had a procedure within the past two years (the time period was chosen to minimise incorrect addresses). The survey provides a snapshot of the experiences of 280 consumers of cosmetic surgery in NSW between 1997 and 1999.

What consumers are having

The survey respondents had a wide range of procedures. Liposuction and breast augmentation were the most popular. Figure 2 summarises the types of procedures.

Figure 2 - what the consumers had



**Estimates and rounded figures only*

Slightly more than half of the respondents had the procedure carried out between one and six months before the survey, 40% between six months and two years before, and 8% less than one month before.

Multiple procedures provided in combination are common for facelifts/eye lift/brow lift/botox injection and with breast enlargement/facelift/liposuction. The survey found 15% of respondents had multiple procedures most frequently in those combinations. Laser treatments tended to be combined with eye lifts and facelifts.

Who provided it and where?

Consumers described the qualifications of the practitioners doing the procedures as plastic surgeons (38%), cosmetic surgeons (29%), dermatologists or ENT specialists (9.6%), general practitioners (5.4%), eye surgeons (5%), beauty therapist (1.4%) and nurses (<1%).

Almost half of respondents had their procedures carried out in a hospital, with 27.5% attending day procedure centres and 22% attending doctors' rooms. About 75% of the procedures were surgical procedures.

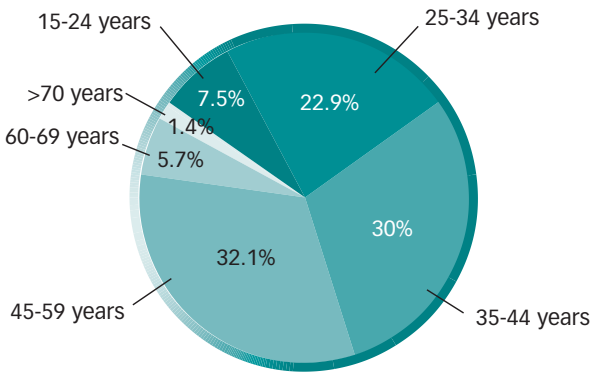
Gender and age

People in the cosmetic surgery industry claim that men make up an increasing proportion of cosmetic surgery consumers, around 20-30%. However, of the consumers who participated in the survey women made up 86% and 14% were men.

The image of cosmetic surgery consumers as middle-aged and middle class is challenged by the age and income profile of the consumers who participated in the survey (depending on your definition of 'middle-aged'). While the largest proportion of consumers were in the 45-59 age group, almost as many were in the 35-44 age group. There were also a large proportion of consumers (23%) in the 25-

34 age group, and a substantial number (7.5%) in the 15-24 age group. No answer was given to this question by 0.4% of respondents.

Figure 3 - age of consumers



Income

A large proportion of consumers were on relatively low incomes or the average wage. Only 20% of respondents were on an income over $60,000. Of those in the paid workforce, a third were receiving an income of $20,000-$39,000, and almost as many were in the $40,000-$59,000 income bracket. The average annual wage is $39,800, based on the Australian Bureau of Statistics average weekly earnings for all employees in May 1999.[32] A quarter of the respondents were not in the paid workforce.

Figure 4 - income of consumers

Where do they live?

The respondents were generally widely dispersed across Sydney, with some in regional and rural areas, and a very small number from interstate. The image of cosmetic surgery as a preoccupation of people of Sydney's north shore and eastern suburbs was confirmed to some extent by the survey results. Mosman appeared most frequently (3.6%), followed by North Sydney (3%) and Vaucluse (1.8%). There were also 2% from Epping and 2% from Lucas Heights.

Previous cosmetic surgery

The commonly held view that once people start having cosmetic surgery they are likely to go back for more is reflected in the survey results. About 43% of the respondents indicated that they had previously had cosmetic surgery: 18.6% had undergone cosmetic surgery once before, 21% between two and 10 times before, and 4% more than 10 times before.

Reasons for having the procedure

The survey sought to ascertain consumers' reasons for undergoing cosmetic procedures. From the options provided in the questionnaire, most respondents chose 'improving appearance' or 'to improve self-esteem'. However, a significant number also said that they had undergone the procedure to please a partner, or to keep a job. Fourteen of the 280 respondents, or 5%, said that they had undergone the procedure to repair previous cosmetic surgery.

Respondents were asked to provide their reasons for undergoing the procedure, and their responses reflected their own particular concerns with health and body image.

'About 43% of the respondents indicated that they had previously had cosmetic surgery.'

Why I had cosmetic surgery

"To make me feel confident and better about myself."

"To keep working as long as I can and keep on lying about my age so I can work."

"To feel more comfortable, ease shoulder/back tension. To buy a bra that fitted properly."

"To remove the object of ridicule."

"The body looked great but the face didn't fit it."

"Slow down the ageing process."

"Improve my sexual psyche."

"At the beach to look more normal, like other men."

"To feel comfortable to wear clothes other than those which covered the birthmark."

"I was not happy with my lips. I always thought thin lips made my face look very hard and serious."

"My only reason for the surgery was to rid myself of some self-consciousness I felt for about seven years regarding the appearance of my breasts – it was disrupting my ability to enjoy my life."

"No success in toning legs and hips. Tried exercise and diet."

"Some people have always wanted to go to Disneyland, Niagara Falls etc. Since I was 11 years old, I have always wanted to get my nose fixed."

"I looked a lot older than I felt."

"I had always wished for and admired big breasts."

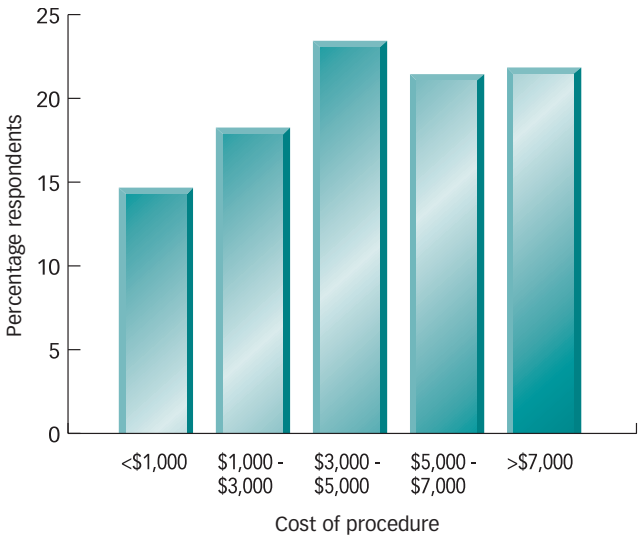
"Being upset when seeing photos of myself."

"I want to look and feel beautiful and healthy, vital and young."

Costs and payment

Cosmetic surgery is expensive and the cost will generally be borne by the patient as Medicare does not cover cosmetic procedures. The cost of the procedures paid by respondents to the survey was reasonably evenly spread between $1,000 and more than $7,000.

Figure 5 - the cost of the procedures



Consumers who participated in the survey largely paid for their cosmetic surgery procedure by cash or cheque from their savings (over 60%). About 23% paid by credit card or bank loan, and 7% used money given to the consumer by someone else. A very small proportion paid by a loan arranged by the hospital or practitioner (0.7%).

'About 23% paid by credit card or bank loan... Over a quarter said the cost of their procedure was covered by Medicare, and almost as many were covered by private health insurance.'

Over a quarter of respondents (26%) said that all or part of the costs of their procedure were covered by Medicare, and almost as many (24%) had all or part of the costs covered by private health insurance. The main procedures covered by Medicare were nose surgery, breast reduction, and surgery of the ear. A large proportion of people who had eye lifts, abdominoplasty and laser facial surgery also reported claims from Medicare. These procedures are covered by the Medicare Benefits Schedule if performed for therapeutic purposes. Similar procedures were claimed under private health insurance, with the addition of breast enlargement, dermabasion, facelifts and brow lifts.

3. THE REGULATORY FRAMEWORK

3.1 Professional regulation

The medical practice acts, and the medical boards established under them in each state and territory, provide a regulatory framework for registration of doctors and protecting the public. The *Medical Practice Act 1992* NSW establishes the NSW Medical Board, made up of doctors appointed by various colleges, the Australian Medical Association and ministerial appointments. The Board protects the public by registering appropriately qualified medical practitioners, disciplining doctors who fail to meet professional standards and monitoring doctors who are impaired. The Act and the *Medical Practice Regulation 1998* define unsatisfactory professional conduct and professional misconduct, and establish standards in areas such as infection control and advertising.

All registered medical practitioners in NSW are recorded in a general register. Members of the public do not know if a doctor is a specialist in a particular field because the NSW Board does not keep a register of specialists. In Queensland and South Australia doctors are required to register their specialist qualifications. The specialist register in Queensland includes a category for plastic surgeons, but there is no category for cosmetic surgeons.[33] The Australian Medical Council advises that the momentum for the introduction of vocational and specialist registration throughout Australia has increased to the point that each state and territory needs to address the issues. A proposed national standards accreditation process for specialist training is expected to be adopted by the Council by the end of 1999.[34] NSW is expected to move to specialist registration within a few years.

'Maintaining professional and clinical freedom is a major preoccupation for professional associations and colleges representing doctors.'

The vast majority of doctors practising as general practitioners or specialists are required to maintain professional standards through programs of continuing medical education, audit and peer review conducted by the Royal Australian College of General Practitioners and the specialist medical colleges. The relevant colleges in the cosmetic surgery industry are discussed in section 2.2. The colleges are not statutory bodies and have no role in regulation. Their primary functions are specialist training and qualifications, and helping members to keep up to date by providing structured training through scientific meetings, special courses and conferences. Maintaining professional and clinical freedom is a major preoccupation for professional associations and colleges representing doctors. Other health professionals, such as nurses, dentists and psychiatrists, must also be registered and they are subject to similar professional standards and regulations.[35]

Complaints about health care providers can be made to statutory-based health complaints commissions in each state. In NSW the Health Care Complaints Commission's (HCCC) role is to maintain standards of health services, providing independent resolution of complaints against health practitioners and health services. In appropriate cases, the HCCC will investigate and prosecute health providers before disciplinary committees such as the Medical Tribunal. Complaints can be made about any aspect of treatment and care from registered and unregistered health providers and hospitals, nursing homes, private clinics and other places providing health care.

Private hospitals and day procedure centres are required to be licensed by the NSW Department of Health under the *Private Hospitals and Day Procedure Centres Act 1988* (NSW). A day procedure centre is a facility where surgery is performed with general, spinal, epidural or major regional block anaesthetic or intravenous sedative, or where endoscopic treatments are performed or where various other types of treatments are performed.[36] The licences for day procedure centres focus on building design as it affects patient safety, and an assessment of the fitness and propriety of the proposed principals. The *Private Hospitals and Day Procedure Centres Act* and *Day Procedure Centre Regulation 1996* set clinical standards, prescribe levels and qualifications of staff, infection control, equipment, and facilities (including specified equipment for emergency procedures), quality assurance and reporting.[37] Other state legislation affecting aspects of medical practice include the *Public Health Act 1991,* the *Pharmacy Act 1964* and the *Poisons and Therapeutic Goods Act 1966.*

The activities of unregistered health care providers, such as beauty therapists, are regulated to some extent. For example, infection control obligations apply where procedures are performed that

penetrate the skin under the *Public Health Regulation 1991* and the *Skin Penetration Guidelines.*[38] The *Guidelines* describe safe practices, minimum standards and infection control procedures. The regulation covers a wide range of procedures, including tattooing, waxing, dyeing, piercing, manicures, and semipermanent makeup. A person who carries out skin penetration procedures must notify the local council, and the *Guidelines* recommend that local councils maintain a register of premises where skin penetration is carried out.[39]

3.2 Insurance, Medicare and accreditation

Other organisations involved in monitoring standards of medical practice are the professional indemnity insurer, United Medical Protection (UMP), the Health Insurance Commission and third party accreditation schemes for health care facilities.

The Health Insurance Commission (HIC) has a number of quality control mechanisms. Patients are required to be referred to specialists through a GP, and specialists must be credentialled by a Specialist Recognition Advisory Committee (established in each state and territory). HIC also monitors over-servicing and collects data that has the potential to be used for analysis.

Professional indemnity insurers protect doctors from professional damage through risk management strategies, and premiums that reflect the perceived level of risk on different areas of practice. Medical indemnity insurance is not a mandatory condition of registration for medical practitioners. UMP cite one surgeon who was responsible for 11 of the total of 89 claims between 1990 and 1998. The surgeon no longer has professional indemnity cover but continues to practise.[40] However, indemnity insurance is a requirement for credentialling in hospitals and some professional organisations require professional indemnity as a condition of membership.[41]

The maintenance of health standards through third party accreditation schemes has become increasingly important. Influenced by the development of Total Quality Management standards in other industries (ISO 9000,9002,9004), the standards seek to provide a measure of quality for funders and consumers. The principal organisation responsible for accreditation of health standards in Australia is the Australian Council on Healthcare Standards (ACHS). It promotes a quality improvement strategy premised on industry-based standards, quality improvement and risk management systems, peer review and accountability through accreditation and outcome measures. The ACHS Evaluation and Quality Improvement Program – EQUiP – was developed to foster a culture of continuous improvement. Most accreditation programs are voluntary and user-pays.

3.3 Common law obligations

The doctor-patient relationship is defined in the common law (made by the courts) in terms of the law of negligence, which imposes a duty of care on doctors to care for patients.[42] As part of the duty of care, doctors are obliged to provide such information as is necessary for the patient to give informed consent to treatment, including information on all 'material risks' of the proposed treatment. In deciding what is material the doctor should consider the 'nature of the matter to be disclosed; the nature of the treatment; the desire of the patient for information; the temperament and health of the patient; and the general surrounding circumstances'.[43] The High Court has recognised that this duty is an onerous one. In a recent High Court decision, *Chappel v Hart,* a doctor's failure to disclose the limits of his experience was regarded as a failure of duty of care in the circumstances of the case.[44]

Lawyers told the Committee that the principles of informed consent are particularly important in cosmetic surgery. The courts regard the duty to warn as more onerous in cosmetic surgery because patients have a choice about whether to have the procedure. If there is a perceived level of inducement to have a procedure, coupled with failure to warn of risks, the doctor has a greater burden to demonstrate that the patient was properly informed. Cosmetic surgery patients may also ask more questions about risk, outcomes and the practitioner's experience.[45]

When a conflict of interest arises the common law imposes a duty of trust between a doctor and patient. The trust, or fiduciary, relationship is based on the principle that doctors have a special opportunity to affect the interests of patients, who are regarded as vulnerable to abuse.[46] The courts impose the duty where a doctor benefits substantially from a patient (other than receiving proper fees). In such circumstances the law presumes that he or she has used undue influence. The trust

relationship means that doctors are legally obliged to avoid a conflict between their own interests and that of the patient, and not to profit at the patient's expense beyond the agreed fees. Where such a conflict arises the doctor must resolve it in favour of the patient. The duty does not necessarily amount to a requirement to disclose financial interests.

3.4 Fair trading

Fair trading acts aim to promote fair trading, competition and consumer protection. The *Fair Trading Act 1987* (NSW) and the *Trade Practices Act 1974* (Clth), Part IVA and V proscribe certain anti-competitive conduct and unconscionable, misleading, false or deceptive conduct. These laws have applied to the professions since 1996 and are administered by the Australian Competition and Consumer Commission (ACCC) and the NSW Department of Fair Trading.

The major policy underpinning the *Trade Practices Act* is the promotion of competition, but with checks and balances. The ACCC can authorise some forms of anti-competitive conduct in a market where the total public benefits of the conduct outweigh the detriment caused by the anti-competitive process. This is particularly important in areas where health and safety are at risk. A central concept in competition is the idea of parties in the market bargaining on a 'level playing field'. Where there are inequities between contracting parties it may be necessary to intervene with regulation.

The ACCC recognises consumers are often unable to independently assess the need for a medical procedure because of the specialised nature of the service being provided. This is known as 'information asymmetry'. In other areas of the economy where there are significant information asymmetries between consumers and suppliers of services, one way of addressing the problem has been to make disclosure of information mandatory.[47] The financial services sector and the legal profession are examples of two industries required by law to make certain disclosures to consumers.

3.5 Drugs and devices

'Therapeutic goods' are regulated by the Therapeutic Goods Administration under the *Therapeutic Goods Act 1989* (Clth) and regulations. In general, therapeutic goods, which include medicinal products and devices, must be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be marketed in Australia. The ARTG has two parts: one for registered therapeutic goods and one for listed therapeutic goods. Registered goods are higher risk therapeutic goods and listed goods are lower risk. There is more stringent per-market evaluation of the higher risk registered therapeutic goods and the sponsor of the product must demonstrate quality, safety and efficacy of the product. The pre-market evaluation of lower risk listed therapeutic goods is less stringent, but the sponsor must still demonstrate safety and quality of the product. Entries for medicinal products contain approved indications for use of the product while medical devices are approved for supply with use not specified.[48]

The drugs and devices used in cosmetic surgery include breast implants, injection products such as collagen, and lasers used for skin and vein treatments, and for removal of unwanted hair. Lasers and breast implants are discussed in sections 5.2 and 5.3.

3.6 Adequacy of safeguards

It is difficult to assess the effectiveness of the regulatory framework in maintaining the quality of clinical standards and consumer safeguards in cosmetic surgery because there are few sources of information.[49] The level and nature of medical negligence claims and complaints against doctors in the cosmetic surgery industry provide some indicator of problems, but not all. Medical indemnity insurers and health complaints bodies found the number of complaints and claims for compensation in cosmetic surgery is not disproportionately higher than other areas of medicine. However, they regard it as a high risk area of practice because of the nature of the complaints, which are primarily about clinical outcomes, and certain characteristics of the industry.[50]

'... the number of complaints and claims for compensation in cosmetic surgery is not disproportionately higher than other areas of medicine. However, it is regarded as a high risk area of practice.'

Legal claims

Statistics provided by UMP cover doctors who perform cosmetic surgical procedures in a category of membership for plastic/cosmetic surgery. The figures do not include claims arising from cosmetic work performed by ENT surgeons or ophthalmic surgeons. Nor do they include UMP's claims experience in relation to sclerotherapy, which is widely practised by GPs. Members in the GP category are covered for this type of work. A new category for cosmetic medicine was created in 1998 to cover non-surgical cosmetic work but statistics from this group were not available. UMP's data identifies 'claims', which includes all claims for compensation and 'other notifications', which covers complaints to the HCCC, requests for medico-legal reports and incidents reported by members. The data on claims and notifications provided by UMP does not include claims or notifications arising from non-cosmetic work by its members in the cosmetic/plastic surgery category.

UMP reports a steep increase in the number of claims and other notifications in the plastic/cosmetic surgery category between 1990 and 1998. In 1990 there were two claims and six notifications against 30 members in that category. In 1996 there were 15 claims and 27 other notifications against 88 members, and in 1998 there were 20 claims and 61 notifications against 82 members. However, UMP says the data reflects the general pattern of increasing claims frequency that has been a feature of litigation involving NSW doctors over the past decade.[51]

Of the 89 claims made between 1990 and 1998, 48 have been resolved. Of these 29 were settled with payment to the claimant prior to trial, and eight cases were resolved prior to trial without payment to the plaintiff. Eleven cases were decided at trial and in nine cases the defendant succeeded, either at first instance or on appeal. Claimants were successful in two cases. UMP says a higher percentage of cosmetic surgery cases are resolved at trial than cases generally, because the issues are generally more simple, the disability (scarring) more readily assessable.

According to UMP the same factors influence the size of claims in cosmetic surgery, which it says are generally of a lower cost than claims in comparable speciality groups, such as gynaecology. Often the adverse outcome relates to scarring as opposed to some other disability that affects a claimant's ability to work or require ongoing care. Claims against plastic surgeons for therapeutic procedures are generally of a higher cost per claim according to UMP.

UMP was not able to provide a breakdown of the procedures giving rise to claims. However, it submitted that cosmetic breast surgery provides the largest number of claims, with over 30% of claims arising from breast augmentation and more than 10% from breast reduction. Liposuction is the next largest source of claims. Dissatisfaction with the outcome of the surgery also accounts for claims in this area.

UMP regards cosmetic surgery as a high risk area of practice. In 1999 plastic/cosmetic surgeon members each paid UMP $34,250 for indemnity for the year. The main reason it gives for the high risk assessment is the different nature of the doctor/patient relationship and the financing of cosmetic surgery.[52] The key factors identified by UMP in determining the cause of adverse outcomes are:

- poor communication;
- poor patient selection;
- lack of training and skill;
- the role of non-medical staff and consultants;
- surgery performed in non-accredited facilities;
- the role of advertising in consumer expectations;
- relatively high cost of cosmetic surgery.

Complaints

The Health Care Complaints Commission (HCCC) received a total of 80 complaints in the category for plastic, reconstructive and cosmetic surgery between July 1995 and March 1999. Most of the complaints related to treatment: 'inadequate', 'incorrect' or 'resulting in an adverse outcome'. Other complaints were categorised as relating to business practices, such as fees and advertising, or to rude

or insensitive communication. Of the 80 complaints, 70 related to medical practitioners, one to a nurse, seven to private hospitals and two related to public hospitals.[53]

A third of the complaints were considered serious enough to warrant investigation for unsatisfactory professional conduct by the HCCC or another body. 15 of the complaints were declined by the Commission after consideration, 15 were referred to the Health Conciliation Registry, four were referred for direct resolution, 15 were referred to another body for investigation (such as the Medical Board) and 13 were the subject of investigation by the HCCC.

The HCCC told the Committee that it declines complaints for a range of reasons. An example is a woman who had breast implants in 1986 and complained that she was not given a warning about possible contraindications. The HCCC assessed the complaint in consultation with the Medical Board and decided to decline it as it related to incidents that were more than five years old.

At the request of the Committee the HCCC conducted a review of all the 80 complaint files to identify the types of cosmetic procedures that gave rise to the complaints. It found that 54 of the 80 complaints

A complaint investigated by the HCCC

The complainant was referred by her GP for bilateral, upper and lower eyelid reduction (blepharoplasty). The operation was performed in the practitioner's rooms under anaesthetic administered by the doctor. On the way home after the surgery the complainant began to vomit and eventually required an injection to stop the nausea. Subsequently the left eye became painful and the left eyelid drooped further than the right. A second operation was performed but the eyelid continued to droop and remained painful. Opinions obtained from consultant surgeons confirmed a drooping, ptosis, of 1-2mm and that further surgery was not recommended. The complainant, in addition to complaining about the outcome of the surgery also complained that since the operation she had found out the doctor was not a member of the Australian Society of Plastic Surgeons. Concern was also expressed at the level of anaesthetic and the lack of information about complications provided pre-operatively.

Opinions were obtained from two plastic surgeons. The first advised that ptosis was a very rare complication of this form of surgery, that the practitioner should have consulted with an ophthalmic surgeon before the second operation and that the majority of plastic surgeons would perform bilateral eyelid reduction in a hospital and, if neuroleptic anaesthesia was used, to have an anaesthetist providing that anaesthetic. The second plastic surgeon advised that the practitioner had departed from acceptable standards in a number of areas including delayed diagnosis of the complication and the practice of performing neuroleptic anaesthesia as the surgical operator and the anaesthetist.

An opinion was also sought from a consultant anaesthetist who concluded that the practitioner had not complied with a number of the guidelines contained within the Policy of the Australian and New Zealand College of Anaesthetists, including inadequate documentation of pre-operative assessment in the practitioner's report, no mention of an assistant appropriately trained in resuscitation being present to monitor level of consciousness and cardiorespiratory function, and no record of informed consent for the procedure and sedation.

The Commission concluded that aspects of the complaint had been sustained. After consultation with the Medical Board the matter was referred to a Professional Standards Committee for hearing. The Committee concluded, on the basis of all of the evidence before it, that the doctor's conduct did not amount to unsatisfactory professional conduct as defined in the *Medical Practice Act*. It found that the doctor had erred in judgement in not administering an anti-emetic (to stop vomiting), but the error of judgement did not amount to "lack of adequate judgement" as defined in the Act. The Committee said it was faced with a conflict of evidence as to the adequacy of the doctor's explanation of complications to the patient, and it had to form an opinion based on which witness was more credible. Even though it was comfortable with the view that the doctor had explained the complications to the patient, the Committee said she now clearly wished that she had never agreed to surgery and had she been told of the possible complications she would not have done it.

arose from cosmetic surgery procedures. The largest proportion were for breast augmentation, eyelid surgery and liposuction (13% for each), followed by nose surgery (9.3%), facelifts (9.3%), laser treatment (7.4%) and injections (7.4%). There were two complaints about advertising.[54]

Complaints data from health complaints commissions in Victoria, Queensland and Western Australia was similar to NSW in that they found most complaints were about clinical issues. A gap between consumer expectations and the final result of the procedure was also identified as a significant factor. Advertising and promotion in the industry were regarded as a major contributing factor to complaints about quality of care.[55]

Breast surgery featured as the procedure that attracted the highest number of complaints. In Queensland breast implants made up 12 of the 47 complaints. In Western Australia 10 of the 49 complaints were about breast reduction procedures and nine were about breast implants. The Health Services Commission in Victoria did not provide a breakdown of complaints by procedure.

The outcomes of complaints in other states are somewhat different to NSW because, unlike the HCCC, those health complaints commissions do not have power to prosecute health providers before disciplinary committees. Therefore they do not have the same level of investigation. However, complaints about cosmetic surgery in those states have also been sufficiently serious to warrant referral to other bodies for investigation. In Queensland complaints about cosmetic surgery have led to disciplinary action against one practitioner and in another case, a review of hospital standards and changes to hospital procedures. In Victoria concerns about multiple complaints against four practitioners have been conveyed to the Medical Board.

Victoria appears to have the highest number of complaints, largely due to 89 complaints against only four medical practitioners in the 10 year period. One doctor has been the subject of 35 complaints since 1990. In the past two years 28 complaints have been received about two dermatologists.[56] The Health Services Commissioner points out that, based on the experience of her office over 10 years, most medical practitioners can expect to be the subject of one complaint during their career. Therefore practitioners who are the subject of multiple complaints are a cause for great concern.

STATE	NO. OF COMPLAINTS	PERIOD	KEY OUTCOMES
Health Care Complaints Commission (NSW)	54	1995 - 99	28 complaints investigated. A small percentage referred for disciplinary action
Health Services Commission (Vic)	66 (248)	1995 - 99 (1988 - 99)	multiple complaints about 4 doctors conveyed to Medical Board
Health Rights Commissioner (Qld)*	44	1996 - 99	4 referred to Medical Board, resulting in 1 disciplinary action, 1 review of hospital standards
Office of Health Review (WA)	49	1992 - 99	(not specified)

**Figures may not be complete due to changes to data collection system*

Consumer submissions

The Committee received 38 submissions from consumers of cosmetic surgery procedures, of which 36 were complaints. A further eight submissions were received from consumer advocacy groups and consumer focussed researchers.[57] While these submissions cannot be regarded as representative of consumers, the issues they raise are relevant considerations for the industry.

The submissions from consumers and advocacy groups canvassed a wide range of procedures. Most arose from breast augmentation (11), laser resurfacing (six) and eyelid surgery (six).[58] The following themes were raised in the consumer submissions:

- failure to adequately warn of risks of complications;
- dissatisfaction with results;
- lack of sufficient information about aftercare;
- the need for independent and reliable information about cosmetic procedures;
- the need for independent and reliable information about providers of cosmetic procedures;

- the need to control advertising which is misleading; and
- the inappropriate use of non-medical staff in marketing and counselling.

Other submissions from consumers raised complaints about lack of proper care, lack of hygiene of facilities, and price. Many submissions described serious injuries from cosmetic procedures. A large proportion had corrective surgery performed by another practitioner.

Consumer satisfaction

'The Consumer Survey... found high satisfaction ratings among 80% of the 280 consumers.'

Patient satisfaction surveys are quite common in cosmetic surgery because the success of the outcome relies on whether the patient is satisfied with the result.[59] Overall, high patient satisfaction ratings are reported in the published literature – between 60%-98%. However, the *Review of the published literature* advised that the results of most of the published studies should be viewed with caution because of serious methodological weaknesses. These include the surveys being conducted by the doctors who provided the service, the inadequate explanation of the method used to select patients and short time periods between the procedure and the survey (usually being six months).[60] The literature is discussed in more detail in section 5.5.

The *Consumer Survey* conducted for the Committee found high satisfaction ratings among 80% of the 280 consumers who completed the questionnaire. The survey covered a wide range of cosmetic procedures, provided by over 22 health professionals in NSW. The questionnaire asked respondents how satisfied they were with the outcomes of the procedure, rating their responses between 1 = not at all satisfied and 5 = completely satisfied. The mean response was 4.11, indicating high levels of satisfaction overall, with the remainder expressing a considerable degree of dissatisfaction (1-3). The higher levels of dissatisfaction were with laser facial surgery and laser hair removal (although the numbers in the latter category were small). The highest levels of satisfaction were for breast reduction and laser eye surgery.[61] Just over half of the respondents had the procedure between one and six months before the survey, 40% between six months and two years before, and 8% less than one month before.

An analysis of the *Consumer Survey* results attempted to relate the levels of satisfaction to types of practitioners. The variability between respondents was relatively large, which meant that any statistical comparison of satisfaction ratings for different types of providers was not statistically different.[62] Other analysis of satisfaction ratings in the *Consumer Survey* is discussed in section 5.5.

Very high levels of satisfaction were found in two patient surveys conducted of patients of the Cosmetic and Laser Surgery Institute in Queensland in 1998. One survey examined patient satisfaction with a range of aspects of the service and clinical outcomes of the breast implants, using a questionnaire with telephone interviews six months after the procedure.[63] The other examined emotional experiences of consumers of laser resurfacing.[64]

4. GENERAL QUALITY AND SAFETY ISSUES

4.1 Quality and safety problems

Cosmetic surgery operates outside the framework for organised medicine in a number of ways:

- Unlike other areas of medicine there is little useful information on the safety, appropriateness and effectiveness of most procedures, and the level of training required to safely and effectively perform them;[65]
- Cosmetic surgery does not come under the auspices of any particular professional body that can establish competency standards and appropriate training and qualifications;
- Much cosmetic surgery is now performed in doctors rooms where there is no regulation of safety, no independent peer review (as there is no credentialling requirement with granting of privileges), and no mandatory reporting of complications;
- Cosmetic surgery is not covered by Medicare, so there is no requirement to be referred by a GP, and no Health Insurance Commission accreditation;
- Any registered doctor can call themselves a surgeon, and there is no legal requirement to have specialised skills and knowledge to be called a 'cosmetic surgeon' or specialist;

The *Review of the published literature* highlights a lack of research on cosmetic surgery. Medical literature usually guides clinical practice, but this is not the case for cosmetic surgery. It has been characterised by unconventional practices and a fear of sharing information on results with peers. The *Review of the published literature* reviewed the literature on six cosmetic surgery procedures: rhinoplasty, augmentation mammoplasty, augmentation phalloplasty, laser resurfacing, liposuction and breast reduction. It identified the following gaps in knowledge:

- Most of the published literature on these topics recounts clinical experience with various techniques, including the occurrence of complications, and surveys of patient satisfaction with the outcomes. However, because of methodological weaknesses, there is a paucity of adequate evaluation of the procedures;
- The literature generally reports a high level of patient satisfaction with the procedures. However, reports of patient satisfaction must be viewed in the light of the methodological weakness of most of the studies;
- The procedures are associated with a fairly high level of morbidity, most of which is described as resolving over the weeks to months following surgery;
- No systematic studies of the contribution of these cosmetic surgery procedures to overall surgical morbidity and mortality;
- The literature does not evaluate outcomes and complications in relation to the level of training and experience of cosmetic surgery practitioners. However, given the complexity of the procedures, the reliance of many of them on rapidly developing technologies, and their potential to cause significant general and local complications, a specialist level of expertise is likely to be important. A detailed knowledge of the surgical anatomy of the operation sites, at the level of a specialist surgeon, is a logical prerequisite for any cosmetic surgery practitioner;
- Practitioners should be encouraged to participate in well-designed rigorous studies to evaluate the procedures. Such studies are not necessarily more complex or expensive than those reported, but they depend on the availability of expertise in research methods. Both new and existing technology for cosmetic surgery (including patient selection, operative procedure, pre- and post-operative management, and instrumentation) warrant proper assessment. Technology assessment should be associated with surveys of patient satisfaction and monitoring of the safety and effectiveness of the procedures.

The *Review* concludes that the literature does not examine whether, and to what extent, professional qualifications and experience contribute to the outcomes of cosmetic surgery.

4.2 The need for independent credentialling

A major issue for the Committee was whether an independent credentialling or accreditation process should be established for the cosmetic surgery industry. Many submissions supported a process to give the public reasonable confidence that a person claiming to be skilled in a particular procedure meets minimum standards of competence and quality.

Any registered medical practitioner can do cosmetic surgery. There are no mechanisms to protect patients from unskilled and inexperienced people or to assist consumers to make judgements about levels of competence of practitioners. Specialist medical colleges and professional associations in the industry provide training and qualifications in aspects of cosmetic surgery procedures, but they are no guarantee of competence in particular procedures.[66] Key factors in assessing competence are training and experience, rather than membership of professional bodies, yet this is the only information available to consumers.

'Many submissions supported a process to give the public reasonable confidence that a person claiming to be skilled in a procedure meets minimum standards of competence and quality.'

The Committee is aware of the criticisms of existing credentialling processes at hospitals and day procedure centres. Medical advisory committees, also known as credentialling committees, are required to be established by hospitals and day procedure centres in NSW to provide advice on who can practice in the facility and what medical procedures they can perform. These committees are made up of doctors practising in the hospital or day centre.[67] A common criticism is that they operate on a 'closed informal basis', often relying on anecdotal rather than objective data for making decisions.[68] Two submissions claimed that credentialling committees in some private hospitals in NSW are often made up of plastic and general surgeons who collude to keep out cosmetic surgeons.[69]

NSW Health have developed a guideline that provides a standardised framework for delineation of privileges in public hospitals and other public health facilites. It clarifies the purpose of credentialling and privileges, and sets out the process to be followed, the composition of credentials committees, with a specific section on new procedures and technology.[70]

Accreditation

Accreditation is a formal system to evaluate a doctor's competence necessary to perform safely and effectively within the scope of the doctor's practice, assessed against specific criteria. The professional colleges have accreditation programs that include training and competency measures assessed through examination. Third party accreditation programs exist for health organisations such as the ACHS EQUiP program. They require applicants to provide qualitative and quantitative data to match predetermined standards criteria.

Credentialling

Credentialling is a process involving a group of peers ratifying the general ability of a practitioner to perform particular types of procedures, usually relying on information provided by the practitioner, such as curriculum vitae, qualifications or college fellowship, a log of procedures or treatments, evidence of continuing medical education and supervised assessment, where appropriate. It gives broad recognition to appropriate qualifications and experience.

Privileges

Credentialling committees provide advice on the competence of medical staff to perform particular roles within the facility. These are referred to as privileges. Privileges delineate the role a practitioner is allowed to perform in the facility. The privileges may be broad, allowing general surgical work up to a certain level, or may be specific to treatments or procedures that are part of the practitioner's training.

4.3 Credentialling or accreditation?

The Committee considered a range of options for independent credentialling or accreditation of cosmetic surgery providers. The first option was a proposal for accreditation of providers on a 'procedure by procedure' basis. This appeared to address consumer demand for information on the competence of a provider to perform the specific procedure(s) they plan to have. However, there are many practical difficulties with this approach. The primary difficulty is the lack of research on skills required for providers of cosmetic surgery, and the link between skills and outcomes. This makes it difficult to develop criteria for assessing training requirements. Also, the speed of new technology and new techniques makes it difficult for an accreditation process to keep up. The Committee acknowledged that accreditation on a 'procedure by procedure' basis has not been done anywhere else in the world.

A major concern about accrediting by procedure is the potential ramifications for other areas of medical practice. A number of submissions described this approach as 'cookbook' medicine because it attempts to recognise specific training outside the wider context of specialist medical training. Committee members agreed that cosmetic surgery is separate from other areas of medicine and there would be no 'flow on' effect to organised medicine. The relevant distinguishing features of cosmetic surgery are:

- cosmetic surgery has developed outside the existing health care infrastructure including credentialling, peer review and reporting of complications;
- the methods and technology are often outside organised medicine;
- the consumer chooses the provider through advertising, media and informal networks of friends and relatives rather than from a general practitioner.

The Committee was divided on the merits of accreditation by procedure, but all agreed that it is not practical at this stage because of the lack of medical research on competency standards and training requirements.

An alternative approach considered by the Committee was to group procedures according to complexity and risks. Three categories were proposed according to the types of providers involved, the type of sedation and anaesthesia, the type of facility in which it is performed and the type of risks to the consumer:

Category 1

- a surgical procedure in the commonly understood sense of 'cutting with a knife', such as breast augmentation, breast reduction, rhinoplasty, surgical face lifts, otoplasty;
- may be performed by general surgeons, plastic surgeons, cosmetic surgeons, or ophthalmologists, ENT specialists, maxillofacial surgeons;
- most commonly performed under general anaesthetic in a day procedure centre or hospital, with an anaesthetist present.

Category 2

- a surgical procedure that involves piercing the skin or entry to an organ, such as liposuction and use of CO_2 lasers to cut the skin;
- performed by plastic surgeons, cosmetic surgeons, dermatologists, or GPs and cosmetic physicians;
- most commonly performed in day procedure centres or doctors' rooms under light sedation, local anaesthetic or minor nerve block with or without an anaesthetist.

Category 3

- procedures involving varying degrees of penetration of the skin including penetration to the dermis, such as laser skin treatments, laser hair removal, dermabrasion, chemical peels, injections, vein removal, sclerotherapy;
- most commonly performed by GPs and cosmetic physicians, dermatologists, and nurses operating within doctors' practices, and beauty therapists;
- usually performed in doctors' rooms or beauty clinics with light sedation, local anaesthetic or minor nerve block.

The Committee found this approach flawed as there is no 'natural' grouping of procedures and no medical speciality with a monopoly on skills. There would be problems with accrediting a provider who has competence in some procedures in a category, but not in others. Ultimately, it would not tell consumers what they need to know – whether the provider has competence to provide the procedures they plan to have.

The Committee agreed a credentialling approach is preferrable. This process provides formal ratification that a provider has appropriate qualifications and experience. The Committee agreed that this is more practical than an accreditation by procedure, or conferral of privileges, which require demonstration of competency based on training.

Government intervention through additional regulatory standards and enforcement was regarded by the Committee as neither practical nor warranted at this stage. It was agreed that a Cosmetic Surgery Credentialling Council should be established to provide credentialling of cosmetic surgery providers. The Council would be industry-controlled and funded through a membership or levy, and voluntary membership.

A key element of the credentialling proposal is the use of a uniform standard of performance criteria that would not be controlled by any one professional group. It is essential to avoid any particular organisation attempting to control credentialling, and to minimise 'turf wars'. The standard should be set by a group of peers who are competent at the procedure. This should be publicly available.

'The primary difficulty is the lack of research on required skills for providers of cosmetic surgery, and the link between skills and outcomes.'

The Council will need to impose appropriate sanctions against credentialled providers who fail to comply with guidelines or performance standards. The Committee agreed that a range of sanctions should be available, other than withdrawing credentials, so that the Council can encourage improved practice, rather than adopting an 'all or nothing' approach. The options should include a right to publish the names of recalcitrant members, providing some public accountability and a sanction that members will take seriously.

The Committee agreed that the credentialling process should cover registered health professions initially. While credentialling of all providers is important, difficulties arise when attempting to cover providers who are not required to be registered because there are different sanctions, and in some cases no legal sanctions for non-compliance.

The Committee agreed that eventually a nationally-based Cosmetic Surgery Credentialling Council would be preferable given the highly mobile nature of the industry and the nature of advertising and promotions.

Recommendation 1

1a. Cosmetic Surgery Credentialling Council (CSCC) be established for all registered providers of cosmetic surgery procedures to provide independent and accountable verification of qualification of credentials. The Council would have the following features:

- provision of reliable information for consumers;
- peer review, but independent of any particular guild or registration body;
- industry-funding, based on membership fees or subscriptions or levies;
- voluntary membership, not affecting practitioners' rights to practice;
- effective sanctions for members who fail to comply with credentialling requirements, including loss of credentials and publishing the provider's name where appropriate.

1b. The CSCC expand membership to include unregistered providers of cosmetic surgery procedures within two years.

4.4 The credentialling process

Given the lack of literature about the industry, the Committee formed the view that credentialling would be based on whether the provider has the appropriate qualifications and experience. Like other credentialling processes, this would be based on the qualifications and experience stated in the practitioner's curriculum vitae, evidence of relevant continuing medical education, references, and evidence of a log of procedures or treatments.

The Committee agreed training is a reliable measure of competence in medicine. Medical research supports the reliability of training in surgical procedures to produce good clinical outcomes and practitioners who know their limitations. Training provides a reliable surrogate for medical practitioners to measure competence of a peer.

An essential requirement for credentialling should be ongoing professional indemnity insurance. Professional indemnity insurance is already required by the major industry organisations. It is a condition of membership of the Australian College of Cosmetic Surgery and the Cosmetic Physicians Society. Members of the Australian Society of Plastic Surgeons are also insured as part of the credentialling and licensing requirements for the facilities in which they work.

The credentialling process should have an independent appeals process, a common feature in hospital credentialling. The credentialling process should also accommodate the potential for conflicts of interest. A medical practitioner seeking to be credentialled should be able to object to another practitioner being on the committee on the grounds of potential conflict of interest, particularly where the member is a significant competitor. The NSW Health *Guidelines for delineation of clinical privileges* provides a model.

The type of facility where the procedure takes place is regarded by the Committee as central to patient safety. It was agreed that credentialling should be closely linked to licensing of doctors' rooms so that key risk factors are addressed (see section 4.6)

Recommendation 2

2a. The CSCC establish credentialling committees of peers to make credentialling decisions. The credentialling process would be based on the following principles:

- peer responsibility for credentialling on a non-discriminatory basis that requires the same standards for all providers, regardless of background training or speciality;
- published requirements for credentialling;
- procedural fairness, including an appeal process for review of unfavourable decisions and a procedure for resolving conflicts of interest.

2b. Credentials will be renewed regularly (two to three years) and will require:

- demonstration of continuing professional indemnity insurance;
- compliance with codes of conduct on advertising, informed consent, appropriate patient/client selection, and financial disclosures; and
- satisfactory participation in a systematic audit process for activity and outcomes.

4.5 Functions, structure and implementation

Functions of the Council

A primary role of the Council would be to provide a process for assessing whether applicant cosmetic surgery providers should be credentialled, and re-credentialled every two or three years. The main purpose of credentialling is to provide consumers with information on the competence of a provider. Therefore, a crucial role for the Council is to educate the consumers about the scheme. Its success will depend on the Council ensuring that consumers can easily recognise a credentialled provider. Consumers would be encouraged to look for a Cosmetic Surgery Credentialling Council logo as an indicator of competence and quality assurance. The Council would also have a substantial

role in providing information to the public about the individual credentialled providers (discussed in section 6).

Another role is to prepare codes of conduct covering areas such as communicating with patients and informed consent, financial conflicts of interest, patient assessment and selection (discussed in sections 6 and 7). Audits of compliance with these protocols should be regularly conducted by the Council in association with re-credentialling.

Training programs for practitioners would continue to be provided by the specialist colleges and associations.

The Committee agreed that the Credentialling Council should collect data on the industry. One of the main roles of the CSCC is to require credentialled providers to record the outcomes of their procedures. The Committee was unanimous that the CSCC collect data on cosmetic procedures and outcomes (morbidity and mortality) and publish them annually. It also suggests that United Medical Protection publish annual statistics on the types of cosmetic surgery procedures that are the subject of notifications and claims.

The Council would handle complaints about credentialled providers. A complaints policy should be developed setting out the Council's process for dealing with complaints and steps that will be taken if patterns of complaints emerge. The policy would include criteria for referring complaints to the HCCC where a matter of public interest or unsatisfactory professional conduct is involved. The Council should publish complaints data annually as part of demonstrating its quality-monitoring role, indicating pattern of complaints (by type of practice and cause of complaint).

Role and functions of the Cosmetic Surgery Credentialling Council

1. Credential and re-credential registered health care providers, ratifying their experience, qualifications and training to perform cosmetic surgery procedures.
2. Educate consumers about the scheme so that credentialling is recognised and members are easily identified.
3. Inform consumers about credentialled cosmetic surgery providers.
4. Develop codes of conduct establishing minimum standards of practice covering areas such as communicating with patients and informed consent, financial conflicts of interest, patient assessment and selection;
5. Liaise with professional colleges and associations on training for providers.
6. Collect and publish data on clinical outcomes and consumer satisfaction.
7. Discipline members who fail to comply with the Council's requirements and guidelines.
8. Complaints handling and referral.
9. Liaise with the Australian Medical Council and other relevant professional bodies on specialist qualifications.

Structure and membership

The Council structure must provide for public accountability so it is not perceived as acting primarily in the interests of cosmetic surgery providers. A number of accreditation schemes administered by professional associations provide examples for the Council's structure and operation. Although they provide third party accreditation, not credentialling, the administrative and accountability arrangements are appropriate models. The basic structure is a public company with stakeholders as owners. Council members are accountable to stakeholder groups represented on the Council as the owners of the company.

The Australian General Practice Accreditation Limited (AGPAL) has been established to provide a workable and acceptable system of accreditation for General Practice that focuses on delivery of

quality care. It is a company limited by guarantee, owned by five member general practitioner organisations – the Royal Australian College of General Practitioners (RACGP), the AMA, Rural Doctors' Association Australia, Australian Divisions of General Practice (ADGP) and the Australian Association of General Practitioners. The Board of Directors comprises two nominees of the member organisations, a nominee of Consumers Health Forum and a nominee of the Commonwealth Minister for Health. The scheme is substantially funded by the Commonwealth Government. The RACGP and the ADGP initially conducted trials of the scheme, and the RACGP developed the standards used by the scheme.

The Infection Control Review and Certification Service (NSW) Pty Ltd (ICRCS) is an initiative supported by the NSW branch of the AMA. The Service provides a reference resource for medical and dental practitioners in NSW on infection control procedures. It provides an independent review of the practitioners' compliance with legal requirements, and recommends advisory standards to the practice, where appropriate. The Board of the Service consists of medical and dental practitioners and specialist infection control nursing or paramedical personnel. Practitioners are retained to act as nominees of the service for assessment of practices. The Service is funded through user fees, based on the size of the practice. The AMA provides the secretariat for the Service.

The Cosmetic Surgery Credentialling Council would be constituted by a representative mix of providers of cosmetic surgery, and representatives of consumers and practitioners with an overview of clinical issues. Members of the Council should be appointed by the appropriate college, professional association, or consumer organisation. The Committee recommends the Council should include a nominee of the Minister for Health in the start-up phase. This is important to establish public accountability, and to provide a link with the government's role as administrator. Based on these principles the membership of the Council would be as follows:

Qualifications of representative	**Nominated by**
Consumer representative (2)	Consumers' Health Forum or Australian Consumers' Association
Cosmetic plastic surgeon	Australian Society of Plastic Surgeons
Cosmetic nurse	NSW College of Nursing
Cosmetic physician	Cosmetic Physicians Society
Cosmetic surgeon	Australian College of Cosmetic Surgery
Cosmetic dermatologist	Australasian College of Dermatologists
Facial plastic surgeon	Australian Society of Otolaryngology/head and Neck Surgery
Facial plastic surgeon	Australasian Academy of Facial Plastic Surgery
General practitioner with an overview of clinical services	Royal Australian College of General Practitioners
Officer of NSW Health	NSW Minister for Health
Oculo-plastic surgeon	The Royal Australian College of Ophthalmologists
Sclerotherapy practitioner	Sclerotherapy Society of Australia
Surgeon with an overview of clinical issues	Royal Australasian College of Surgeons

Implementation

During the Inquiry Commissioner Walton, Chairperson of the Committee, met with representatives of the Australian Medical Association (AMA) NSW branch to discuss the possibility of the AMA auspicing the Council. The Committee initially supported AMA by providing a secretariat for the CSCC. The AMA is independent from any particular professional interest group in the industry, and it is already involved in self-regulatory initiatives for the medical profession.

However, the Committee believes the NSW Department of Health should be responsible for establishing the Council. Without Government intervention the scheme will risk appearing to be an initiative to serve the interests of health professionals rather than the public interest. Some seed funding will be required for the first year of operation to ensure that the organisation is established on a sound footing. There may be an

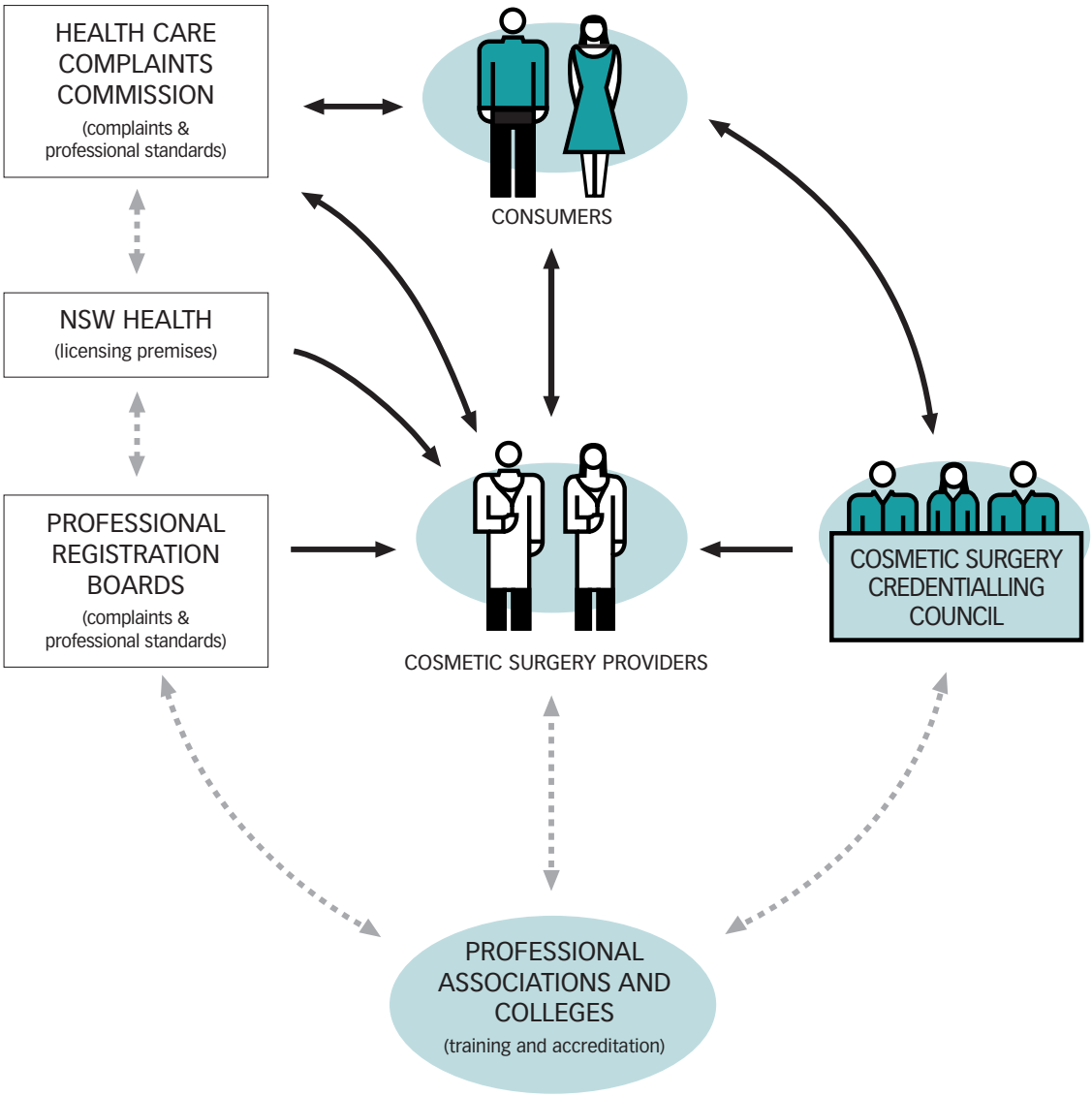
opportunity to recoup some of these costs through membership fees. The public interest justifies government support for the CSCC to ensure that it is established on a credible and sustainable basis.

Recommendation 3

3a. The Department of Health sponsor and set up the Cosmetic Surgery Credentialling Council.

3b. The structure and membership of the CSCC be representative and accountable to all stakeholders in the industry.

Figure 6 - The Council's relationship to regulators



4.6 Regulating where cosmetic surgery is performed

What is done where?

Cosmetic surgery is performed in private hospitals, day procedure centres, and doctors' rooms. Day procedure centres and hospitals are regulated in NSW, while doctors' rooms are not. This raises questions about the level of consumer safety when cosmetic surgery procedures are performed in doctors' rooms.

A large proportion of cosmetic procedures are now performed in doctors' rooms, including the more popular procedures such as liposuction and laser resurfacing. These are frequently performed using local anaesthetic, minor sedation and minor nerve blocks. The recent developments in sedation techniques are described in a recent article in the British Medical Journal:

> Large volumes of dilute local anaesthetic and adrenaline are now used for subcutaneous infiltration, enabling up to 10% of the body surface to be anaesthetised locally and perioperative bleeding to be significantly reduced... Infiltration with a large volume of local anaesthetic furthermore reduces the need for general analgesics. Hypnotics can also be avoided in favour of intravenous sedation for simple procedures, so patients can keep control of their airway and vital functions. Such patients can even be upright during the procedure, and the surgeon can observe the effects of gravity and voluntary muscle activity during surgery.[71]

The ability to perform cosmetic surgery procedures without general anaesthesia or major nerve blocks is also linked to the development of less invasive techniques. For example, surgical procedures have been replaced by laser 'surgery' for removal of lesions, to resurface the skin, and hair removal. Endoscopic techniques are now used for facelifts and liposuction, providing an alternative to surgical techniques.

The trend in surgical procedures being performed in doctors' rooms is not particular to cosmetic surgery. The Health Insurance Commission pays a rebate for specialist services conducted in approved out-of-hospital facilities. Protocols have been developed by the Australia New Zealand College of Anaesthetists for gastroenterologists and dentists performing procedures in their rooms using sedation.

'A large proportion of cosmetic procedures are now performed in doctors' rooms, including the more popular procedures such as liposuction and laser resurfacing.'

Regulation

The primary criteria used to define whether a facility is a regulated day procedure centre is the level of anaesthesia used. It provides broad criteria not linked to a specific medical procedure, and covers the main indicator of risk, which is complications arising from mismanagement of anaesthesia. This approach to regulation, based on principles of risk and safety, is more effective than attempting to prescribe types of medical procedures and how they should be performed.

A facility must be a licenced 'day procedure centre' if patients are admitted and discharged on the same day for medical, surgical or other treatment in circumstances prescribed by regulation.[72] The following treatment and circumstances are prescribed by the *Day Procedure Centre Regulation 1996*:

> (a) surgical treatment that involves the administration of a general, spinal, epidural or major regional block anaesthetic or intravenous sedative otherwise than for the purpose of simple sedation;
>
> (b) endospcopic treatment that involves the administration of a general anaesthetic or intravenous sedative otherwise than for the purpose of simple sedation;
>
> (c) treatment that involves dialysis...;
>
> (d) treatment that involves prolonged intravenous infusion of a single cytotoxic agent or sequential intravenous infusion of more than one cytotoxic agent;
>
> (e) treatment that involves cardiac catheterisation.[73]

Cosmetic procedures are performed in doctors' rooms using local anaesthetic, minor sedation and minor nerve blocks. They are therefore not covered by the circumstances prescribed in the *Day Procedure Centre Regulation*.

The regulatory framework addresses risk factors by prescribing levels and qualifications of staff, infection control measures, equipment, emergency measures, quality assurance, reporting of complications, and building requirements as they affect the care and safety of patients. The regulation requires information about treatments performed and the timing and dosage of any drugs administered to be recorded in patient records.

There are a number of guidelines and policies dealing with use of sedation in specialists' rooms. The Australia and New Zealand College of Anaesthetists (ANZCA) has developed policies to deal with sedation used by dentists and gastroenterologists. The policies were developed co-operatively with the respective professional associations.[74] The Australian Day Surgery Council is currently developing *Guidelines for the accreditation of office-based surgery*.[75] It defines 'sedation' as including:

> the administration by any route or technique of all forms of drugs which result in depression of the central nervous system.

The draft Guideline prescribes the requirements for two types of facilities: those where procedures are performed under local anaesthesia and those where procedures are performed using both local anaesthesia and sedation. Using similar risk factors as the *Day Procedure Regulation* it prescribes the facilities, equipment, the level and skill of staff, record keeping and transfer arrangements with hospitals. It also requires records to be kept of the timing and dosage of drugs. For procedures involving use of both local anaesthetic and sedation there are specific requirements for patient assessment and selection, and for patient recovery and discharge arrangements. It sets out the knowledge requirements of the medical practitioner administering the sedation drugs and requires appropriately trained nursing staff to be present during the procedure and in recovery. The Australasian Day Surgery Association is another organisation that may be appropriate to develop guidelines.

Risks

A lack of data makes it difficult to gauge the complications arising from procedures being performed in doctors' rooms. Unlike day procedure centres and hospitals, complications do not need to be notified to the Department of Health and records of treatments and drugs do not need to be kept where medical practitioners are performing procedures in their rooms. The Committee was told that deaths arising from cosmetic procedures performed in doctors' rooms are unlikely to be identified. The stated cause of death on death certificates will typically identify the clinical cause of death, but not the link to cosmetic surgery, and deaths by anaesthesia may not always be reported.[76] Researchers in the US have identified the lack of reporting requirements for complications arising from liposuction as a major obstacle to identifying levels of risk for that procedure.[77]

The risk factors associated with procedures performed in doctors rooms are similar to those in day procedure centres, even though actual risks may be different:

- patients under 'light' sedation are regarded as being able to maintain control of their airway and vital functions, but adequate levels of staff with appropriate qualifications are still required;
- adequate equipment is necessary, appropriate to the procedures performed, and including equipment to deal with complications and emergencies;
- adequate transfer arrangements with hospitals are needed to care for patients when a complication occurs;
- patient assessment and selection for different types of drugs is important;
- adequate provision for patient recovery and discharge is required;
- appropriate building requirements are also relevant to patient safety.

The Committee heard that cosmetic surgery procedures in doctors' rooms are being performed with inadequate levels of properly qualified staff. Some doctors are providing the anaesthesia and performing the surgery. This puts patients at risk because there is inadequate monitoring of the patient and the doctors often do not have sufficient knowledge of anaesthesia or how to deal with

complications. Many submissions stated that a doctor cannot be both surgeon and anaesthetist.[78] Patients are exposed to significant risks if the medical practitioner administering local anaesthetic and sedation drugs does not comply with strict limits on volume and combination of drugs. A specialist anaesthetist told the Committee:

> there is a very small difference between the dose of most drugs that we use that keeps people quiet and relaxed and sedated and the dose that stops them breathing. I'm not sure that a lot of people who are injecting these drugs have any concept of the dangers of what they're doing of how to get out of problems if they get into them.[79]

A Sydney dermatologist told the Committee that Australian doctors performing liposuction in their rooms follow the strict limits set by the American Association of Cosmetic Surgeons on the amount of xylocaine (local anaesthetic) and adrenalin that can be used, and fluid management. He regards these limits as crucial, but told the Committee he was not aware of any guidelines set by relevant Australian colleges.[80]

There was disagreement in the submissions on whether an anaesthetist should be present for all types of sedation, or whether a nurse assistant is adequate in some circumstances. In the US there are recognised nurse anaesthetists, but in Australia no such qualification is available. A number of plastic surgeons and cosmetic surgeons emphasised the need for anaesthetists to be present for day surgery procedures whether they involve general anaesthesia, or local anaesthesia and sedation.[81]

The Committee heard there is also often a lack of adequate arrangements for recovery and for transfer of patients to a hospital in an emergency.[82] The representative of the Australian Society of Otolaryngology told the Committee that patients should be asking questions pertaining to resuscitation, staffing and equipping of the facility. Where proper transfer arrangements are not in place a patient with complications is put in a taxi and sent to a public hospital to wait in casualty, instead of being provided with appropriate ongoing care during transfer and arrival at the hospital.[83]

'The Committee was told that deaths arising from cosmetic procedures performed in doctors' rooms are unlikely to be identified.'

There may also be insufficient pre-operative patient assessment by providers, resulting in complications. Adequate provision for recovery of patients and appropriate discharge arrangements for patients was also raised as a concern. The Australian Society of Plastic Surgery told the Committee 'It's unreasonable, unsafe, and unfair to send a patient out after a very short stay – sometimes in the care of their relatives – after what is sometimes fairly substantial surgery.'[84]

The Committee heard little about risk factors associated with adequate design and physical layout of doctors rooms, except risks associated with the environment in which lasers are used. These include risks covered in the Australian Standard on *Safe use of lasers in health care*, such as blindness and hearing loss. Some submissions said there is a risk of infection from fragments of skin and blood escaping into air conditioning systems. This can only be addressed by requiring separate air conditioning for the room in which lasers are used.[85] The facilities where lasers are used must be adequately designed to address risk factors for laser operators, staff and consumers.

Developments in the USA

Until about a decade ago 80% of cosmetic procedures in the USA were performed in hospital settings, but now about 60% of procedures are performed outside the hospital setting.[86] In response to a number of deaths reported in the media from cosmetic surgery performed in doctors' rooms the Florida and California legislatures have proposed strict regulatory controls. In other states guidelines for 'office based surgery' have been developed.[87] The American College of Surgeons first published *Guidelines for Optimal office based surgery* in 1994.

In January 1998 the Florida Board of Medicine proposed an amendment to its 'office based surgery' rules. The proposed rule would expand the definition of surgery to cover cosmetic procedures. It uses three classes of facility defined according to the type of procedure. Level 1 covers minor procedures where the risk of complication is regarded as remote. It is defined as 'excision of skin lesions, moles, warts, cysts, lipomas and repair of simple lacerations performed under topical or local anaesthetic not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilisation

of the patient.' Level 2 procedures require specified training and level 3 procedures require hospital privileges. The rule sets minimum staffing levels, requires reporting of complications and transfer agreements with hospitals. It also requires the facilities to be accredited by a third party accreditation scheme. The proposed rule sets an upper time limit of four hours for surgery, and upper volume limits for removal of fat by liposuction. In level 1 facilities liposuction is only allowed for excision of up to 1000cc supernatant fat, and an upper limit of 2000cc and in level 2 and 3 facilities.[88]

Similar reforms were introduced into the California Senate in a Bill to amend the *Business and Professions Code* in April 1999. The proposals, which are supported by the Medical Board of California, would require 'cosmetic surgery' using anaesthesia to be performed in licenced facilities. Cosmetic surgery is defined broadly, but exempts removal of cysts, warts or moles and repair of simple skin lacerations, skin biopsies and small joint dislocations. The definition of anaesthesia exempts procedures using local anaesthesia, peripheral nerve blocks, or both, in doses that do not place the patient at risk 'for loss of life preserving protective reflexes'. The Bill prescribes that doctors rooms must have a minimum of two staff on the premises, including one health care professional. Third party accreditation of the facility is a condition of licencing. Written discharge criteria for patients are also required. Release of a patient other than in accordance with the discharge criteria is 'unprofessional conduct'.[89]

Options to address risks

Two options were considered by the Committee to address the serious risks to patients posed by the unregulated performance of cosmetic surgery procedures in doctors' rooms:

- rely on voluntary accreditation through guidelines, such as the policies on sedation developed for dentists and gastroenterologists, or the draft *Guidelines for Accreditation of office based surgery*;
- make accreditation of doctors' rooms compulsory through a licensing requirement.

'A major obstacle to effective implementation of voluntary accreditation is the lack of a single recognised professional organisation covering the industry.'

Organisations such as the AMA and the Cosmetic Physicians Society supported an accreditation scheme for doctors rooms. However, a major obstacle to effective implementation of voluntary accreditation is the lack of a single recognised professional organisation covering the industry. Without an organisation to establish and monitor a voluntary guideline that forms the basis for accreditation there is little likelihood of effective compliance.

The Committee preferred the regulatory option as it is the only effective way to limit the risks to patients. The *Private Hospitals and Day Procedure Centre Act* provides an appropriate framework for such a regulation as it already regulates medical procedures performed in health care facilities. The Act and the *Day Procedure Centre Regulation* could be amended to prescribe a new type of 'treatments or circumstances' covering facilities where procedures are performed using both local anaesthetic and sedation. The amendment should address appropriate risk indicators, including level of drugs and drug combinations, appropriate level and qualifications of staff, equipment needs, patient assessment and selection, adequate provision for patient recovery and discharge, arrangements for transfers to hospitals, and physical design requirements to address risks associated with the use of lasers.

The Committee recommends a system of licensing based on certification by an approved third party accreditation agency so that the cost of licensing is borne by the industry. The Australian Council on Healthcare Standards or another organisation, such as the AMA, could be invited to tender to provide the certification service for the Department of Health.

The Australian Medical Association representative on the Committee dissented from the Committee's view on this recommendation. He says:

> The inquiry has not uncovered significant complications arising in NSW from office based procedures. The increase in frequency however does indicate that the Cosmetic Surgery Credentialling Council should gather data to guide this area and the Council should develop guidelines for doctors performing such procedures. Third party accreditation should be optional until the council determines that guidelines are insufficient because it adds a cost and administrative burden to practice in this area, and the need has not been established.

Recommendation 4

4a. Amend the *Private Hospitals and Day Procedure Centres Act* and the *Day Procedure Centre Regulation* to require licensing for facilities where medical procedures are performed using local anaesthetic and sedation. New risk factors should be defined under the Act, including level of drugs and drug combinations, patient assessment and selection and adequate provision for recovery and discharge of patients and risks associated with lasers. (majority view)

4b. The licence should be conditional on certification by a third party accreditation body, provided on a fee-for-service basis.

4c. Consistent with the *Private Hospitals and Day Procedure Centres Act* and regulations, medical practitioners with licensed facilities should be required to:

• maintain records of surgical procedures and drugs administered, including type of procedure, duration, adverse events and post-operative care; and

• notify NSW Health if the procedure results in death or removal to a hospital within 72 hours of cosmetic surgery or other medical procedure.

4d. Amend the *Medical Practice Act, Nurses Registration Act* and *Dentists Act* to deem non-compliance with licensing and reporting requirements unsatisfactory professional conduct.

4.7 Collecting information

The Committee was continually hampered by the lack of basic information about the cosmetic surgery industry, including crucial information on skills required of providers, clinical outcomes and complications. The lack of data on clinical outcomes, the necessary skills for providers and appropriate training should be addressed as a matter of priority. A number of measures are suggested in Recommendation 4 (reporting requirements under licensing of doctors' rooms), Recommendation 8 (tracking register for breast implants) and Recommendation10 (patient satisfaction). The Cosmetic Surgery Credentialling Council will also produce information integral to its functions, such as the level and nature of complaints. These would be enhanced by additional reporting by the Cosmetic Surgery Credentialling Council and United Medical Protection on outcomes and complications.

Recommendation 5

5a. The Cosmetic Surgery Credentialling Council collect data on the number and type of cosmetic procedures performed and outcomes (morbidity and mortality), and publish it annually.

5b. United Medical Protection should publish annual statistics on the number and types of cosmetic surgery procedures about which notifications and claims are made, and the basis for the claims.

Information to be collected and reported

1. Data on numbers and types of cosmetic procedures and outcomes (morbidity and mortality) to be published annually by the Cosmetic Surgery Credentialling Council.

2. Patient satisfaction surveys conducted and published regularly by the Cosmetic Surgery Credentialling Council.

3. The number and type of cosmetic surgery procedures that are the basis for notifications and claims reported annually by UMP.

4. Complications arising from cosmetic procedures performed in hospitals, day procedure centres, and doctors' rooms to be notified to the Department of Health.

5. Number and types of complaints about credentialled providers, published regularly by the Cosmetic Surgery Credentialling Council.

5. SPECIFIC QUALITY ISSUES

5.1 Who is a 'surgeon'?

Many submissions raised concerns about the use of the term 'cosmetic surgeon' by medical practitioners without the surgical training qualifications of Fellows of the Royal Australasian College of Surgeons (FRACS).[90] Any registered medical practitioner in NSW can called themseves a surgeon. The basic medical degree is MBBS, bachelor of medicine and bachelor of surgery. However, a minimal amount of surgery is performed in medical schools and in the first two years of training in hospitals. A plastic surgeon told the Committee that some universities, such as the University of Newcastle, acknowledge the evolution of the practice of surgery by not awarding a degree that recognises surgery at all.[91]

'Any registered medical practitioner in NSW can call themselves a surgeon.'

The FRACS qualification, or equivalent, is the standard used for appointment to public hospitals and is usually required to be credentialled to perform surgery in private hospitals. It requires completion of Part 1 basic surgical training for two years after the intern year, followed by successful completion of Part 2 examination, undertaken after four or more years of Advanced Surgical Training. A Trainee must win a place in an Advanced Surgical Training program. The Part 2 examination is conducted in a number of specialities including plastic and reconstructive surgery, otolaryngology (head and neck surgery) and ophthalmology.[92] The various training and accreditation requirements of the medical colleges and professional associations in the cosmetic surgery industry are summarised in section 2.2.

The Committee considered that requiring appropriate minimum training for doctors performing cosmetic surgical procedures would give some credence to assumptions already made about cosmetic surgeons. The Committee did not seek to prescribe membership of any particular organisation. Nor did it seek to prescribe the training required for minor surgical procedures carried out by GPs, such as removal of cysts or warts. The Committee discussed a range of definitions of 'surgical procedure' that would reflect this view. The term 'invasive surgery' was considered broadly appropriate, but there was no resolution as to the procedures that would be covered by this term. One definition proposed was surgical procedures involving incision of the deep fascia, which excludes superficial dermal procedures. As discussed in the context of credentialling, in section 4.3, the Committee found there is no natural grouping of 'surgical' and 'non-surgical', or 'invasive' and 'non-invasive' procedures.

The Committee considered leaving the question of qualifications for performing surgical procedures to the Credentialling Council, but on reflection agreed that, given the public interest, the Committee needed to state a view on the issue. The Committee agreed that a medical practitioner performing invasive cosmetic surgical procedures should have adequate training, being the training required for Fellows of the Royal Australasian College of Surgeons, or equivalent.

The representative of the Australian College of Cosmetic Surgery on the Committee dissented from the view of the Committee on this issue. He preferred that training requirements for performing surgical procedures be determined by the Credentialling Council.

Recommendation 6

6. Medical practitioners performing invasive cosmetic surgical procedures should have adequate surgical training, being that required for Fellows of the Royal Australasian College of Surgeons, or equivalent. (majority view)

5.2 Lasers

What are lasers used for?

Lasers are used in cosmetic procedures to improve facial wrinkles around the eye, upper lip and glabella, for removal of spider and veins, removal of pigmented lesions and vascular components of

scars, cutaneous photoageing and removal of tattoos and unwanted hair. Some lasers are also used for incisions, replacing the scalpel.[93]

Twelve submissions were received by the Committee raising concerns about lasers in cosmetic surgery. A *Discussion Paper: Use of lasers for cosmetic procedures* was circulated in June 1999 seeking information about level of safeguards and risks to consumers. Regulators, manufacturers, a range of professional bodies and many individual medical practitioners made submissions in response to the Discussion Paper (see Appendix 4).

Laser treatments for cosmetic procedures in Australia have the following characteristics:

- there are an estimated 200-250 providers using lasers including cosmetic physicians, GPs, nurses, dermatologists, plastic surgeons, cosmetic surgeons, and beauty therapists;
- laser procedures make up an estimated 10-15% of all cosmetic procedures, and the popularity of the treatments is growing with new technology that reduces risks;
- many providers have not been organised into professional associations that address qualifications and training needs, although this is changing;
- manufacturers and distributors of the equipment play a significant role in training and promotion of the use of the equipment;
- Australian Standards on *Safe use of lasers in health care* and *Laser Safety* exist, but there is no regulation or industry standard on the necessary skills, qualifications and training for use of lasers.

What lasers are used and where?

Lasers are broadly divided into pigment specific lasers (such as the Q switched YAG, Alexandrite, etc.) and vascular lasers (such as the Argon, Krypton, and other wavelengths that are absorbed by oxyhaemoglobin). Vascular lasers are used for treating capillaries on the face, superficial veins, and vascular birthmarks. Another broad group are resurfacing lasers, used for vaporising layers of skin to treat sun damage, acne scars, wrinkles, etc. Resurfacing lasers are also used to cut the skin, with laser blepharoplasty (eyelid surgery) being the most common.[94] The Carbon Dioxide laser (CO^2) which has been around in its present form for about eight years, and the newer Erbium laser are the two current lasers in use. So called 'photoderm' and 'epilight' lasers are examples of light sources used for cosmetic treatments but they are not actually lasers. New, non-laser light sources are under development.

Cosmetic treatments using lasers are mostly performed in doctors' rooms, day procedure centres, or beauty clinics. Where procedures are performed in doctors' rooms a variety of anaesthetic measures may be used – nerve blocks, local anaesthesia and sedation. Laser treatments may also be performed under general anaesthetic or with regional blocks or light sedation in day procedure centres and hospitals.

Who uses lasers?

Beauty therapists mostly use less powerful lasers (class 3A) for hair removal, but some use the higher powered lasers (class 3B and 4). The Hairdressers and Beauty Therapists Association told the Committee the only restriction on greater use of lasers by beauty therapists is the expense of the machines and a sense of caution while adequate training programs are not available to them. The Association points out that removal of unwanted hair has always been the prerogative of beauty therapists.

Nurses make up an unknown proportion of cosmetic treatment providers using lasers, and they provide assistance to medical practitioners using lasers. The submissions acknowledged that nurses are competent providers of laser treatments, mostly working under the supervision of doctors.[95] The level of supervision that occurs in practice was questioned in some submissions.[96]

The Australian Nurses Acupuncture Association told the Committee that class 3B lasers have been widely used by acupuncturists treating soft tissue injuries for years with no record of injury, and with the encouragement of professional indemnity insurers.[97] Lasers have been part of their curriculum for some time.

Doctors providing laser therapies in cosmetic medicine come from diverse backgrounds. About half are estimated to be cosmetic physicians, or GPs who have received specific training in these procedures, often in the USA. Dermatologists often use lasers as part of cosmetic treatments: laser training has been part of their curriculum for many years. ENT specialists, facial surgeons, cosmetic surgeons and plastic surgeons also use lasers.

'The use of lasers could be restricted to the extent that it is regarded as part of the practice of medicine.'

Regulation

Medical lasers are not regulated in NSW. A licensing and registration framework for lasers is provided under the *Radiation Control Act 1990* (NSW). Western Australia has regulated the use of all medical lasers for some years, requiring licences for use of medical lasers and for the premises at which medical lasers are used.[98] Queensland recently introduced licensing requirements for people who possess class 4 lasers, and for those who use class 4 lasers, for health related and cosmetic purposes. It will commence operation in January 2000.[99] Infection control in the context of laser use is regulated in NSW under the professional registration regulation and the *Public Health Act*.[100]

The *Guide to safe use of lasers in health care*, Australia/New Zealand Standard 4173:1994, limits and classifies lasers used for medical purposes according to the degree of hazard. There are four classes of lasers. Class 1 is regarded as intrinsically safe. A range of injuries are identified for class 3B and 4 lasers, the worst being blindness from direct exposure to the scattered beam. The types of lasers used in cosmetic procedures are class 4 and class 3B. Two types of lasers used for dermatological applications are identified in the Standard – CO2 and Argon ion. The Erbium laser is not listed in the Standard as it has only been used in Australia for the past two years. The Standard covers laser hazards, principles and procedures for laser safety, safe use, training of personnel, medical surveillance, laser safety monitoring and reporting, operator approval, quality testing, preventive maintenance, and adequacy of facilities. There is also a standard on *Laser Safety*, AS2211.

The use of lasers may be restricted to the extent that it is regarded as part of the practice of medicine. The *Medical Practice Act* makes it an offence for a person who is not a registered medical practitioner to hold themselves out as a medical practitioner.[101] However, as the New South Wales Medical Board told the Committee, there is no definition of what constitutes the practice of medicine under that provision and prosecutions have been notable for their lack of success.[102] The Board has primarily focused on cases where unregistered persons have used titles such as doctor in misleading circumstances. The supervision of staff by medical practitioners is also important. There have been disciplinary cases brought under the *Medical Practice Act* where medical practitioners have used untrained or unqualified staff in inappropriate circumstances, or failed to properly supervise staff.[103]

There is some regulation of medical lasers to the extent that the lasers (not the users) are covered by the *Therapeutic Goods Act*. Lasers are on the Australian Register of Therapeutic Goods (ARTG) as listed medical devices if they are used for therapeutic purposes. Lasers used by beauticians to alter appearance are not regarded as medical devices used for therapeutic purposes and therefore are not entered on the ARTG. The operation of lasers is outside the jurisdiction of the *Therapeutic Goods Act* regardless of whether a laser is on the ARTG or not.[104]

What training is available?

There is little formal training in the use of lasers in cosmetic procedures in Australia. The Australian Standard on *Guide to safe use of lasers in health care,* recognises that all personnel using and handling lasers should have training appropriate to the task they perform.[105]

The Committee heard that one of the main problems is the lack of structured training in newer laser techniques such as laser resurfacing. The Australasian College of Dermatologists Registrar Program provides the most long standing formal training program in laser use for doctors. The Royal Australasian College of Surgeons now includes laser training as part of plastic surgery training. Laser manufacturers provide weekend training programs, but these are not regarded as adequate. The general lack of availability of adequate training in Australia has meant that most doctors have

received training in the USA.[106] However, all of the medical colleges and industry associations involved in cosmetic surgery told the Committee they have recently developed, or are developing, new examination-based training and accreditation programs for lasers. The Hairdressers and Beauty Therapists Association in Victoria advised of a new course in Advanced Dermal Therapy at Victoria University of Technology covering laser technique, laser safety and laser physics.

The Cosmetic Physicians Society is currently instituting a laser training, examination and accreditation program similar to the International Society of Cosmetic Laser Surgeons. In developing the course they are working with Facial Plastic Surgeons and others. The Australian College of Cosmetic Surgery is developing a Registrar Training scheme that includes laser training and accreditation.[107]

A number of submissions suggested that the proliferation of training programs on lasers by the five different specialty groups of medical practitioners might result in variable standards. Laser distributors and individual practitioners favoured a joint effort to develop a common industry standard, focusing on patient care rather than 'turf wars'. Effective regulation lasers used for cosmetic procedures would require accredited training programs as the basis for recognition of skill.

Risks

Most submissions said medical practitioners, whether specialists or general practitioners, pose the same level of risks to consumers if they are not properly trained, experienced, and aware of their limits. The Australasian College of Dermatologists told the Committee that lasers are a 'disaster waiting to happen' because the equipment is widely available without proper training. This view was endorsed by some.[108] The Committee also heard that while complications are common they may be treated and often resolve if treated properly.[109]

The use of lasers in cosmetic medicine pose a range of risks to consumers:

- from an operator who is inadequately trained in laser use and in recognising and treating complications;
- from use of lasers that are not suitable for the particular procedure;
- risks associated with anaesthesia and sedation (discussed in section 4.6);
- from inadequate or inappropriate facilities and inadequately maintained equipment.

Operator skill is paramount. It is relevant to patient selection, operation of the laser and successful treatment of complications.[110] Complications associated with laser skin treatments, particularly for laser resurfacing, are minimised by careful patient selection.[111] Adverse outcomes from this procedure include infection, hypo-pigmentation and scarring.[112] The Cosmetic Physicians Society say the risks need to be balanced against the consistently superior results from laser resurfacing compared to alternative techniques such as peels and dermabrasion. Pigment lasers often have a shorter healing period and require less or no anaesthetic compared with Erbium lasers, but there is a risk of ocular damage, and dyschromia is a more frequent complication. Complications from class 4 lasers used to remove unwanted hair include changes to pigment, burns, and possibly permanent scarring.[113]

A number of submissions raised the need for adequate facilities for laser use. Most of the risks are recognised in the Australian Standard on *Safe use of lasers in health care*, such as blindness and hearing loss. Risk of infection from fragments of skin and blood escaping into air conditioning systems was an additional risk raised by some.[114] The need for adequately designed facilities where lasers are used is addressed in section 4.6, *Where cosmetic surgery is performed,* and recommendation 4.

Overuse of lasers in circumstances where less traumatic and less expensive alternatives should be preferred was raised by the Hairdressers and Beauty Therapists Association. They are alarmed by the hard sell tactics used by laser distributors to encourage use of laser treatments, even for people with inappropriate skin types. They believe lasers are being offered to people too young, leading to a higher risk of hypo-pigmentation.[115]

Should lasers be regulated?

Most submissions on *Use of lasers* said unregulated use of lasers poses an unacceptable risk to consumers and operators. There was division on whether voluntary accreditation or licensing could

provide a system to address the risks. A licensing regime was favoured by regulators, United Medical Protection, the Australasian College of Dermatologists and some laser manufacturers.[116] The need for regulation of facilities was also emphasised.[117] A self-regulatory alternative of credentialling or accreditation of users was favoured by most professional groups and individual practitioners. Some submissions sought legislative restriction on the use of lasers to medical practitioners.

The main argument in favour of licensing is that class 3B and 4 lasers are potentially hazardous devices and operator knowledge is fundamental for safe use. Licensing aims to ensure all operators are sufficiently knowledgeable to safely operate the device and provide beneficial outcomes for consumers. A voluntary credentialling system cannot achieve this aim because it will leave some operators outside the system, and these are the ones likely to pose the greatest risk.[118] A licensing regime would have the additional benefit of facilitating a common industry standard for training requirements as training programs and qualifications would need to be accredited.

> ***'Medical practitioners, whether specialists or general practitioners, pose the same level of risks to consumers if they are not properly trained, experienced, and aware of their limits.'***

The main argument against licensing is that the industry can self-regulate. This argument is unconvincing because there is no medical college or professional association to take a leadership role for all laser users, and there are some cosmetic medicine providers who are not a member of any relevant organisation. The providers who pose the greatest risks to patient safety would not be covered. A second argument against licensing is that it would be slow to respond to rapid developments in technology and techniques. A licensing regime addressing risk factors, rather than prescribing procedures, would be sufficiently flexible to adjust to technological advancements. A concern about licensing is that it will impose an unreasonable cost burden on providers, and ultimately consumers. The cost of licences could be kept to a minimum if the licence for use is based on certification of successful completion of recognised training.

Preferred regulatory model

The *Radiation Control Act 1990* (NSW) provides a framework for effectively licensing the use of lasers in cosmetic surgery procedures in NSW, consistent with developments in other states. The Act has provisions to licence persons to use lasers and to register laser equipment. Licences are issued on the recommendation of the Radiation Advisory Council (RAC). The radiation control licences would address concerns about training users of lasers. They would not directly address other issues such as the types of lasers used, the adequacy of facilities or anaesthesia and sedation.[119]

The licence for laser use issued by the RAC would focus on the training of the user. However, training programs for laser users would remain a matter for the medical colleges and industry associations. To be satisfied that the training of a laser user is satisfactory the RAC would review any training course prior to accepting it as a qualification for a licence.[120] The RAC could appoint an advisory committee, or it might seek the advice of the Cosmetic Surgery Credentialling Council for the purpose of assessing the adequacy of laser training programs. The Credentialling Council could play a complementary role by developing an industry standard for training and accreditation in the use of lasers. In Queensland the Radiation Safety Council plans to appoint a Laser Safety Committee to provide advice on specific issues relating to laser use and possession.[121]

Obligations to maintain safe laser equipment and premises could be separately addressed through licensing requirements under the *Private Hospitals and Day Procedure Centres Act* (proposed in recommendation 4). In Queensland a separate licence to possess lasers is required under the *Radiation Safety Act 1999* dealing with safety of premises, equipment, and adequate staffing.

The Australian Medical Association representative on the Committee dissented from the Committee's view on licensing lasers. He said:

> The complications of laser resurfacing will be addressed in the development of training and guidelines of laser usage. It is unclear how licensing of lasers will further add to this benefit, but licensing will create an extra cost and administrative burden to this field of medicine. There is no

data to indicate that licensing will help reduce any problems of laser usage. The role of licensing should be analysed by the credentialling council after it has gathered further data on laser complications.

Recommendation 7

7a. Prescribe the use of class 3B and class 4 lasers for health related and cosmetic purposes under the *Radiation Control Act* so that users of lasers are required to be licenced, and prescribe laser equipment used for those purposes so that the equipment must be registered. (majority view)

7b. The Cosmetic Surgery Credentialling Council facilitate development of guidelines and accreditation of training programs for the use of lasers by registered cosmetic surgery providers.

5.3 Breast implants

Augmentation mammoplasty, or breast enlargement, is a surgical procedure usually conducted under a general anaesthetic or intravenous sedation in day procedure centres and hospitals. The two major types of implant are silicone gel-filled and saline implants. The procedure has a number of distinctive features:

- it is one of the most popular cosmetic surgery procedures with an estimated 6,000 being performed for cosmetic purposes last year in Australia, and its popularity is growing;
- there are studies that report high complication rates, including complications requiring further surgery;[122]
- about 3,000 surgical procedures for removal of breast implants, or removal and replacement, were claimed under Medicare each year for the past three years;[123]
- 30% of litigation against cosmetic and plastic surgeons is about breast augmentation;[124]
- patients give high satisfaction ratings for the procedure, although most studies have methodological limitations;[125] and
- a national support group exists, Breast Implant Resource Service.

'About 3,000 surgical procedures for removal of breast implants were claimed under Medicare each year for the past three years.'

The Committee excluded from the scope of the Inquiry 'the link between implantation of silicone breast implants and connective tissue disorders'. However, submissions on breast implants were received on informed consent, recognised complications, consumer access to information, advertising and standards of care by plastic and cosmetic surgeons.

Thirteen written submissions were received from consumers of breast implants and the Breast Implants Resources Service. All complained about damage to the health and well-being of recipients of implants and their children. Four witnesses appeared before the public hearings presenting personal and tragic stories of their experiences of adverse outcomes from breast implants. Submissions were also received from people who had conducted research on consumers' experiences of breast implants.[126] Most of the issues raised in those submissions are addressed in the recommendations in sections 6 and 7.

The *Review of the published literature* identified capsular contracture, haemotoma, implant rupture seroma, infection, and problems with lactation as the main adverse outcomes of breast augmentation. The literature shows that overall complication rates of the procedure are high. It refers to three studies on rates of complication:

- a 1997 study found 208 of 749 women (27.8%) followed up (on average after 7.8 years) underwent 450 additional implant related procedures. At least one clinical complication was experienced by nearly 80%;
- a 1970 study of 10,941 patients attending 2,665 surgeons reported similar rates of complications and infection;

- a 1995 study reported complication rates for 77 patients who had inflatable implants, with 64.9% reporting further surgery after the initial placement of the implant.[127]

However, the Committee heard that there is other literature that reports lower complication rates. The definition of 'complication' for the most common complication, capsular contracture, includes reactions that are not always regarded as an adverse clinical outcome. A smaller proportion of women (4-15%) experience symptoms characterised as a poor clinical result – hard, painful, tender and distorted breasts, requiring corrective surgery.[128] Capsular formation is regarded as a normal reaction, occuring in about 85% of women who have breast implants, and recipients of other foreign implants. It involves development of scar tissue around the implants, forming a 'cap'. The etiology, or causes, of capsular contracture are not known although there are a number of theories. Treatment to minimise it, such as antibiotics and corticosteriods, have had some success.[129]

The Breast Implant Resource Service (BIRS) raised concerns about treating capsular contracture by closed capsulotomy – a procedure that explodes the scar capsule by squeezing the breast until there is an audible 'pop'. The alternative is open capsulotomy, a surgical procedure performed in a hospital and covered by the Medicare Benefits Schedule. Some medical literature supports the successful use of closed capsulotomy. However, the results of open capsulotomy and implant replacement are also disappointing.[130] The Therapeutic Goods Administration advise against closed capsulotomy in the *Breast Implant Information* booklet.

The 3,000 surgical procedures performed each year for removal of breast implants, or removal and replacement, reported by Medicare are not necessarily all surgical treatments for complications. A significant proportion are thought to be performed in circumstances where the consumer was dissatisfied with the original implant for other reasons, such as it was not big enough, or it did not achieve the right shape. Medicare provides a rebate of between $180 and $480 per procedure, depending on the type of procedure.

The *Review of the published literature* concluded that the absence of Australian research on the causes and treatments for the main adverse outcomes of augmentation mammoplasty, particularly capsular contracture should be remedied.[131]

Breast implants are regulated as devices under the *Therapeutic Goods Act* (1989). Silicone gel-filled breast implants have been classed as high risk registerable devices since 1992. The status of silicone breast implants means they can only be legally supplied in Australia through Special Access Schemes, the most commonly used being the Individual Patient Usage (IPU) scheme. It is also possible for patients to personally import silicone breast implants for their own use. There have been about 7,100 silicone breast implants IPU applications approved over the past three years. The criteria under which silicone-filled breast implants can be supplied through the IPU scheme were recommended by the Therapeutic Devices Committee Evaluation Committee some years ago.[132] The Therapeutic Goods Administration (TGA) keeps a record of patient identifiers for each IPU approved but there is no monitoring of patients by the TGA.

The TGA has a device incident reporting scheme and reports concerning silicone breast implants are received from time to time. The TGA told the Committee that the reporting scheme is voluntary, and it is impossible to determine the level of completeness of the reporting of incidents involving breast implants. Leakage of silicone in older patients and deflation of saline-filled implants make up the majority of incident reports.

The Register of breast implants initiated by the Australian Society of Plastic Surgeons and the Australasian Society of Aesthetic Surgery is voluntary and the data entered is far from complete. The Society told the Committee that 50% of their members include information on the register, and about 2,000 implants have been registered in the past 12 months.

The TGA told the Committee that they support the principles of device tracking in general. To assess the feasibility of device-tracking the TGA has conducted four pilot studies. None have included breast implants. Professor Clifford Hughes, Chairman of the TGA's Therapeutic Device Evaluation Committee, told the Committee that device- tracking is essential as pre-market device assessment has

found only about half the defects of therapeutic devices. Device-tracking is the only method to provide a reliable mechanism to identify significant device failures, and to enable rapid dissemination of appropriate information to patients at risk. A difficulty with existing device-tracking registers is that they are voluntary, and only the better performers contribute. Another factor is the need to ensure doctors who are looking after patients with medical devices are kept up to date with information about complications or faults in the product.[133]

Questions were raised with the Committee about the adequacy of information provided to consumers. A number of studies of women with breast implants conducted in 1994 found that the women were either not warned, or inadequately warned, of the risks of complications.[134] A great deal has been done in the last five years to address consumers' needs for information. Two editions of a *Breast implant information* booklet have been published by the TGA and the Department of Health since 1995. They provide information on the risks of breast implants. The booklets include a patient consent form and a patient information and identification record which are to be retained by the doctor and the patient. The 1995 booklet was revised in 1998. The TGA told the Committee that they have distributed 10,000 copies of the booklet over the last 18 months, and another 5,000 have been printed for distribution. The primary distribution point is through surgeons who are providing breast augmentation, and some directly to women contemplating the procedure.

The BIRS believe that a large proportion of consumers who had breast implants in the past did not give informed consent because they were given insufficient information about complications. The BIRS called for a Royal Commission into the efficacy of breast implants in the past and the present.

Recommendation 8

8a. The National Health and Medical Research Council fund research on the main adverse outcomes of augmentation mammoplasty in Australia, particularly capsular contracture.

8b. The Therapeutic Goods Administration be given legislative authority to establish a mandatory device-tracking register for current and future recipients of breast implants.

5.4 Liposuction

'Comments on the safety and effectiveness of liposuction must be heavily qualified because most of the published studies are methodologically weak.'

Liposuction is a procedure for the removal of localised fat deposits by aspirating fat using a cannula attached to a suction machine. The purpose of the procedure is to remodel the body contour. It is usually applied to the hips, outer thighs, abdomen, buttocks, front of the neck, waist, knees, calves and ankles. It can also be used for breast reduction. Liposuction also has some therapeutic applications, such as the removal of fatty tumours (lipomas).[135]

Liposuction is one of the most popular cosmetic procedures in Australia and the USA. There are no restrictions or guidelines in Australia on who can perform the procedure and where or how it is performed.

The *Review of the published literature* found:

> The procedure can cause substantial morbidity, and the literature attempts to describe the nature and extent of both general and local complications, whether transient or persistent. There were occasional reports of deaths associated with liposuction, either from causes directly related to the procedure (such as necrotising fasciitis) or from causes more generally related to surgery (such as fat embolism and thrombotic pulmonary embolism). It appeared that mortality rates were low, but the literature did not examine this point with sufficient analytic rigour to reach a firm conclusion.[136]

It said that comments on the safety and effectiveness of liposuction must be heavily qualified because most of the published studies are methodologically weak.

Based on the published literature, it is difficult to provide clear recommendations on the level of training and skill needed in a practitioner who is to perform liposuction safely and competently. The

Review also reported that because the procedure can have many local and general complications, it seems clear that the practitioner should have expertise in the management of patients undergoing large-scale invasive procedures.

A recent New York study of five deaths related to tumescent liposuction concluded that drug absorption and drug interactions, fluid management, prothrombogenic factors and liposuction volume should be re-evaluated for the procedure.[137]

The Florida Board of Medicine responded to pressure for restrictions on liposuction by proposing specific rules, as discussed above in section 4.6.

A Sydney dermatologist who provides laser skin treatments and liposuction in his rooms gave the Committee a description of how liposuction is typically performed. Below is an edited version of what he told the Committee:

> ...minimal sedation is used, or even no sedation sometimes, just local anaesthetic put in through little tiny nicks in the skin with very small amounts of adrenalin which is vaso-constrictive. The actual procedure might take two to four hours using little cannulas and criss-crossing to get a nice, even result. We have very strict limits as to how much xylocaine (local anaesthetic) we can use, and adrenalin, and fluid... most practitioners belong to the American Association of Cosmetic Surgeons, and they have strict limits in their guidelines which we all use...
>
> The actual time the patient is there is not that relevant, because they are awake and I anticipate are not sedated... We need two or three hours to do it properly. We ask the patient to move around so we get the right shape. The volume of fluid is critical, and especially in someone who has a compromised cardiovascular system, and we always address that in a pre-operative way.[138]

There was no evidence before the Committee that liposuction procedures in Australia are putting patients at risk. Information from United Medical Protection on claims made in relation to liposuction is inconclusive. Liposuction makes up less than 10% of all claims, but no information was given on the nature of the events that gave rise to those claims. The proportion of claims is relatively small given it is a popular procedure, making up possibly 20% of surgical cosmetic procedures (see section 2). However, given the inadequacies of reporting mechanisms, no conclusions can be drawn one way or the other.

The major risk indicators for liposuction performed in doctors' rooms are addressed in Recommendation 4, on licensing procedures performed in doctors' rooms. The recommendation also requires complications arising from liposuction to be reported to NSW Health. This may provide a basis for consideration of safety controls in future.

However, the absence of local guidelines for liposuction should be addressed. The relevant medical colleges should be responsible for this in conjunction with the Cosmetic Surgery Credentialling Council. The guideline should:

- set minimum knowledge requirements for medical practitioners performing liposuction, including knowledge of anatomy comparable with that of a specialist surgeon and expertise in the management of patients undergoing large-scale invasive procedures (as recommended by the *Review of the published literature*); and
- prescribe limits to address drug absorption, drug interactions, fluid management, and volume of fluid removed.

Recommendation 9

9. The relevant medical colleges and professional associations, in conjunction with the Cosmetic Surgery Credentialling Council, develop guidelines for liposuction addressing qualifications of medical practitioners, limits on drug use, fluid management, and patient selection.

5.5 Patient satisfaction

Measuring patient satisfaction is an essential component of assessing health outcomes. It is relevant in cosmetic surgery because desired outcomes are directly linked to consumer satisfaction with the

changes in appearance. The *Review of the published literature* found patient satisfaction surveys on all six procedures reviewed. The surveys generally report high patient satisfaction with cosmetic procedures. The *Consumer Survey* conducted for the Committee also found a high satisfaction rating among 80% of 280 consumers of a wide range of cosmetic procedures (see discussion section 2).[139]

However, the *Review of the published literature* found the published studies have methodological weaknesses.[140] These include inadequately described methods of patient selection for participation in the survey, and surveys being conducted by the doctor who performed the procedure. The surveys were also limited because most were conducted within 6-12 months of the procedure. Some examples of the methodological limitations of the surveys noted by the *Review* are:

liposuction: The most substantial of six studies describes the experience of 2061 patients over five years, of whom 97% were followed up for 6-12 months following the procedure. All the procedures were performed by the author of the article and it was not clear how patients were selected. There is little information on short- and long-term patient satisfaction with specific aspects of treatment outcomes, such as the achievement of planned body contour and the amount of fat removed.

'The surveys generally report high patient satisfaction with cosmetic procedures. However... the published studies have methodological weaknesses.'

breast augmentation: Despite the high incidence of complications, reported satisfaction rates are high, ranging from 60-98%. Improvement in body image confidence and self-esteem have been noted, as have the apparent tendency for patients to alter marital status following the procedure. There was a lack of clear description of patient selection in some studies and much variation in the type of implant, the positioning, the clinical setting, the timing of the surveys and the instruments used to measure satisfaction. Some studies found that women become less satisfied with their implants over time (2-3 years post-operatively). Another study found that satisfaction remains high after an average of five years.

phalloplasty augmentation: A large number of papers examine aspects of patient satisfaction with prostheses. Most indicate very low failure rates, low complication rates and high patient satisfaction rates – around 70-80%. The methodological weaknesses include irregular and inadequately described methods of patient selection, and low response rates to follow-up questionnaires. Studies of patient satisfaction with surgical outcomes fail to account adequately for pre-operative levels of functioning and report very low response rates or patient reports of partner satisfaction.[141]

The *Review of the published literature* found that long-term patient satisfaction (more than 6-12 months post-surgery) is not well researched.[142] A recent study of the American psychological literature in cosmetic surgery came to the same conclusion.[143] It also found an absence of research that measures body image satisfaction in cosmetic surgery patients. The study recommends further research on the link between body image perceptions in cosmetic surgery patients.

Patient satisfaction surveys of cosmetic surgery using subjective and reproducible methodology should be conducted regularly. The questionnaire designed for the *Consumer Survey* conducted for this Inquiry identifies the types of issues that are relevant for industry-wide surveys.

Recommendation 10

10. The Cosmetic Surgery Credentialling Council conduct regular patient satisfaction surveys to improve understanding of consumer experiences of cosmetic surgery. The *Consumer Survey* conducted for this Inquiry provides a model.

6. CONSUMER INFORMATION

6.1 Access to information

Sources of information

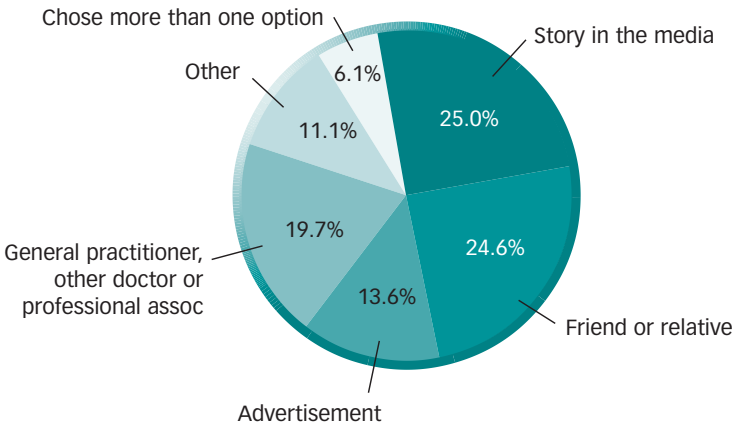
Cosmetic surgery consumers obtain information from a wide range of sources:

- stories and advertising in the popular media and specialist magazines;
- websites and telephone information services of professional associations and medical colleges;
- referral and information agencies;
- telephone information and referral services provided by manufacturers of devices;
- consumer information brochures produced by government agencies, professional associations, cosmetic surgery providers, and manufacturers of devices;
- information and claims made by cosmetic surgery providers and their staff;
- information provided by other doctors, such as GPs; and
- friends and relatives.

Information on health professionals who have been the subject of complaints is not legally available from the Health Care Complaints Commission. Information on any specialist qualifications of doctors is not available from the NSW Medical Board as it does not maintain a specialist register. The Board can only tell the public if a doctor is a registered medical practitioner, or has conditional registration.

Most people hear about cosmetic surgery procedures from friends and relatives and the media. The *Consumer Survey* found that most consumers heard about the procedure they had from a story in the media, a friend or relative, or advertising (see figure 7). Less than 20% heard about the procedure from another doctor or a professional association.

Figure 7 - How did you hear about the procedure?



When choosing a doctor or other health professional respondents relied more on doctors and friends or relatives, and much less on the media. The *Consumer Survey* found that 23% of respondents relied on referral by a GP, and nearly 14% relied on another specialist or professional association and 27% relied on friends and relatives. Advertising and stories in the media made up a total of under 18% (see figure 8).

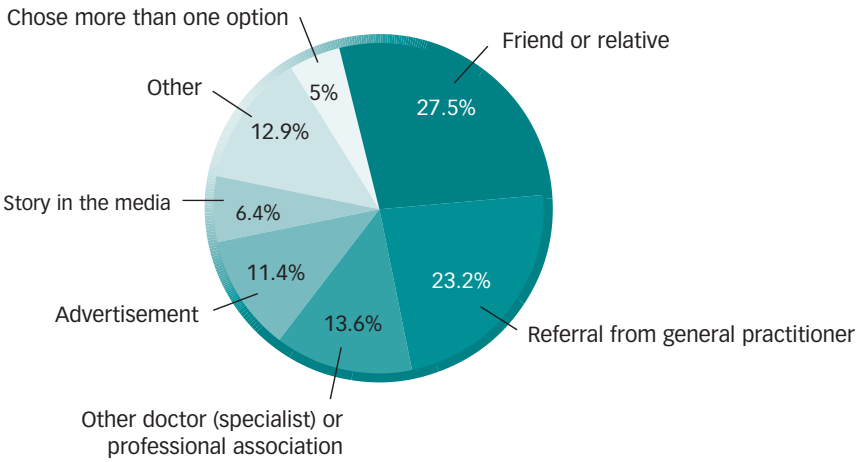
The *Consumer Survey* suggests that cosmetic surgery consumers actively seek information about both providers and procedures. Respondents identified the following as the main issues about which they sought information from providers:

- Side effects;
- Recovery period and needs for post-operative care;

- How good will the result be;
- How will the scars look;
- Safety issues - dangers involved;
- Level of pain;
- Long term effects;
- Cost;
- Experience of practitioner.

The usefulness of this information was given a generally high satisfaction rating by respondents.

Figure 8 - How did you find your cosmetic surgery provider?



Many consumers tend to shop around before choosing their cosmetic surgery provider. Forty per cent of respondents to the *Consumer Survey* said they had sought more than one professional opinion before making their final choice of practitioner.[144] However, a survey of laser surgery patients in a Queensland clinic found that some laser recipients are less cautious. They sought advice from friends and siblings, rather than partners, and moved towards surgery after seeing magazine articles or TV programs in the absence of advice from other medical practitioners or advisory services. A percentage made the decision to proceed within a few weeks of first hearing about the treatments and irrespective of the views of partners and without evaluating financial and health implications. The study contrasts this with breast implants recipients who are over 30 and in stable relationships, who had a prolonged period of decision making.[145]

Obligations to provide information

The information given to patients by doctors is governed by a range of obligations under professional regulation, the common law and consumer protection laws. These cover obligations to provide information on material risks of procedures, alternative treatment options and obligations not to engage in conduct that is misleading or deceptive. In some circumstances it includes a requirement to disclose financial interests.

'The doctor's duty to warn of material risks is regarded as more onerous in cosmetic surgery...'

Doctors are obliged to provide patients with sufficient information in an appropriate manner to form the basis for their informed consent to treatment offered, including information on all 'material risks'.[146] In one case this was taken to include information about the limits of the provider's skills.[147] The doctor's duty to warn of material risks is regarded by the courts as more onerous in cosmetic surgery because the procedure contemplated is 'truly elective'.[148] Good communication and documenting discussion between the doctor and a patient is paramount. Submissions from health complaints commissions, lawyers and

insurers indicate that information given to consumers by some cosmetic surgery practitioners is not adequate.[149]

Fair trading laws reflect similar principles. Even though there is no positive obligation to provide information, these laws require that information provided to consumers must not be misleading or deceptive. This includes the omission of relevant information. Fair trading regulators recognise that consumers face significant difficulties when they approach a health service provider directly, including:

- information asymmetry between the doctor and patient is exacerbated where there is no referral from a general practitioner;
- providers are exposed to 'moral hazard' in encouraging people to have cosmetic procedures;
- consumer reliance on the professional ethic to intervene only in their best interests, resulting in a failure to act as prudently as they would otherwise;[150]
- potential vulnerability of consumers because of the subjective reasons for seeking cosmetic surgery, being tied to self-esteem and body image.

As a result, the Australian Competition and Consumer Commission identified a number of consumer problems that are likely to occur, including:

- over-supply of the service;
- a tendency to decrease the quality of the service and increase the price; and
- incorrect treatment choices by consumers.[151]

6.2 Information about providers

Specialist medical colleges provide training, examinations and qualifications that reflect expertise in recognised specialities. However, consumers cannot rely on membership of any particular specialist medical college or professional association as the primary indicator of competence in cosmetic surgery procedures.[152] Many procedures, such as liposuction, are recent developments and are not part of the formal medical training curriculum. Also, a proliferation of professional organisations are associated with cosmetic surgery. The submissions from professional associations, individual practitioners, and consumers supported a system that provides consumers with an independent and reliable system of verification of provider's skills.

The Committee believes that the initial source of information about providers should be the Cosmetic Surgery Credentialling Council. The Committee believes that information about qualifications, relevant training, experience and clinical outcomes is useful to consumers.

Cosmetic surgery providers should give consumers information about:

- their qualifications, credentials and training,
- their experience in performing the procedure(s),
- the number of times the procedure has been performed recently,
- their clinical outcomes, and number of adverse events.

More detailed information, such as complication rates, should be provided by the individual practitioners when they meet with the consumer. Many doctors, particularly in cosmetic surgery, already provide information about their skills and qualifications following the High Court decision in *Chappel v Hart*. In that case the High Court adopted a supposedly 'common sense' assumption that the risk of injury is lesser with the surgeon who has the most experience and the best reputation in the field.[153]

The Committee considered a proposal that information on complaints and medical negligence claims against individual doctors should be available to the public.[154] The proposal envisaged that professional indemnity insurers would provide the information to the Credentialling Council for

publication. This information is available to consumers in the USA from state Medical Boards.

The Committee recognises that a claim of medical negligence against a doctor is not a good indicator of the quality of care they provide. The fact that a doctor has been sued in negligence does not mean that they are incompetent. It is more important that doctors know their own clinical outcomes and provide that information to their patients.

The Joint Committee on the Health Care Complaints Commission (HCCC) is currently considering how the Health Care Complaints Commission can fulfil its statutory function to investigate the frequency, type and nature of allegations made in legal proceedings of malpractice by health practitioners. One option is mandatory reporting of all medical practitioner malpractice actions to the HCCC or the Medical Board by professional indemnity insurers.[155]

Recommendation 11

11a. The Cosmetic Surgery Credentialling Council provide the following information to the public about credentialled providers to address consumer uncertainty about the level of skill and qualifications of cosmetic surgery providers:

- the provider's relevant qualifications, experience and whether or not credentialled with the Council;
- the provider's relevant training (as assessed by the Council);
- the extent of the provider's experience and clinical outcomes.

The information should be made publicly available by the Council via telephone, website and any other appropriate methods.

11b. Cosmetic surgery providers should give consumers the following information:

- their qualifications, credentials and training;
- their experience in performing the procedure(s);
- the number of times they have performed the procedure recently;
- their clinical outcomes, and number of adverse events.

6.3 Information about procedures

Poor communication with patients is the major cause of complaints against doctors and is a significant factor in medical negligence claims.[156] The obligation to communicate effectively with patients is even higher in cosmetic surgery for a number of reasons. As discussed above, the courts have recognised that because cosmetic surgery patients have a choice about whether to have the procedure there is a more onerous obligation on doctors to inform them of all possible risks. Another factor is the biases that may occur as a result of the financial arrangements in many practices.[157] A range of strategies are used by cosmetic surgery providers to meet this higher standard of disclosure.

Information brochures

Cosmetic surgery providers routinely prepare printed information brochures about the procedures. Information about some of the more controversial procedures have also been prepared by health authorities. For example, the Therapeutic Goods Administration has produced a *Breast Implants Information Booklet* since 1995 and the National Health and Medical Research Council have produced an information leaflet on laser eye surgery. The Australian Society of Plastic Surgeons has a series of information sheets on the common surgical procedures, such as breast implants, abdominoplasty and rhinoplasty. Some manufacturers of devices also produce information packs for consumers (e.g. *Collagen Aesthetics Australia* and *Restylane*) and for doctors (breast implant manufacturers).

However, information brochures place the onus on the prospective patient to read about possible risks of the treatment. The ability to understand written information varies from patient to patient.

In one case the ASPS Information Sheet on abdominoplasty was found by a judge to be overly technical, and even confusing, to the point of being almost misleading.[158]

Professor Mienczakowski's study of patients who had laser resurfacing highlights the importance of using a range of aids to communicate information about aftercare for this procedure. He suggests it would be useful to ensure that the patient's family also understands the aftercare instructions. He recommends frequent reiteration of verbal instructions to help reduce anxiety, and access to a short post operative care video that patients can view at the surgery or borrow. This would supplement the existing patient information handbook already used by the clinic.[159]

'Before and after' photographs

Visual aids such as 'before and after' photographs, slides and videos are used by doctors in the consultation with patients to help them visualise what they might reasonably expect, but they can also raise people's expectations. Photos can be useful to assist communication only if they are representative of reasonable expected outcomes in the long- and short-term. The Committee believes there should be a standard set of photos, presenting subjects in the same setting and lighting. One standardised photo of a common complication should also be shown.

Some doctors take 'before and after' photos are in a standard setting to document the aims of the cosmetic procedure and the results achieved. The photos are kept as part of the patient record. This practice is encouraged because it provides a record of the physical changes that have been achieved, which can be important if the consumer is not satisfied with the results.[160]

Recommendation 12

12a. Cosmetic surgery providers should use information brochures during the consultation to help consumers to understand the nature of the procedure(s) and the risks of complications.

12b. Visual aids, such as appropriate 'before and after' photos, should be used during the consultation to help provide consumers with realistic expectations of outcomes, including a photo of a common complication.

Face to face meeting with the treating doctor

Doctors must discuss proposed procedures with patients in a way that properly conveys the nature of the procedure(s), the treatment options, the risks and the likelihood of success. Written information and visual aids are not enough. In cosmetic surgery this is important because the decision making process is sometimes accelerated. The usual referral from a GP to a treating surgeon is often not present. In some practices patients meet the treating surgeon on the day of surgery, with prior medical examinations and counselling provided by nursing staff, or non-medically trained staff. As a result, patients have not had a proper medical consultation from the treating doctor prior to treatment. Consent forms are presented to patients for signing immediately prior to surgery.

'In some practices patients meet the treating surgeon on the day of surgery... Consent forms are presented to patients immediately prior to surgery.'

Some patients may pressure a doctor to perform the procedure as soon as possible. The study by Mienczakowski found that some patients arrived at the clinic having already decided on their procedure.[161]

These practices result in a lack of proper history taking, examination, and patient assessment, putting patients at risk. Professional organisations expressed concern about the practice of non-medically trained staff providing assessments and advice to patients on the types of procedures available to them. The Australian Society of Plastic Surgeons (ASPS), the Cosmetic Physicians Society and the Australian College of Cosmetic Surgery support the development of a best practice guideline to address patient assessment and informed consent. Most favoured the development of a guideline requiring the treating doctor to take a history of the patient, conduct a medical examination, investigation, and assessment of the patient, before offering a plan of

treatment. A number of cosmetic and plastic surgeons have a formal protocol for informed consent to treatment that includes a minimum of two consultations with the patient, and provision of a range of visual aids – a practice endorsed by defendant lawyers.[162] The ASPS say the guideline should require a comprehensive assessment of the patient's suitability for the proposed procedure, including any clinical or psychological contraindications.[163]

Some medical colleges have policies that prescribe the elements of patient examination and assessment before treatment. Some examples are the Australia and New Zealand College of Anaesthetists' policy on *Sedation for diagnostic and surgical procedures* and The Royal Australian College of Ophthalmologists draft *Preferred practice patterns for cataract and intra-ocular lens surgery*.

The Committee favoured the development of a guideline on pre-operative patient examination and assessment. It should require at least one face to face meeting with the treating doctor at which a medical examination occurs, the patient is assessed and treatment options are discussed.

Model for effective doctor-patient communication

- at least one face to face meeting between the patient and the treating doctor at which a full medical consultation occurs and information about procedure(s) is provided and discussed;
- information brochures to assist consumers to understand the nature of procedures and the risks of complications;
- visual aids, such as standardised 'before and after' photos, to help provide consumers with realistic expectations of outcomes, including a photo of a common complication.
- a cooling-off period of at least five working days between the first consultation and providing the treatment.
- use of consent forms to help structure and record communication between the doctor and patient, signed and retained by both.

Cooling-off period

The need for a cooling-off period between the first consultation and treatment was supported by a range of professional organisations, regulators and researchers. The Australian Competition an Consumer Commission and the Department of Fair Trading cited the use of cooling-off periods in other industries where the consequences of a buyer's actions can involve major financial and life costs. Examples include purchase of homes and franchise agreements.

Professor Mienczakowski's study found that a percentage of laser patients made hasty decisions to proceed within a few weeks of first hearing about the treatments. He recommends that when patients arrive at a practice seeking one treatment and are advised to have an alternative treatment, there should be a cooling-off period of six weeks before any treatment is provided.[164]

Roberta Honnigman, a Melbourne social worker who consults for cosmetic and plastic surgeons, also urged a cooling-off period. She says this enables patients to return to the surgeon for further discussion and helps to eliminate hasty decision making. It may also give the surgeon the opportunity to reassess realistic patient expectations and to define more clearly the service being offered.[165]

Some Committee members were concerned that requiring a cooling off period might disadvantage people from rural and remote areas. It was agreed that any potential disadvantage is outweighed by the benefits of sound clinical practice.

Recording communication

Recording the issues discussed between the patient and the doctor is important. It helps to provide a structure for communication of information and assists if a dispute or complications arise. Insurers and lawyers emphasised the importance of keeping comprehensive records, as did the Consumer subcommittee. A number of well-designed informed consent forms have been developed for health

professionals. For example, the ASPS Information Sheets include a consent form in a sticker format for signature and retention by both parties.

The Consumer Issues subcommittee recommends the consent form cover:

- whether the consumer has consulted someone else;
- information given to the consumer about risks and complications;
- an explanation of aftercare needs and the minimum reasonable recovery period;
- questions designed to check that the consumer's understanding of the risks;
- a statement of the provider's understanding of the patient's comprehension of the information.

Recommendation 13

13a. Effective communication between doctors and patients requires:

- at least one face to face meeting between the patient and the treating doctor during which a full medical consultation occurs and written information about procedure(s) is provided and discussed;
- a cooling-off period of at least five working days between the first consultation and providing the treatment.

13b. Cosmetic surgery providers should use well designed informed consent forms to help structure and record communication between the doctor and patient, signed and retained by both parties.

13c. The Cosmetic Surgery Credentialling Council prepare a *Code of Conduct on Communicating with Patients and Informed consent*. It should be widely promoted to providers and consumers.

Other sources of information

The proliferation of information provided through the media, brochures, the internet and telephone services can be confusing. The Consumer Issues subcommittee recommended that a consumer organisation establish an information service to provide consumers with objective information about cosmetic surgery. A benefit of such a service would be that it could provide the basis for collaborate with consumers in research on quality. In other areas of medicine collaboration with consumers is recognised as a necessary part of a quality heath service.

The Committee noted the benefits of the proposal. However, it also recognised some practical difficulties. The service would need to be user-pays because other funding sources are unlikely to be available or may be perceived as biased. It would have the same limitations as many of the existing information services: staff who are not medically trained providing advice by telephone are not able to give advice about the procedures most suited to individual consumers. A number of national consumer organisations consulted about the proposal expressed no interest in establishing such a service.

Agencies such as the HCCC and the ACCC have a role in providing independent advice to consumers about rights and complaints. The HCCC produced a leaflet seven years ago, entitled *Cosmetic Surgery: in the public interest,* providing information about common procedures, the pitfalls, the steps that should be followed by a prudent consumer, and how to obtain information about the chosen practitioner. The leaflet is now out of date due to advances in some techniques. The Federal Trade Commission in the USA has produced a number of consumer education leaflets dealing with problems in certain types of health services, including impotency treatment, varicose vein treatments and vision correction procedures.[166]

Recommendation 14

14. The HCCC and NSW Department of Fair Trading prepare consumer information guides to assist consumers to identify factual information about cosmetic surgery.

6.4 Disclosures

Financial interests influencing treatment

Financial interests can influence the advice and treatment provided by doctors in a number of ways. While there was no specific evidence to the Committee about conflicts of financial interest compromising patient care in the cosmetic surgery industry, the Committee was concerned about the potential for such conflicts to occur. Doctors are legally obliged to avoid conflicts of interest under professional standards under the *Medical Practice Act*, and obligations of trust recognised in the common law (known as fiduciary duty). There are also specific legal obligations on doctors and dentists to disclose financial interests where they have investments in hospitals, nursing homes and related services.[167] Fair trading laws also require disclosure of all relevant information to the extent that silence can be misleading. Doctors should disclose financial interests that are relevant to patient care and treatment at the first face to face meeting with patients. This should be done orally and in a written disclosure notice. The doctor should provide information about other doctors who offer a similar service so that consumers can exercise a choice in light of the disclosure.

Information about costs

Many cosmetic surgery providers offer an itemised quote stating all the costs, including the doctor's fees, anaesthetist's fees, hospital charges, and any other costs. Consumers may also be told of treatments that may be claimed under Medicare or private insurance. Informed financial consent to treatment is important where there is a potential for hidden or unexpected costs. Mandatory disclosure requirements are now commonplace in industries where consumers are at a significant disadvantage because the information available to them is incomplete. For example, lawyers are required by law to provide information to consumers about the level of fees and the basis for charging before any contract of service can be entered into.[168]

> ***'... cosmetic surgery consumers are reluctant to discuss complications or disappointment with outcomes because they feel it is their fault, that they have been vain.'***

When a drug or device is not approved

The practice of medicine is not based on rigorous scientific testing, although this is changing with the emergence of evidence-based medicine. Procedures used in cosmetic surgery are sometimes unconventional and to that extent may be used without first conducting a trial and evaluation. However, therapeutic drugs and devices must be assessed and approved by the Therapeutic Goods Administration (TGA). Where a product has been approved by the TGA it is listed in the Australian Therapeutic Goods Register. The listing for drugs states approved indications for use of the product. Drugs are sometimes used in cosmetic surgery in a way that is not approved in the ARTG. For example, botox (purified neurotoxin complex, a protein produced by the bacterium *Clostridium botulinum*) is listed on the ARTG for use in the treatment of blepharoplasm, or twitches in eye muscles. It is also widely used in cosmetic medicine to treat creases formed by the two horizontal muscles of the forehead located between the eyebrows. The botulinum can be injected into these muscles causing them to 'go to sleep' for a period of up to six months. This use is not indicated on the ARTG because it is not regarded as a therapeutic use within the terms of the *Therapeutic Goods Act*. In such cases consumers should be informed that the manner in which the drug is used is not approved.

Recommendation 15

15. To address gaps in the information provided to consumers cosmetic surgery providers should:

provide a disclosure notice setting out relevant financial interests, and information about alternative providers if a conflict of interest exists;

provide a statement of the cost of all relevant services;advise consumers if a drug is used in a manner different to the indications for use given by the Therapeutic Goods Administration.

6.5 Aftercare and complications

Many doctors offer remedial treatment in the event of an unsuccessful outcome. This is good practice. However, if the patient loses confidence in the provider there can be difficulties: the patient may feel there is nowhere to turn for support, or for information about their rights and how to obtain a second opinion. A Melbourne social worker told the Committee that cosmetic surgery consumers are reluctant to discuss complications or disappointment with outcomes because they feel it is their fault, that they have been vain. In this situation consumers need recognition of their experience and an acknowledgement of a surgical complication or dissatisfaction with the aesthetic outcome.[171] Cosmetic surgery providers need to be understanding and courteous in dealing with dissatisfied patients. Undertakings from the doctor about what will be done if something goes wrong should be considered before the treatment is provided.

Requiring patients to return for a follow-up visit is good clinical practice. It is also linked to higher patient satisfaction ratings. The *Consumer Survey* found that satisfaction levels were significantly higher among those respondents who had a follow-up visit than for those who did not. Most respondents were required to attend for follow-up visits some months after the procedure was performed (85%).[172]

Assessing a patient's ability to care for themselves is an important part of patient selection. With procedures such as laser resurfacing patient aftercare is a critical factor in preventing complications. Professor Mienczakowski's study highlighted the need for a wide range of communication tools to adequately prepare laser patients for aftercare. He found that effective communication is affected by stress and anxiety, which is commonly experienced by survey participants prior, during and after treatment.[173]

Adequate provision for care of patients when the treating surgeon is visiting from another city or interstate for the day was another concern of the Committee. In these circumstances a qualified medical practitioner should be available to answer questions and provide care for the patient following surgery or other treatment. There should also be adequate discharge arrangements and follow-up. The Committee agreed that a guideline should be developed to address post-operative care of patients.

Recommendation 16

16a. Providers of cosmetic surgery give undertakings to consumers as to what the provider will do if there are complications or the consumer is not satisfied.

16b. Providers of cosmetic surgery make adequate provision for aftercare of patients. As a minimum this would include:

- the doctor's contact details if questions or complications arise;
- if the treating doctor is not available, the contact details of an appropriately qualified medical practitioner with whom the provider has a prior arrangement;
- the hospital to attend in an emergency, the hospital being a facility with which the medical practitioner has a prior arrangement;
- appropriate discharge procedures and information to the patient about recovery;
- appropriate instructions for medication and other aftercare procedures that the consumer needs to follow;
- details of the date and time of the follow-up visit.

6.6 Alternative treatment options

There are a range of alternative procedures available in cosmetic surgery. For example, liposuction is regarded as an alternative to abdominoplasty, and laser resurfacing may be regarded as an alternative to surgical face lifts, injections, peels, and dermabrasion. Providers who have more experience in one procedure than the alternatives may provide advice to consumers that favours the procedure they perform more frequently.

The *Consumer Survey* showed consumers had a clear problem with the information provided to them about alternative treatment options. The level of satisfaction with the information about alternative procedures was significantly lower than for other types of information. A quarter of

respondents said they received no information on possible alternative procedures. The dissatisfaction with information on alternative treatments was not confined to any particular group of procedures.

The Committee canvassed with stakeholders the extent to which information on alternative treatment options should be provided to patients.[174] United Medical Protection said a patient should be able to expect that all of the risks for each alternative procedure should be provided and explained. Some specialists expressed a similar view, saying it is not difficult to fulfil the obligation.[175]

Others said it is unrealistic to expect providers to give full information on all alternative options because providers do not agree on the relative merits of different treatments.[176] The *Review of the published literature* found a lack of published literature comparing alternative methods and devices such as:

- no comparison of laser resurfacing and older methods of skin treatment;
- no comparison of the safety, efficacy and effectiveness of phalloplastic surgery with other treatments for erectile dysfunction; and
- no adequate analytic comparison of different techniques of liposuction and the application of those techniques to different types of patients.[177]

> ***'...consumers had a clear problem with the information provided to them about alternative treatment options.'***

Professional bodies emphasised that consumers should be given information about alternatives that are appropriate to their individual circumstances. There should be a proper medical examination and assessment of the patient, and an assessment of the patient's requirements before any plans for treatment are made.[178]

Some submissions emphasised that awareness of alternatives will be influenced by the level and type of training of the provider. They said comprehensive training for providers is essential to be able to give balanced advice.[179] Beauty therapists emphasised that they offer the full range of modalities for removal of unwanted hair and are trained in the risks associated with the use of lasers for that purpose.[180] The influence of financial imperatives on the objectivity of advice on alternatives was acknowledged in some submissions.

Adequate information about alternative treatment options is also necessary in relation to treatment of complications of cosmetic surgery. The Breast Implant Resource Service raised concerns about the use of closed capsulotomy to treat capsular contracture rather than surgical treatments.[181] The literature shows that the clinical outcomes for surgical and non-surgical treatments for capsular contracture have limitations.

Recommendation 17

17. The NSW Medical Board inform cosmetic surgery practitioners of their obligations to give consumers objective information about the risks and benefits of alternative treatment options, including treatment options for complications. The information should follow a full medical examination and assessment of the treatment options most suitable for the consumer.

6.7 Appropriate patient selection

Patient selection in cosmetic surgery is important because of the psychological factors involved in addition to the usual clinical considerations. Some consumers have cosmetic surgery procedures not only to change their physical appearance, but to improve their body image and self-esteem.

Psychology of cosmetic surgery patients

Little is known about the psychology of people seeking cosmetic surgery, or the potential psychological changes following surgery. According to a 1998 study of the American psychological literature on cosmetic surgery by Sawer, early psychiatric evaluations of cosmetic surgery patients in the 1940s and 1950s characterised them as highly neurotic and narcissistic. More recent studies using clinical interview found significant psychopathology in a majority of cosmetic surgery patients. However, studies using standardised tests found no serious psychological disturbance.[182]

Information for consumers

Information about cosmetic procedures:

- a full medical consultation at which written information about the proposed procedures is provided and discussed;
- information about the nature of procedures, the risks of complications and expected outcomes for the consumer;
- objective information on the risks and benefits of alternative treatment options (including treatment of complications);
- undertakings as to what the provider will do if there are complications or the consumer is not satisfied with outcomes;
- a disclosure notice setting out relevant financial or other pecuniary interests;
- a statement of the costs of all relevant services;
- notice if a drug is used in a manner that is not approved by the Therapeutic Goods Administration.

Information about aftercare:

- contact details for a doctor to contact if questions or complications arise;
- the hospital to go for treatment in the event of an emergency;
- appropriate instructions for aftercare procedures; and
- details of the date and time of the follow-up visit.

The Sawer study found pre-operative psychological studies of cosmetic surgery patients have used two methods: clinical interview and surveys using standardised tests. The two methods have produced quite different results. Investigations conducted by clinical interview reported significant psychopathology in cosmetic surgery patients. Generally 70% were diagnosed with psychiatric disturbance, most commonly neurotic depression and passive dependent personality. However, the methodology used in these studies is flawed because there was no standardised assessment procedure and patient categorisations were so vague as to make replication impossible.[183] Studies that used standardised tests to assess psychopathology generally have reported less disturbance. For example, no significant psychopathology, or only mild psychopathology, was reported in separate studies of patients for facelift, breast augmentation, breast reconstruction and rhinoplasty.[184]

The researchers found post-operative psychological studies of cosmetic surgery patients have not yet yielded definitive results because of the small number of studies and their methodological weaknesses. No studies where found that systematically examine the relationship between baseline measures of psychopathology pre-operatively and psychological status post-operatively.[185] The study concludes it is therefore premature to conclude that cosmetic surgery produces psychological benefit in the majority of patients.

However, a recent American study using pre- and post-operative assessments found that cosmetic surgery significantly improves quality of life outcomes.[186] This 1998 study examined 105 patients recruited through three plastic surgery practices pre-operatively and post-operatively at one month and again at six months. The instruments used were four self-report questionnaires collecting data on: the quality of life index, depression, social support and coping. These were determined pre-operatively and post-operatively using standardised tests. The largest number of survey participants underwent liposuction (31%), nose surgery (20%), breast augmentation (10%) and facelift (12%). Significant improvements were found in scores for quality of life outcomes and depression from pre-operative assessment to six months post-operative. There were no significant differences in the results for social support and ways of coping.[187]

Inappropriate candidates for surgery

Despite a recognition of the importance of psychological factors, the Sawer research noted an absence of literature on indicators for patients who are not appropriate for cosmetic surgery for

psychological reasons. It found the link between body image and surgical change is poorly understood. No studies were found using widely accepted and validated measures of body image with cosmetic surgery patients.[188]

The *Review of the published literature* showed most of the medical literature is premised on the principle that body image problems can be cured by surgery. It identified a lack of clear clinical and psychological indicators for performing different types of augmentation phalloplasty procedures. It also highlighted the lack of literature on patients who are not appropriate candidates for breast implants for psychological reasons and by reasons of youth:

> The procedure appears to have been embraced as an appropriate treatment for problems with self-esteem and body image without any real consideration of whether other, less invasive, assistance can be offered. There is a surprising absence in the literature of whether some patients are not appropriate candidates for the procedure for psychological or other reasons. These issues merit some consideration and debate, particularly if breast augmentation is to be carried out on a younger population or on a wider population.[189]

'Most of the medical literature is premised on the principle that body image problems can be cured by surgery.'

Dysmorphobia, or body dysmorphic disorder, is the only diagnostic term directly addressing body image concerns. It is defined as a preoccupation with a defect in appearance that is either imagined, or if slight, leads to markedly excessive concern.[190] The proportion of cosmetic surgery patients suffering from dysmorphobia is not known.

Emotional distress can compromise a patient's ability to give informed consent. Plastic and cosmetic surgeons recognise this, and some have formal procedures to screen patients who are emotionally or psychologically inappropriate for surgery.[191] The American Society of Plastic and Reconstructive Surgery's information sheet on *Psychological aspects of plastic surgery* addresses the categories of people who are good candidates for cosmetic surgery and those who are not. Among those it identifies as inappropriate candidates for surgery are:

- people in crisis – going through a divorce, death of a spouse, or loss of a job;
- patients with unrealistic expectations;
- patients obsessed with a minor defect;
- patients with a mental illness, and exhibiting delusional or paranoid behaviour.

A number of submissions emphasised the importance of patient screening. Professor Mienczakowski's study indicates that significant emotional events in their lives play a significant role in a patient's decision to seek treatment. A Melbourne social worker says cosmetic surgery can be hazardous if insufficient attention is paid to patient selection, resulting in disability in some patients.[192] The Committee agreed that doctors should have systems in place to be able to recognise and respond appropriately to people who are not appropriate candidates for cosmetic surgery. This should be facilitated by the development of a code of ethics by the Cosmetic Surgery Credentialling Council on patient assessment and selection.

Recommendation 18

18. The Cosmetic Surgery Credentialling Council develop a *Code of Ethics on Appropriate Patient Selection*. The code should incorporate:an evaluation of the physical condition of patients and potential risks associated with treatment options;a discussion with patients about their expectations in terms of self-esteem. This should include an explanation that determinants of self-esteem are multifactorial and cosmetic surgery is only one aspect of improved self-esteem;an evaluation of whether the patient's expectations are realistic. This should include consideration of deleterious psychological or emotional outcomes that may eventuate if an adverse surgical outcome occurs.

7. PROMOTION OF COSMETIC SURGERY

7.1 Advertising and popular media

Cosmetic surgery is promoted extensively in the popular media and the internet. People who have had cosmetic surgery first hear about it more often in a story in the media or advertising than any other source, according to the *Consumer Survey*.[209] Almost all the submissions to the Committee commented on promotional issues, expressing concerns about claims made by individual doctors and the wider health and social impacts of promotions.

Women's magazines and lifestyle magazines routinely carry advertisements and stories about cosmetic surgery. Local newspapers and street magazines, such as *Nine to Five,* advertise procedures such as impotency treatments, hair replacement, liposuction and breast implants alongside advertisements for beauty products. Cosmetic surgery also features on television programs. Channel 9's *Good Medicine* program includes a story on cosmetic surgery procedures in almost every program. Producer, Maxine Gray, acknowledges this is in response to the popularity of cosmetic surgery among viewers. Current affairs programs, such as *A Current Affair* and *Today Tonight*, also frequently provide stories on cosmetic surgery.

'Cosmetic surgery tends to be promoted as a panacea for a range of body image, self-esteem and relationship problems.'

Two specialist cosmetic surgery magazines started in Australia in 1998 providing detailed information and advertising about cosmetic surgery procedures, providers and products – *Australian Cosmetic Surgery Magazine* (quarterly) and *Art of Cosmetic Beauty* (biannual). Editor-in-chief of *Cosmetic Surgery Magazine* (ACSM), Michelle Kearney, told the Committee the magazine aims to provide non-sensational, authoritative, medical information. Before the magazine commenced publication the only source of information about cosmetic surgery for consumers was general interest women's magazines. In ACSM doctors write articles about their areas of expertise, and there are also feature articles by journalists. Doctors advertise in the magazine and sometimes the doctors writing the articles advertise. The Editor-in-chief advises that the two relationships are independent. She says:

> ACSM describes in detail the different procedures available, and explains what each costs, what is involved, what the individual risks are and answers to most commonly asked questions. There are many warnings throughout each issue about the seriousness of surgery and possible risks and complications.[210]

Social researcher, Anne Ring, says the overall message from these magazines is positive, favouring the benefits of cosmetic surgery. She told the Committee that general informational articles and case studies are utilised to present the benefits of a wide variety of procedures to resolve every category of body image concern, particularly for women.[211] Her submission reviewed four publications – *The Complete Guide to Cosmetic Surgery and anti-ageing*, *Australian Cosmetic Surgery Magazine*, *The Art of Cosmetic Beauty* and *Gloss*. She is concerned about the medical ethics of cosmetic surgery providers, because of their need to create a market.

Body Image and Health Inc. raised concerns about the impact of cosmetic surgery promotions on women's health status. Director, Thea O'Connor, told the Committee that cosmetic surgery tends to be promoted as a panacea for a range of body image, self-esteem and relationship problems. She says in some cases cosmetic surgery promotions undermine the importance of adopting a healthy lifestyle. She said:

> Cosmetic surgery is promoted as an anti-ageing device, which pathologises the process of natural bodily change and devalues older people in our community, especially older women... By altering normal bodies that undergo normal changes throughout the life cycle, and by removing or altering physical characteristics that impart individuality, cosmetic surgery acts as a powerful force that promotes and maintains a narrow beauty ideal. The socio-culturally defined body ideals for women and men are one of the factors involved in the creation and maintenance of body image dissatisfaction and eating disorders.[212]

Professional associations and many individual practitioners raised more specific concerns about the content of specific claims made by doctors in cosmetic surgery advertisements. The Australian

Society of Plastic Surgeons expressed concern about the promotion of an attitude that cosmetic surgery is just another beauty product. Dr Cholm Williams, of the ASPS, told the Committee:

> ... patients who seek this surgery are vulnerable to more or less any form of suggestion that the concerns they have can be fixed by surgery – vulnerable to having extra operations or inappropriate operations sold to them. We are aware that a lot of patients have a mind-set that they want to have plastic surgery, they've made up their mind, they don't want to hear the doctor say that there are complications, they resist being told about the details of what could go wrong... almost equivalent to going along and buying a new lipstick. That is often the attitude that's put forward by the women's magazines, regrettably, and the media generally. It takes some time to convince people that it's surgery, it's serious, it can make a patient worse, or they can die.[213]

Regulation

Claims made in the promotion of cosmetic surgery are regulated by fair trading laws and professional registration acts. The primary consumer protection laws are the *Fair Trading Act 1987* (NSW) and the *Trade Practices Act 1974* (Clth), Parts IVA and V. These mirror provisions apply to anyone supplying and promoting goods or services, including health professionals. The relevant provisions prohibit unconscionable conduct and misleading and deceptive conduct.

When deciding what constitutes unconscionable conduct the courts may consider whether any unfair tactics were used against a consumer by a service provider, the relative strengths of the bargaining positions of the service provider and the consumer, whether the consumer was able to understand the information provided about the service and the amount for which, and the circumstances under which, the consumer could have acquired identical or equivalent services from another service provider.[214]

The broad prohibition on misleading or deceptive conduct or conduct that is likely to mislead or deceive is one of the fundamental precepts of fair trading laws.[215] The law covers all forms of promotional activities, including brochures at point of sale, direct mail, advertising and any statements by practitioners and their employees. It requires health practitioners, and others involved in promoting their services, to tell the truth or to refrain from giving an untruthful impression. However, statements that are literally true, but convey a secondary meaning which is false, may also be regarded as misleading and deceptive.[216] A statement may be misleading even if true if it omits factors that should have been mentioned or because the message has been composed to highlight appealing aspects of a service.[217] The court will consider what ordinary members of the target audience will conclude from the information or conduct. Silence can also mislead or deceive.

There are a number of specific prohibitions about false and misleading representations. These include prohibitions on representations as to the standard or quality of goods or services, representations about the need for goods or services, or about the uses or benefits of a service.[218] Warranties that services will be carried out with due care and skill and are fit for the purpose for which they were provided are implied in contracts for the supply of services by the *Trace Practices Act*.[219]

Professional standards of behaviour are regulated under professional registration acts and regulations (discussed in section 3). The *Medical Practice Regulation 1998* (NSW) prohibits advertising that is:

- false, misleading or deceptive;
- creates an unjustified expectation of beneficial treatment; or
- promotes the unnecessary or inappropriate use of medical services.[220]

There has been a substantial change in the approach to regulation of advertising by health professionals in recent years as a result of National Competition Policy. Traditionally regulation of advertising by doctors and other registered health professionals was more restricted, and based on subjective values. The *Medical Practice Regulation 1993* (NSW) is an example. It included provisions that prohibited advertising medical services that are:

- vulgar or sensational; or
- claim or imply that any particular medical practitioner is superior to another or other medical practitioners; or
- unprofessional or likely to bring the profession into disrepute.

In Victoria the *Medical Practice Act 1994* (Vic) has a similar provision, prohibiting advertising of medical services if it is intended to be false, misleading or deceptive, offers a discount, gift or other inducement without setting out the terms of the offer, uses quotes or testimonials or unfavourably contrasts medical or surgical services provided by a medical practitioner. The effectiveness of maintaining this type of provision as part of professional regulation was recently reviewed in Victoria.[221]

It is also an offence to claim to be a doctor or surgeon or to possess qualifications of a medical practitioner while not being currently registered.[222] In Queensland, where specialist registration exists for medical practitioners, it is an offence to purport to be a specialist unless included in the specialist registers of the Queensland Medical Board.[223]

Claims made about therapeutic goods are regulated under the *Therapeutic Goods Act.* The Therapeutic Goods Administration must approve advertisements for some categories of goods and certain representations about drugs and devices are legally prohibited. There is also a mandatory Therapeutic Goods Advertising Code for advertisements about therapeutic goods that can be purchased without prescription.[224]

Industry codes

Misleading and deceptive conduct and conflicts of interest are dealt with in codes adopted by the major industry organisations involved in promoting the cosmetic surgery industry.

The Australian Medical Association's position statement on advertising and endorsement states that:

> the promotion of a doctor's medical services as if the provision of such services were no more than a commercial product or activity is likely to undermine public confidence in the medical profession.

It also states that advertisements should be demonstrably true in all respects, not be 'vulgar or sensational', and should 'seek to maintain the decorum and dignity of the profession'. It advises against endorsements, a message more specifically reinforced in the AMA Code of Ethics:

> 2.3.2 Ensure any announcement or advertisement directed towards patients or colleagues is demonstrably true in all respects, does not contain any testimonial or endorsement of your clinical skills and is not likely to bring the profession into disrepute.
>
> 2.3.3 Avoid public endorsement of any particular commercial product or service.

The Australian Society of Plastic Surgeon's *Guidelines for Professional Conduct* supports advertising by its members, but only for the purpose of providing information about advances in medical science and about the services offered by members. The Guidelines reflect the values in the 1993 *Medical Practice Regulations*. For example, it prohibits advertising that:

- is misleading or deceiving (with guidance on what this means);
- sensational or in poor taste;
- contains testimonials;
- claims that a member is superior to other members; and
- is likely to bring the profession into disrepute.[225]

'... promotion of cosmetic surgery is having an impact on consumer expectations about what can be achieved.'

The Australian College of Cosmetic Surgery Code of Practice on Advertising simply requires compliance with advertising codes established by state medical boards.

The *Code of Ethics of the Media, Arts and Entertainment Alliance: Australian Journalists Association* has provisions on the disclosure of financial conflicts of interest, and on not allowing commercial considerations to undermine accuracy, fairness and independence. The *Public Relations Institute* also has a code of conduct dealing with financial conflicts.

Adequacy of regulation

Complaints about advertising that breaches the *Medical Practice Regulation*, or some other professional standard, can be made to the Health Care Complaints Commission (HCCC). The Australian Competition and Consumer Commission and the NSW Department of Fair Trading receive complaints about advertising and promotion that breach fair trading laws. These agencies report that few complaints have been received about advertising of cosmetic surgery. The HCCC and the Health Services Commissioner in Victoria say this is hardly surprising as the complaints mechanisms are inaccessible to consumers. However, all the health complaints bodies noted that promotion of cosmetic surgery is having an impact on consumer expectations about what can be achieved.

A number of practices in advertising, media and information services about cosmetic surgery may be in breach of professional standards and fair trading laws. They include:

- use of models, implying the model has had the procedure or that the procedure can achieve the results (with or without a disclaimer);
- 'before and after' photos that have been enhanced, or are different in size, colour or pose, or give a misleading impression of long-term effects of a treatment;
- use of the terms 'surgeon' and 'skin specialist' by medical practitioners who are not a member of the relevant specialist medical college, and do not have equivalent qualifications;
- claims about membership of organisations that suggest a qualification or recognised level of training;
- claims that minimise the risk and discomfort of a medical procedure, such as advertisements using terms such as 'painless' or 'completely safe';
- claims that exaggerate the benefits or results of procedures, such as claims of 'permanent' laser hair removal;
- endorsements and testimonials from former patients that are unsubstantiated and cannot be verified.

Another major issue is the opportunity for 'advertorials' in popular magazines and television programs, blurring the line between advertising and information. These may promote a professional association, an individual doctor or clinic, a particular procedure or a product.

Options to solve the problems

The ACCC produce guides on the requirements of the *Trade Practices Act* for particular industries from time to time. An example is the *Guide to the Trade Practices Act for the promotion of private health insurance* produced jointly with the Private Health Insurance Ombudsman in 1998. The purpose of these guides is to help an industry comply with the *Trade Practices Act*, especially misleading and deceptive conduct provisions. To ensure the guides are effective they are developed in consultation with the relevant industry. The guides do not extend the law or regulations, nor do they constitute an industry code. They simply describe the law, and applications of the law by the courts, to the particular problems experienced by that industry. The guides can include 'dos and don'ts' and advice on specific claims that should not be used.

While there is no guarantee that the courts will apply everything in the guide, people who choose to ignore the guide may find themselves at greater risk of prosecution by the ACCC or another regulatory body. They have been effective to educate the public and improve poor advertising practices. The limitation of a guide is that it cannot prescribe or outlaw any particular conduct beyond the general fair trading prohibitions.

A voluntary code of practice could be developed to address particular consumer protection problems. If an industry code places restrictions on competition, the industry would have to apply to the ACCC to have the conduct authorised. For authorisation to be granted, the ACCC must be satisfied that the conduct in question will result in a benefit to the public that outweighs any anti-competitive effect.

The following criteria for a voluntary code to be effective were identified by the ACCC:

- commitment from the relevant sector, including backing in resources;
- proper administration of the code;
- mechanisms for complaints;
- effective sanctions;
- monitoring and review.[226]

The cosmetic surgery industry is characterised by a proliferation of professional and industry bodies, and a range of stakeholders who are involved in promotional activities. Some of these bodies have codes of conduct, but none claim success in enforcing them.

Codes of practice can be made mandatory industry codes, enforcable by the ACCC. Decisions to prescribe a particular code are the responsibility of the Minister, not the ACCC.[227] The NSW Department of Fair Trading has similar powers to develop and enforce mandatory industry codes of practice.[228]

'People who choose to ignore the guide may find themselves at greater risk of prosecution by the ACCC or another regulatory body.'

The Californian legislature is considering a Bill that, if passed, would prohibit doctors advertising cosmetic surgery from using photographic or other visual imagery that is enhanced or modified. It also specifically prohibits misleading 'before and after' photographs by doctors.[229] The Bill was supported by the Medical Board of California following a review of advertising of cosmetic surgery. The review recommended the Medical Board develop a 'regulation' defining certain activities as misleading and providing guidance on what is and is not adequate substantiation of claims. The review identified similar problems in advertising cosmetic surgery to those identified by this Inquiry. The claims include 'before and after' photos, use of models, use of terms such as 'painless', 'entirely safe', 'satisfaction guaranteed', claims about membership of organisations, claims of superiority that would mislead, such as 'the only physician able to perform [the procedure]'.[230]

A guide to promotions

Establishing the merit of new legislation requires a demonstration of need and public benefit. The primary problem with the promotion of cosmetic surgery is a lack of compliance with the law rather than a demonstrated need for new laws. Another consideration is the difficulty of introducing a specific prohibition that would be effective. The more specific the prohibition the more easily it can be avoided through adjustments in practices. Professional and industry education, and possibly litigation to test the limits of the current law, are first steps in changing attitudes and practices.

The Committee agreed that the ACCC and HCCC should produce a joint guide that addresses the problems with the promotion of cosmetic surgery, as a first step. The impact of the guide would be monitored through surveys so that changes in practice are measured. A report on the impact of the Guide should be produced within 18 months of its release, and include consideration of the need for a code of conduct for the cosmetic surgery industry.

In June 1999 the ACCC and HCCC agreed to develop a *Guide to the promotion of all health services*. It will cover the problems identified with cosmetic surgery. Health care complaints bodies in each state and territory have nominated the NSW Health Care Complaints Commissioner, Merrilyn Walton to act on their behalf. A draft guide is expected to be released for comment in October 1999.

Recommendation 19

19a. The ACCC and HCCC develop a guide on the application of fair trading laws to the promotion of health services.

19b. The impact of the guide be monitored and a report on its impact and an assessment of the need for a mandatory industry code be made within 18 months of release of the guide.

7.2 Financial relationships

Regulation

In addition to advertising and claims in the media, other claims made in the course of dealing with consumers are regulated by fair trading laws, including claims made in the course of a consultation between a doctor and patient. This means that information provided to consumers must not be misleading or deceptive, material information should not be omitted, and the dealings with the consumer not be unconscionable (as discussed above).

In addition, legal and ethical obligations on health care providers require them to act in the best interests of their patients, putting patient interests above their own. However, these obligations can be blurred with commercial considerations. Conflicts of interest can be addressed by requiring disclosure of financial interests that might affect patient choice or quality of care. Mandatory disclosure is used widely as a regulatory strategy to curb abuses in private transactions without imposing direct government constraints on the disclosed activity.

The NSW Medical Tribunal has ruled that a medical practitioner's failure to disclose direct financial interests in treatment provided to patients is a breach of professional standards in NSW.[231] However, the Tribunal recognised that some forms of 'remote benefit arising out of an indirect financial interest' do not give rise to an obligation to disclose. An example given by the Tribunal is where a practitioner has investments with a financial institution that holds in its portfolio of investments a substantial shareholding in a private hospital. The *Final Report of the Review of the Medical Practice Act 1992* recommended that 'failure to disclose a conflict of interest in a service' be included in the definition of 'unsatisfactory professional conduct'.[232] The HCCC supported a wider disclosure obligation to cover failure to disclose any financial or pecuniary interest in any form of treatment offered or recommended, including any such interest in products or appliances offered or recommended.[233]

The common law imposes a general obligation on doctors to not put themselves in a position where their interests would conflict with the patient's interests. Where this occurs the conflict must be resolved in favour of the patient.[234]

'Failure to disclose a financial relationship that is material to consumers' choice of service may constitute misleading and deceptive conduct.'

There are specific statutory obligations on doctors and dentists to provide disclosure of their 'pecuniary interests' in private hospitals, day procedure centres and nursing homes before referring a patient to them.[235] The disclosure must be made orally, in writing and be displayed in a notice.[236] The definition of 'pecuniary interest' includes an interest in the premises (including share capital in a corporate owner), a holding of 5% or more in the share capital of a public company which is the licensee, a pecuniary interest in the services provided, or related services such as pathology, and relevant interests of relatives of the practitioner.

Failure to disclose a financial relationship that is material to consumers' choice of service may also constitute misleading and deceptive conduct, in breach of fair trading laws and the *Medical Practice Regulations*. Silence is regarded as potentially misleading 'if in all the circumstances constituted by the acts, omissions, statements or silence there has been conduct likely to mislead or deceive.'.[237]

Industry practices and problems

In cosmetic surgery health professionals, their staff and agents are engaged in the task of persuading consumers of the benefits of their service, the products to be used, the price of the service (and in some cases how it should be paid for) and the facility in which the procedure will be performed. In these circumstances, the provider and their staff may have a range of business and financial relationships. A number of practices may be in breach of professional standards or fair trading laws, including:

- non-medically trained referral agents securing patients for doctors where there is a financial relationship that is not disclosed to consumers;
- financial incentives for staff in clinics to secure patients, resulting in patients who attend for therapeutic treatments being subjected to 'hard sell' tactics to purchase cosmetic procedures;

- referrals to doctors by consumer helplines conducted by product manufacturers;
- doctors facilitating 'cosmetic surgery loans' to patients.

The Committee was particularly concerned about people with no medical training providing consumers with referrals to doctors and making judgements about preferred procedures. The main concern is the potential to compromise patient care in such circumstances. Another concern is referral of patients to doctors where the referring agent has a financial arrangement with the doctor that is not disclosed to consumers.

The Chief Executive of Clinical Beauty, Ms Noon, a referral and information agency in cosmetic surgery, told the Committee that the role of her business is to:

> publicise cosmetic surgery procedures, not doctors... to meet with patients... [to] discuss the type of surgery they are inquiring about, explain to them how it is performed... and finally to send them off to a surgeon or doctor that will perform it for them well.[238]

In assessing whether to make referrals to a doctor Pamela Noon said Clinical Beauty uses a number of criteria, including the doctor's training, unassisted experience in each cosmetic procedure and whether she agrees with the method used for particular procedure. The service is promoted as a free service to consumers. The Committee heard that doctors within Clinical Beauty's network pay an 'administration cost' to the company. The amount depends how much of the business is organised for them, but there is no commission or referral arrangement as such. Ms Noon said Clinical Beauty provide referrals to doctors other than those who have a commercial relationship with the company. However, other submissions disputed this claim.

'The Committee was particularly concerned about people with no medical training providing... referrals to doctors and making judgements about preferred procedures.'

The 'hard sell' tactics of receptionists and nursing staff in cosmetic surgery clinics based on financial commissions may also be in breach of fair trading laws, depending on the circumstances. The Committee was told it is common for staff in clinics to be paid a financial reward for securing clients. Where a consumer attends a clinic for a quote for cosmetic surgery the law would probably regard them as being on notice to expect some marketing. However, the situation is different if a patient attends a doctor's rooms for a therapeutic procedure and is pressured to undergo cosmetic procedures.

Referrals by manufacturers of products to doctors who use their product through telephone 'help lines' may also be a problem if their conduct amounts to unsubstantiated endorsements or implied undertakings as to the level of skill and training of the doctor. This would be in breach of fair trading laws.

The Committee was provided with a copy of a letter sent to cosmetic surgeons and physicians from a loan company instructing the doctor to encourage patients to take out 'cosmetic surgery loans' offered by the company. This raises potential ethical and legal problems for doctors. The Committee was also told of a doctor in Sydney who allegedly provides a beauty therapist with access to laser equipment through a sham lease agreement. Some of these issues will be discussed in the *Guide to the promotion of health services*.

Preferred options

More work is required to understand the business practices in the cosmetic surgery industry, particularly where it compromises patient care or encourages unethical behaviour by doctors. The Committee strongly supports the development of a code of ethics on this issue, drawing on existing codes of ethics. A number of clauses in the AMA Code of Ethics 1996 deal with financial conflict of interest problems that provide a starting point for discussion:

> 1.3.14 Do not refer patients to institutions or services in which you have a financial interest, without full disclosure of such interest
>
> 2.2 Do not enter into any contract with a colleague or organisation which may diminish the maintenance of your patient's autonomy, or your own or your colleague's professional integrity

Another example of a financial conflicts of interest policy is the American College of Surgeons Statement on Disclosure of Commercial Interest, 1989:

> In situations in which a Fellow's failure to disclose his or her financial interest in, or arrangement with, a commercial enterprise makes it likely that other professionals or the public will be unable to evaluate accurately statements made about the products or services, the statements may be misleading or deceptive. Under such circumstances, failure to disclose remuneration or financial interest may constitute grounds for disciplinary action.

Recommendation 20

20a. Amend the *Medical Practice Act* to prohibit doctors from entering into financial arrangements with agents who refer patients.

20b. Amend the *Medical Practice Act* so that 'unsatisfactory professional conduct' includes failure to disclose to patients their financial or pecuniary interests in treatments offered or recommended.

20c. The Department of Health, the Medical Board and professional organisations educate doctors and consumers about conflicts of interest in the health services sector.

20d. The Cosmetic Surgery Credentialling Council develop a *Code of Ethics on Financial conflicts of interest*. Compliance with the code should be a condition of credentialling and re-credentialling.

7.3 Cosmetic surgery as a prize

Cosmetic surgery procedures as prizes in competitions was brought to the Committee's attention by consumers, providers and publishers. During April, May and June of 1999 three different competitions offered cosmetic procedures or products as a prize. One competition offered breast augmentation as a prize. Another competition, the 'Go Non- Stop Lifestyle' contest promoting a new bottled water product H_2GO, offered plastic surgery or $5,000 cash as first prize. Another competition by Restylane, a new injection product similar to collagen, offered free Restylane as a prize.

The HCCC and professional organisations object to cosmetic surgery being offered as a prize because it trivialises the seriousness of cosmetic surgery procedures. It is dangerous because it suggests that anyone can diagnose themselves as suitable for the procedure offered. The Australian Society of Plastic Surgeons, the Australian College of Cosmetic Surgery, and the Royal Australasian College of Surgeons all issued public statements condemning the practice.

The promoters of the 'Go Non-Stop Lifestyle' contest argue the promotion was meant to be tongue-in-cheek.

> We were trying to have a bit of fun when we created this promotion. It was never really intended to be a serious inducement for someone to get plastic surgery... the people who buy our product tend to be the kind of people who would consider having plastic surgery. They lead extravagant lifestyles.[239]

Competitions for the promotion of trade in NSW must be granted a permit from the Minister for Gaming and Racing under the *Lotteries and Art Unions Act* (NSW). The Act precludes tobacco products as a prize.[240] The Committee unanimously agreed that offering cosmetic surgery as a prize causes sufficient danger to public health that it should be prohibited.

Recommendation 21

21. The NSW Government not grant permits for competitions offering cosmetic surgery procedures and products as prizes, and amend the *Lotteries and Art Unions Act* (NSW) to prohibit competitions offering cosmetic surgery as a prize.

7.4 Patenting of surgical procedures

Ethical objections to the patenting of cosmetic surgery procedures in Australia were discussed by the Commercial Issues subcommittee. Concerns about the patenting of surgical procedures generally are reflected in the AMA Code of Ethics:

> [Medical practitioners should] ensure that any therapeutic or diagnostic advance is described and examined through professional channels and, if proven beneficial, is made available to the profession at large. (clause 2.3.4)

The Committee considered that the patenting of a surgical procedures may give rise to ethical problems and these should be discussed.

Recommendation 22

22. The public policy issues arising from patents on surgical procedures should be referred to the Australian Health Ethics Committee for their consideration.

END NOTES

[1] Information provided by *Collagen Aesthetics Australia* at public hearings of the Committee 9 April 1999 and follow-up discussions with the secretariat.

[2] See discussion following on *How many providers?*

[3] Letter from ASPS, 19 August 1999 sets out the number of members who provide breast reduction, breast augmentation, rhinoplasty, eyelid surgery, liposuction and facelifts. The figure 190 is an average of those numbers.

[4] Submission from Australian Society of Plastic Surgeons, no. 65; http://www.asps.asn.au/cosmetic

[5] Membership list provided by ACCS 24 August 1999, and information provided by Dr Colin Moore by telephone 30 August 1999. A cross-check against membership list of the Cosmetic Physicians Society as at 24 August 1999 showed 15 members of CPS are members of ACCS.

[6] Submission from the Australian Association of Cosmetic Surgery, no. 60.

[7] Submission from Cosmetic Physicians Society, no. 38, and CPS membership list current to 24 August 1999, available at www.cosmeticphysician.org.au.

[8] Submission by the Australasian Society for Aesthetic Plastic Surgery, no. 77.

[9] Submission by Australasian Academy of Facial Plastic Surgery, no. 42.

[10] Submission of the Australian Society of Otolaryngology, no. 47, and evidence presented to the public hearings.

[11] Submission from the Australasian College of Dermatologists, no. 71; discussion with Alan Cooper, Chairman, Australasian College of Dermatologists, 6 September 1999.

[12] Submission of the Royal Australian College of Ophthalmologists, no. 55, and Dr Ross Benger, public hearings of the Committee, 19 March 1999.

[13] Letter from Dr David Jenkins, committee member, Sclerotherapy Society of Australia, 26 August 1999.

[14] Submission on *Use of lasers* from the NSW College of Nursing and the NSW Nurses Association.

[15] Submission from Collagen Aesthetics Australia, no. 82 and public hearings.

[16] APS Equipment, Candela Corp (Australian Distributor), Coherent Surgical, Spectra Medical Pty Ltd, distributors for Sharplan, Medical Laser Technology.

[17] The main suppliers in Australia are Surgiplus Medical, Mentor, and Device technologies.

[18] The ASPS have 190 members performing cosmetic surgery procedures. The ACCS have 49 members of whom about 30 have surgical training, 15 are cosmetic physicians and about five are dermatologists or ENT specialists so they are counted in that category.

[19] In 1998 UMP provided indemnity for 82 members providing plastic and cosmetic surgery in NSW, 62 of whom are members of ASPS (not including ENT specialists and ophthalmologists). United Medical Protection have only recently created a separate category of membership for cosmetic medicine and did not provide statistics for that category. See submission from UMP, no. 64 and subsequent discussions with senior staff.

[20] Submissions on *Use of lasers* from Coherent Surgical, Environment Protection Authority (NSW) Radiation Control Unit, Office of Health Review (WA).

[21] Submission on *Use of lasers* from Cosmetic Physicians Society.

[22] Information presented at the public hearings of the Committee by Jenny Vallance, Collagen Aesthetics Australia and in follow-up conversations with Committee secretariat. They estimated that there are a total of 150 practitioners who use collagen in NSW, and NSW accounts for about 35% of their business nationally.

[23] Letter from Sclerotherapy Society of Australia, 26 August 1999.

[24] Mr Richard Barnett of the ASPS agreed with an estimated average of 150-200 cosmetic procedures per year for ASPS members. Dr Darryl Hodgkinson estimated an average of 200 cosmetic surgical

procedures by 300 cosmetic surgery providers (a total of 50,000 per year) in a paper presented to Plastic, Reconstructive and Cosmetic Surgery Negligence conference, LAAMS, Sydney, February 1999.

[25] One manufacturer of breast implants estimates 4,500, another says 6,000, breast implants were provided in Australia in the past year for cosmetic purposes. Dr Darryl Hodgkinson estimates 6,000 breast implants per year, and 10,000 liposuction, 3,000 blepharoplasty and 3,000 facelifts annually.

[26] Submission on *Use of Lasers* from Dr Daniel Fleming.

[27] The estimate was provided by a laser and vein clinic and Collagen Aesthetics Australia.

[28] Medicare Benefits Schedule Book of November 1998 para. 1.1.4 – where an eligible person incurs medical expenses in respect of a professional service Medicare will pay benefits for that service. 'Professional service' means a clinically relevant service, which means a service rendered by a medical or dental practitioner, or an optometrist that is generally accepted as being necessary for the appropriate treatment of the patient.

[29] Letter from Health Insurance Commission, 23 July 1999.

[30] 'The cosmetic surgery pie: What piece do plastic surgeons have?', *Plastic surgery news*, American Society of Plastic and Reconstructive Surgeons Inc, February 1999, pp. 1, 24-25.

[31] There were 3,000 breast implant removals reported.

[32] Australian Bureau of Statistics figures for average weekly earnings in May 1999 state that the average weekly earnings for all employees total earnings is $612.30 per week.

[33] Submission from the Chief Health Officer, Queensland, no. 24.

[34] Australian Medical Council, *Accreditation and recognition of vocational and specialist education in Australia - overview*, 1999.

[35] *Nurses Act 1991* (NSW) and the *Dentists Act 1989* (NSW).

[36] *Day Procedure Centre Regulations 1996* NSW and the *Private Hospitals Regulations 1996* NSW. The other treatments are treatment that involves dialysis, or prolonged intravenous infusion of a single cytotoxic agent or treatment involving cardiac catheterisation. The *Day Procedure Centre Regulation*s are discussed in detail in section 4.6.

[37] *Day Procedure Centre Regulations 1996* NSW and the *Private Hospitals Regulations 1996* NSW.

[38] *Skin Penetration Guidelines*, NSW Health, 1999, made under Public Health Regulation 1991, clause 12(2)(c).

[39] Public Health Regulation 1991 clause 11, and *Skin Penetration Guidelines* 1999, clauses 1.2 and 1.4.

[40] Submission from UMP, no. 64, at p. 11.

[41] Submissions from Cosmetic Physicians Society, no. 38, and the Australian Association of Cosmetic Surgery, no. 60 said that indemnity is a requirement of membership. Members of the Australian Society of Plastic Surgeons would be required to hold professional indemnity insurance as part of being credentialled to provide surgical procedures in hospitals or licenced day procedure centres.

[42] *Rogers v Whitaker* (1992) 175 CLR 479; *Breen v Williams* (1996) 138 ALR 259.

[43] King CJ in *F v R* (1983) 33 SASR 189; cited with approval in *Rogers v Whitaker* (1992) 175 CLR 479, at 490.

[44] *Chappel v Hart* (1998) ALJR 1344.

[45] Submissions from Jason Downing, Ebworths solicitors, no. 87 at pp. 11-12; William Madden, for Australian Plaintiff Lawyers Association, no. 85 at pp. 4-7.

[46] *Breen v Williams* (1996) 138 ALR 259, per Gummow J. Also see Dawson and Toohey JJ, with whom the other judges concurred on the issue of fiduciary duty.

[47] Submission from the ACCC, no. 98, at p. 20.

[48] Letter from Terry Slater, National Manager, TGA, 3 September 1999.

[49] See *Review of the published literature*, and discussion in section 4.1.

[50] Submissions from UMP, no. 64, and Health Care Complaints Commission, no. 91.

[51] Submission from UMP, no. 64, at pp. 3-6.

[52] Submission from UMP, no. 64, p. 6.

[53] Submission from HCCC, no. 91.

[54] Supplementary data provided by HCCC, July 1999.

[55] Submissions from Health Services Commissioner (Vic), no. 74, Health Rights Commissioner (Qld), no. 26, and the Office of Health Review, no. 63.

[56] Submission from Health Services Commissioner (Vic), no. 74.

[57] Submissions from Body Image and Health Inc., no. 12, Breast Implant Resource Service, no. 62, Public Interest Advocacy Centre, no. 68, Women's Information National Network and Emergency Relief, (WINNER), no. 52, Roberta Honnigman, no. 83, Merilyn Evans, Southern Health Care Network, no. 78, Professor Mienczakowski, no. 32, and Anne Ring, InterAlia Research, no. 61.

[58] Other submissions raised complaints about 'tummy tucks' (four), facelifts (two), brow lifts (two), liposuction (two) and hair transplants (two).

[59] *Review of the published literature*, at pp. 8-10, 16-17, 22, 28, 31, 33, 39, 44, 46, 49, 50. The results are discussed in more detail in section 5.5.

[60] *Review of the published literature*, at pp. 39-40; citing Beale et al (1995), Fiala (1993) and Handel (1995).

[61] *Consumer Survey*, p. 16.

[62] *Consumer Survey*, p. 17.

[63] *Breast Implant Satisfaction survey*, Roy Morgan research, prepared for Cosmetic and Laser Surgery, 1998, in submission from Dr Daniel Fleming, no. 29.

[64] *An investigation into the emotional experience of cosmetic and laser surgery*, Griffith University, Gold Coast campus, in the submission from Professor Mienczakowski, no. 32.

[65] *Review of the published literature*, conclusions.

[66] Public hearings of the Committee on 18 and 19 March, questions to professional associations and medical colleges.

[67] *Private Hospitals and Day Procedure Centres Act (NSW)*

[68] M Walton, *Trouble with Medicine*, Allen and Unwin, 1998 at p. 139; Walton also cites the *Report of the Working Party on Minimal Access Surgery*, the Australian Health Technology Advisory Committee, consultation draft, Canberra, September 1996, p. 6; it said the current credentialling process for doctors is flawed because of the lack of structure and transparency.

[69] Submissions from Dr Darryl Hodgkinson, no. 50, and Dr Daniel Fleming, no. 29 and information presented at public hearings on 9 and 12 April 1999 .

[70] *Guidelines for the delineation of clinical privileges of medical staff*, circular 95/24, NSW Health.

[71] J Hoeyberghs, 'Cosmetic surgery', BMJ 318: 512.

[72] *Private Hospitals and Day Procedure Centres Act* (NSW) section 3(1) and 13 and *Day Procedure Centre Regulation 1996 (*NSW).

[73] *Day Procedure Centre Regulation 1996* (NSW), section 8.

[74] Submission from the Australia and New Zealand College of Anaesthetists, no 53.

[75] The draft Guidelines have been distributed for comment to a number of organisations, including the Royal Australasian College of Surgeons, the ASPS, the Australia and New Zealand College of Anaesthetists; a copy of the draft guideline was provided as an appendix to the submission from Australia and New Zealand College of Anaesthetists, no. 53.

[76] Dr Howard Roby, specialist anaesthetist, public hearings 18 March 1999, submission no. 46.

[77] R Rao, M S Ely et al, *Deaths related to liposuction* NEJM 340/19: 1471.

[78] For example, Dr Roby, public hearings 19 March, Dr Hodgkinson and Dr Olbourne, and AMA, 8 April 1999, and Cosmetic Physicians Society, Dr Bruce Fox, 9 April.

[79] Dr Roby, public hearings, 19 March 1999.

[80] Evidence from Dr James Walter at public hearings on 18 March 1999, for the Australasian College of Dermatologists.

[81] Dr Hodgkinson, Dr Olbourne, public hearings 8 April 1999.

[82] Public hearings of the Committee, information presented by Dr Howard Roby, 18 March 1999, the Australia and New Zealand College of Anaesthetists, 19 March 1999, and Dr Olbourne 8 April 1999.

[83] Public hearings of the Committee, information presented by Dr Howard Roby, 18 March 1999, and Dr Havas, Australian Society of Otolaryngology, 19 March 1999.

[84] Dr Williams for the ASPS, public hearings of the Committee 18 March 1999. Similar comments were made by Dr Howard Roby on the same day.

[85] Australian Standard 4173: 1994 submissions on *Use lasers* from Dr Noel Cleeve and the Australasian College of Dermatologists.

[86] Evidence provided to the Senate committee hearing submissions on the cosmetic surgery amendments by the Californian Medical Board, Sacramento, 19 April 1999.

[87] Oregon Medical Society, *Standards for Accreditation of Office based facilities for procedures requiring conscious sedation*; New York, *Clinical Guidelines for Office based surgery;* Texas Medical Board, draft rules for administering anaesthesia in an office based setting; American College of Surgeons first published *Guidelines for Optimal office based surgery*, second edition, 1998.

[88] Florida Board of Medicine, proposed rule 64B8-9.009, April 1999.

[89] California Senate Bill 595, 1999.

[90] For example, submissions from the Australian Society of Plastic Surgeons, no.65, the Royal Australasian College of Surgeons, no. 65; Australia and New Zealand College of Anaesthetists, no. 53; the Royal Australian College of Ophthalmologists, no. 55, and many individual plastic surgeons.

[91] Submission from Dr Olbourne, no. 96.

[92] *Guide to Surgical Training*, Royal Australasian College of Surgeons, 1996.

[93] *Review of the published literature*, chapter 3; submission on *Use of lasers* from Cosmetic Physicians Society.

[94] Submission on *Use of lasers* from Dr Bruce McGeorge and Dr Daniel Fleming.

[95] Submissions on *Use of lasers* from Dr Noel Cleeve, Dr James Walter, the Australian College of Cosmetic Surgery.

[96] For example, submission on *Use of lasers* from UMP; and Australian College of Cosmetic Surgery.

[97] Submission on *Use of lasers* from Australian Nurses Acupuncture Association.

[98] *Radiation Safety Act 1975* (WA), sections 25 and 28 and *Radiation Safety Regulations* 1983, clause 6.

[99] *Radiation Safety Act 1999* (Qld), to commence in January 2000.

[100] Regulations under professional registration acts and the *Private Hospitals and Day Procedure Centres Act* govern infection control for registered health professionals. The *Skin Penetration Guidelines* under the *Public Health Act* govern unregistered professionals such as beauty therapists.

[101] Section 105 *Medical Practice Act* (NSW).

[102] Letter from Andrew Dix, Registrar, NSW Medical Board, 3 September 1999.

[103] For example, *Edelsten and the Medical Practitioners Act*, NSW Medical Tribunal, 29 November 1988.

[104] Letter from Terry Slater, National Manager, Therapeutic Goods Administration, 3 September 1999.

[105] AS4173:1994, clause 7.5.

[106] For example, the American Board of Laser Surgery has an examination for which suitably experienced Australians can sit.

[107] Submission on *Use of lasers* from CPS and ACCS.

[108] Submissions on *Use of lasers* from ACCS; the Australasian College of Dermatologists comment was endorsed in submissions on *Use of lasers* from Office of Health Review (WA), EPA (NSW) and Dr Fleming.

[109] Submissions on *Use of lasers* from Dr Cynthia Weinstein, and Dr James Walter.

[110] Submissions on *Use of lasers* from Australasian College of Dermatologists, Hanimex Medical Imaging.

[111] *Review of the published literature*, p 17; submission on *Use of lasers* from ASPS; Dr Bruce McGeorge and Dr Weinstein.

[112] Submissions on *Use of lasers* from Cosmetic Physicians Society, Dr Cynthia Weinstein, and Dr Paul Varcoe.

[113] Submission on *Use of lasers* from Cosmetic Physicians Society.

[114] Australian Standard 4173; submissions on *Use lasers* from Dr Noel Cleeve and the Australasian College of Dermatologists.

[115] Submission on *Use of lasers* from the Hairdressers and Beauty Therapists Association.

[116] Submissions on *Use of lasers* from the NSW Environment Protection Authority, some laser distributors, UMP, the Australasian College of Dermatologists.

[117] Submissions on *Use of lasers* from the Cosmetic Physicians Society, ASPS, the Royal Australian College of Ophthalmologists and Dr Bruce McGeorge.

[118] Submissions on *Use of lasers* from EPA (NSW) and Australasian College of Dermatologists.

[119] Submission on *Use of lasers* from the EPA (NSW).

[120] Submission on *Use of lasers* from the EPA (NSW).

[121] Telephone contact with Radiation Health, Queensland Health, 23 August 1999.

[122] *Review of the published literature*, already cited p. 34 and Medicare figures cited in section 2.

[123] Figures provided by Health Insurance Commission 9 August 1999 for item nos. 45548-45554.

[124] See section 3.3.

[125] *Review of the published literature*, p. 39

[126] Public Interest Advocacy Centre, Body Image and Health Inc; Merilyn Evans, Southern Health Care Network; Roberta Honnigan.

[127] *Review of the published literature*, p. 34.

[128] (Brody 1997); *Review of the published literature* , at p. 35.

[129] *Selected Readings in Plastic Surgery, Augmentation mammoplasty*, JA Salomon and F Barton, vol. 8, no. 28, p. 12-13.

[130] *Selected Readings in Plastic Surgery, Augmentation mammoplasty*, JA Salomon and F Barton, vol. 8, no. 28, p. 10.

[131] *Review of the published literature*, p. 40.

[132] Letter from Terry Slater, National Manager, TGA, 3 Septmeber 1999.

[133] Telephone contact with Professor Hughes, 23 August 1999.

[134] Public Interest Advocacy Centre, *Common Interests*, 1993, submission no. 68; and Health Services Commission, no. 74, citing Gallois, L, (1994), *Women and plastic surgery: breast implants, women's motives and public policy*, unpublished, University of Melbourne.

[135] *Review of the published literature*, at p. 6.

[136] *Review of the published literature,* pp. 9-10.

[137] R Rao, M S Ely et al, *Deaths related to liposuction* NEJM 340/19: 1471.

[138] Dr James Walter, The Australasian College of Dermatologists, public hearings 18 March 1999.

[139] The results of the *Consumer Survey* and its methodology are discussed in more detail in section 2.

[140] *Review of the published literature*, already cited, p. 3.

[141] *Review of the published literature*, at pp. 8-10, 16-17, 22, 28, 31, 33, 39, 44, 46, 48.

[142] *Review of the published literature*, at pp. 8 - 10, and 39.

[143] D Sawer, T Wadden, M Pertschuk, L Whitaker, *The psychology of cosmetic surgery: a review and reconceptualisation*, Clinical Psychology Review, (1998) 18/1: 1-22, at p. 18.

[144] *Consumer Survey* at p. 12.

[145] *An investigation into the emotional experience of cosmetic and laser surgery*, a research project based on clients and staff interviews conducted through the Cosmetic and Laser Surgery Institute of Australia, Professor Mienczakowski, Griffith University, Gold Coast Campus, 1999, at p. 51.

[146] King CJ in *F v R* (1983) 33 SASR 189; cited with approval in *Rogers v Whitaker* (1992) 175 CLR 479, at 490. Also see discussion in section 3.

[147] *Chappel v Hart,* (1998) ALJR 1344.

[148] *Tekanawa v Millican*, District Court of Queensland (Brisbane), Morley DCJ, 6 September 1994, no. 810/90, unreported, cited in submission from Jason Downing, Ebworths solicitors, no. 87 at pp. 7-8, 11, 13-14; also discussed in submission from William Madden, for Australian Plaintiff Lawyers Association, no. 85 at pp. 4-7.

[149] For example, Health Services Commissioner (Vic), no. 74, United Medical Protection, no. 64, Australian Plaintiff Lawyers Association, no. 85 and Jason Downing, Ebworths solicitors, no. 87.

[150] Submission from the NSW Department of Fair Trading, no. 92.

[151] Submission from Australian Competition and Consumer Commission, no. 98.

[152] This message was confirmed at the public hearings on 18 and 19 March with the Australasian College of Dermatologists, the Australian College of Ophthalmologists, Australian Society of Plastic Surgeons, Australian Society of Cosmetic Surgery, and others.

[153] Submission from Jason Downing, no. 87, pp. 13-14.

[154] For example, submissions from Australian Plaintiff Lawyers Association, no. 85 and Breast Implant Resource Service, no. 62.

[155] Terms of reference, Joint Committee on Health Care Complaints Commission, *Notification of medical negligence actions to the Commission*, 1999.

[156] Submissions from UMP submission, no. 64, Jason Downing, no. 87, Australian Plaintiff Lawyers Association, no. 85, and Cancer Council, *Effective Communications Skills for Health Professionals: an overview*, 1997.

[157] Submission from UMP, no. 64; discussion in section 6.1.

[158] Submission from Jason Downing, no 87, at p. 15-17.

[159] Prof. Mienczakowski, cited above, supplement to submission no. 32.

[160] For example, submission from Jason Downing, no. 87, p. 16.

[161] Professor Mienczakowski, cited above, at pp. 42-43, 49-51.

[162] For example, submissions from Dr Olbourne, no. 96, and Jason Downing, no. 87.

[163] Submission from the ASPS, no. 65 at pp. 5-6, 11; submission on *Use of lasers* from Cosmetic Physicians Society and submission from Australian Association of Cosmetic Surgery, no 60.

[164] Professor Mienczakowski, cited previously, pp. 51-52.

[165] Submission from Roberta Honnigman, no 83.

[166] www.ftc.gov/bcp/menu-health.htm, July 1999.

[167] The primary obligations are in the *Medical Practice Act* and the *Private Hospitals and Day Procedure Centres Act.* A detailed discussion of these issues is in section 7.2. [168] Submission from ACCC, no. 98, at p. 20; *Legal Profession Act 1987* (NSW), section 184.[169] Submission from Roberta Honnigman, no. 83.

[170] *Consumer Survey* at p. 19.

[171] Mienczakowski, cited above, at pp. 31-34. The clinic that was reviewed, Cosmetic and Laser Surgery Institute, provides consumers with 24-hour access to medical help and advice, as well as written information.

[172] *Discussion paper: Use of lasers for cosmetic surgery*, June 1999, NSW Committee of Inquiry into Cosmetic Surgery (*Use of lasers*).

[173] Submissions on *Use of lasers* from Dr Bruce McGeorge, dermatologist and Dr Paul Varcoe.

[174] Submissions on *Use of lasers* from Dr Daniel Fleming, Dr David Jenkins and Medical Imaging.

[175] Review of the published literature, at pp. 10, 19, and 52.

[176] Submissions on *Use of lasers* from the Australian Society of Plastic Surgeons, Cosmetic Physicians Society, Australasian College of Dermatologists, Australian College of Cosmetic Surgery.

[177] Submissions on *Use of lasers* from the Australian Society of Plastic Surgeons, Australasian College of Dermatologists, and Dr Paul Varcoe.

[178] Submission on *Use of lasers* from the Hairdressers and Beauty Therapists Association.

[179] Discussed in section 5.3. Tele-conference between BIRS representatives and Committee Chairperson, Commissioner Walton, 15 July 1999.

[180] D Sawer, T Wadden, M Pertschuk, L Whitaker, *The psychology of cosmetic surgery: a review and reconceptualisation*, Clinical Psychology Review, (1998) 18/1: 1-22.[181] Sawer et al, cited above, at pp. 3-8. [182] Sawer et al, cited above, at pp. 4- 8. The most commonly used measure has been the Minnesota Multiphasic Personality Inventory.[183] Sawer, cited above, p 9.[184] M Rankin et al, *Review of quality of life outcomes after cosmetic surgery,* Plastic and reconstructive Surgery, November 1998: 2139.[185] M Rankin et al, *Review of quality of life outcomes after cosmetic surgery,* Plastic and reconstructive Surgery, November 1998, at 2141.[186] Sawer et al, cited above, p. 10.[187] *Review of the published literature*, pp. 41-52.[188] Sawer et al, p. 15.[189] For example, Dr Hodgkinson requires prospective patients to complete three questionnaires – a life satisfaction index (LSI), self-esteem inventory (SEI) and body image inventory (BII).

[190] Prof Mienczakowski study, cited previously, and submission from Roberta Honnigman, no. 83.[191] *Consumer Survey*, p. 12. A quarter of respondents to the survey said they first heard about the procedure in a story in the media and 13% heard about it in an advertisement. Another quarter said that they had heard about it from a friend or relative. See section 6 for more details.[192] Submission from ACSM, no. 69, and public hearings of the Committee 12 March 1999.[193] Submission from Anne Ring, InterAlia Research, no. 61.[194] Submission from Body Image and Health Inc., no. 12, and public hearings on 12 March 1999.[195] Public hearings, 8 April, Dr Cholm Williams for the Australian Society of Plastic Surgeons, and submission no. 65.[196] Section 51AB TPA and section 43 FTA. Also see submissions from the ACCC, no. 98, and the NSW Department of Fair Trading, no. 92.

[197] Section 52 TPA and section 442 FTA.

[198] *ACCC v On Clinic Australia, Men Only Clinic and Potent-C-Clinics* (1996) ATPR 41-517; *Tobacco Institute of Australia v AFCO* (1992) 38 FCR 1; ACCC submission.

[199] *Telstra Corporation v Optus Communications* (1997) ATPR 41-541; ACCC submission , no.98.

[200] Sections 51A, 53, 55A TPA and sections 41, 44, 47, and 49 FTA; submissions from the ACCC and the NSW Department of Fair Trading.

[201] Section 74 TPA.

[202] Section 9, *Medical Practice Regulation 1998 NSW*, and section 114 which makes it an offence to advertise other than in accordance with the regulations.

[203] Section 64, *Medical Practice Act* (Vic): *Review of the Nurses Act 1993 (Vic) and Medical Practice Act 1994 (Vic) Discussion paper*, October 1998. In other Australian states and territories advertising by medical practitioners is regulated by guidelines, statements of policy or by-laws by medical boards.

[204] Section 105 *Medical Practice Act 1992* NSW, *Nurses Act 1991* (part 4, div. 6) and the *Dentists Act 1989* (section 56).

[205] The *Medical Act 1938* (Qld).

[206] *Therapeutic Goods Act and Regulations* (Clth); Therapeutic Goods Advertising Code, February 1999.

[207] Australian Society of Plastic Surgeons, Guidelines for Professional Conduct 1996

[208] Submission from the ACCC, no. 98, pp. 22-23.

[209] TPA sections 51AD and 51AE.

[210] Sections 74 and 76, *Fair Trading Act 1987*; Department of Fair Trading, no. 92.

[211] Amendment to the *Business and Professions Code* introduced in the California legislature in April 1999.

[212] Legal advice to the California Medical Board, November 1998, submission from the California Medical Board. State Medical Boards in the USA have limited powers to adopt regulations which provide guidance to the law for licensees, to clearly prohibit certain practices and to clarify existing laws.

[213] *Re Dr J H Bannister,* NSW Medical Tribunal, unreported, 28 April 1992.

[214] *Final Report of the Review of the Medical Practice Act,* NSW Health, Dec 1998, rec. 10, (p. 41-42). The amendment was supported by the Medical Board and would be consistent with the Australian Medical Association Code of Ethics.

[215] *Submission of the HCCC to the review of the Medical Practice Act 1992*, October 1998, p. 10.

[216] *Breen v Williams*, cited previously.

[217] The obligation to make disclosures applies to day procedure centres, private hospitals and nursing homes: *Private Hospitals and Day Procedure Centres Act 1988*, section 46, *Nursing Homes Act 1988*, section 43 and *Private Hospitals Regulations 1996*, *Nursing Homes Regulation 1996* and *Day Procedure Centres Regulations 1996,* sections 16 and 17.

[218] A breach of the obligation is an offence that may result in a fine, and a conviction is recognised as 'unsatisfactory professional conduct' under section 36 of the *Medical Practice Act*. The final report of the *Review of the Medical Practice Act 1992 (NSW), Dec 1998* recommended that this be extended to cases where a finding of guilt is made but no conviction is recorded (recommendation 10).

[219] *Demagogue v Ramensky* (1992) 32 FCR 31.

[220] Pamela Noon, Clinical Beauty, public hearings of the Committee 19 March 1999.

[221] 'Row over plastic surgery', Fiona Connolly, *The Sunday Telegraph*, 1 August 1999.

[222] *Lotteries and Art Unions Act* (NSW), section 4B.

APPENDIX 1

Members of Committees for the Inquiry into Cosmetic Surgery

Ministerial Committee

Chairperson: Commissioner Merrilyn Walton, Health Care Complaints Commission, and Adjunct Assoc. Professor

- Mr Richard Barnett, President, Australian Society of Plastic Surgeons, NSW
- Professor John Horvath, President, NSW Medical Board
- Dr Martyn Mendelsohn, Australian Medical Association
- Mr Colin Moore, Australian Association of Cosmetic Surgery
- Mr Kel Nash, Department of Fair Trading
- Professor Thomas Reeve, General Surgeon
- Ms Susan Sharpe, Australian Consumers Association
- Dr Simon Willcock, Royal Australian College of General Practitioners
- Dr Andrew Wilson, Chief Health Officer, NSW Health Department
- Dr Ross Wilson, Director, Quality Assurance Royal North Shore Hospital

Consumer Issues subcommittee

Commissioner and Adjunct Assoc. Professor Merrilyn Walton (chairperson)
Dr Simon Willcock
Ms Susan Sharpe
Mr Kel Nash
Professor Thomas Reeve
Dr Rosemary Cant, School of Behavioral & Community Health Sciences University of Sydney
Ms Christine Tiley, Breast Implant Resource Service (North Coast)
Mr David Hearsh, Cashman and Partners
Ms Karen Legge, Consumer Advocate, Illawarra Area Health Service

Clinical and training Issues subcommittees

Dr Ross Wilson (chairperson)
Commissioner and Adjunct Assoc. Professor Merrilyn Walton
Mr Richard Barnett
Dr Colin Moore
Dr Simon Willcock
Ms Susan Sharpe
Professor John Horvarth
Dr Ross Benger, Royal Australian College of Ophthalmologists
Dr James Walter, Australasian College of Dermatologists
Dr Thomas Havas, Australian Society of Otolaryngology
Ms Audrey Lee, United Medical Protection
Dr Robert Hodge, Australian Medical Association

Commercial and regulatory Issues subcommittee

Professor Thomas Reeve (chairperson)
Commissioner and Adjunct Assoc. Professor Merrilyn Walton
Mr Kel Nash
Professor John Horvath
Ms Julie Hamblin, Ebsworth & Ebsworth
Mr Michael Jacobs, Australian Competition & Consumer Commission
Mr Terry Downing, Manager Policy Division, NSW Department of Fair Trading
Dr Craig Lillienthal, Australian Medical Association

APPENDIX 2

Submissions to the Inquiry into Cosmetic Surgery

1 Mrs A
2 Breast Implant Resource Service, Taree, Ms B
3 Ms Christine Tiley, Breast Implant Resource Service
4 Ms D
5 Mrs E
6 Mr F
7 Mr G
8 Mrs H
9 Dr Trevor J Harris, AM, Plastic & Reconstructive Surgeon
10 Ms I (Confidential)
11 Ms J
12 Body Image & Health Inc., Ms Thea O'Connor
13 Mr K (Confidential)
14 Ms L
15 Mr AC
16 Dr Peter Gregory Vickers, Consultant Oral & Maxillofacial Surgeon
17 Optometrists Association of Australia
18 Ms M
19 Royal Australasian College of Surgeons (Victoria)
20 Mr N
21 Ms Lorraine Williams, Breast Implant Resource Service
22 Ms Fran Bates, Breast Implant Resource Service
23 International Confederation for Plastic, Reconstructive & Aesthetic Surgery
24 Dr Diana Lange, Chief Health Officer, Queensland Health
25 Ms P (Confidential)
26 Health Rights Commission (Queensland), Commissioner, Mr Ian Staib
27 Breast Implant Resource Service, Ms Yasmin Plichta
28 Dr Barrie C Milroy, Surgeon
29 Dr Daniel Fleming, Cosmetic and Laser Surgery Institute of Australia
30 Clinical Beauty Pty Ltd, Ms Pamela Noon
31 Dr Christopher J Edwards, Plastic & Reconstructive Surgeon
32 Prof Jim Mienczakowski, Central Queensland University (Confidential & non-confidential submissions)
33 American Society of Plastic & Reconstructive Surgeons
34 Ms R
35 Ms S (Confidential)
36 Dr James Walter, Neutral Bay Laser & Dermatology Clinic
37 Ms T
38 Cosmetic Physicians' Society (NSW/ACT)
39 Ms U
40 Ms V
41 Dr David Widdup
42 Australasian Academy of Facial Plastic Surgery
43 Mrs W (Confidential)
44 Mrs X
45 Dr Donald R Marshall, Clinical Assoc Professor of Surgery
46 Dr Howard P Roby, Specialist in Anaesthesia & Intensive Care
47 Australian Society of Otolaryngology Head and Neck Surgery Ltd
48 Dr Simon Rosenbaum, Image Centre

49 Mr David David, Australian Cranio-Facial Unit, Women's and Children's Hospital & Associated with the Royal Adelaide Hospital
50 Dr Darryl Hodgkinson, Cosmetic and Restorative Surgery Clinic
51 Royal Australasian College of Surgeons (NSW)
52 Women's Information National Network and Emergency Relief
53 Australian and New Zealand College of Anaesthetists, NSW Regional Committee
54 Ms Katherine Hassler, Cosmetic and Restorative Surgery Clinic
55 Royal Australian College of Ophthalmologists
56 Australasian Board of Plastic & Reconstructive Surgery
57 Ms Y
58 Dr Bruce Fox, Plastic & Reconstructive Surgeon
59 Ms Sue Pickavance
60 Australian Association of Cosmetic Surgery
61 InterAlia Development and Research Enterprises Pty Ltd, Dr Anne Ring
62 Breast Implant Resource Service, Mr Kim Boyd
63 Office of Health Review, W.A., Mr David Kerslake, Director
64 United Medical Protection, Dr Richard Tjiong, Executive Chairman
65 Australian Society of Plastic Surgeons Inc (Confidential & non-confidential submissions)
66 Dr John V Newton, Plastic & Reconstructive Surgeon (Confidential)
67 Dr William J Pouw, Cosmetic/Plastic Surgeon
68 Public Interest Advocacy Centre
69 Australian Cosmetic Surgery Magazine
70 Ms Nicki Greenberg
71 Australasian College of Dermatologists
72 Mrs AA (Confidential)
73 Medical Board of California
74 Health Services Commissioner, Victoria (Confidential)
75 Ms AD
76 New Zealand Association of Plastic Reconstructive and Aesthetic Surgeons
77 Australasian Society of Aesthetic Plastic Surgery
78 Ms Merilyn Evans, Southern Health Care Network
79 New Zealand Foundation for Cosmetic Plastic Surgery
80 Dr Mark Donohoe
81 Ms Judith Feldman
82 Collagen Aesthetics Australia Pty Ltd
83 Ms Roberta Honigman, Social Worker
84 Ms AE (Confidential)
85 Australian Plaintiff Lawyers Association, Mr William Madden, Blessington Judd
86 Ms AF (Confidential)
87 Mr Jason Downing, Ebsworth & Ebsworth, solicitors
88 Ms Marianne Nicolle, Ebsworth & Ebsworth, solicitors
89 Australian Medical Association (NSW) Ltd
90 Royal Australian College of General Practitioners
91 Health Care Complaints Commission (NSW)
92 Department of Fair Trading (NSW)
93 Ms AG
94 Ms AH (Confidential)
95 Mr George Mayson, Sydney Cosmetic Clinic
96 Dr Norman Olbourne
97 Dr Anoop Rastogi
98 Australian Competition and Consumer Commission

APPENDIX 3

Presenters at Public Hearings

Thursday March 18, 1999 – Health Care Complaints Commission

Dr Howard Studniberg & Dr Jim Walter, Australasian College of Dermatologists
Dr Cholm Williams, Australian Society of Plastic Surgeons
Dr Maura McGill, Australian Association of Cosmetic Surgery
Mr David Storey, Royal Australasian College of Surgeons (NSW)
Dr George Lewkovitz, Australasian Academy of Facial Plastic Surgery

Friday, 19 March, 1999 – Health Care Complaints Commission

Dr Thomas Havas, Australian Society of Otolaryngology
Dr Howard Roby, specialist in Anaesthesia & Intensive Care
Ms Pamela Noon, Clinical Beauty Pty Ltd
Dr Ross Benger, Royal Australian College of Ophthalmologists

Thursday, 8 April, 1999 – NSW Parliament House

Dr D Hodgkinson,The Cosmetic and Restorative Surgery Clinic
Mr Bill Madden, Australian Plaintiff Lawyers' Association
Ms Nicki Greenberg, Slater & Gordon, solicitors
Mr Jason Downing & Ms Marianne Nicolle, Ebsworth & Ebsworth, solicitors
Dr Richard Tjiong & Ms Megan Keaney, United Medical Protection

Dr Norm Olbourne, plastic surgeon
Ms Jenny Wallace, Collagen Aesthetics Australia Pty Ltd
Assoc Professor Peter Thursby & Dr Craig Lillienthal, Australian Medical Association (NSW) Ltd
Dr Peter Gibson, Royal Australian College of General Practitioners

Friday 9th April – NSW Parliament House

Ms Monika Bhatia, Women's Information National Network and Emergency Relief
Ms Frances Bates, Breast Implant Resource Service
Mr Kim Boyd, Breast Implant Resource Service
Ms Lorraine Williams, Breast Implant Resource Service
Ms Sue Pickavance, Breast Implant Resource Service
Ms Julie Kinross & Mr Tom Galloway, Health Care Complaints Commission (NSW)
Ms Beth Wilson, Health Services Commission, Victoria
Ms J (anonymous)

Ms Sharron Phillipson, Cosmetic Physicians Society (NSW/ACT)
Dr Matthew Crawford, Australian and New Zealand College of Anaesthetists
Dr Barrie Milroy, on his own behalf and on behalf of International Confederation for Plastic, Reconstructive & Aesthetic Surgery
Dr Bruce Fox, cosmetic laser surgeon

Monday, 12th April, 1999 – NSW Parliament House

Dr Anne Ring, InterAlia Development and Research Enterprises Pty Ltd
Ms Thea O'Connor, Body Image & Health Inc
Ms Michelle Kearney, Australian Cosmetic Surgery Magazine
Mr David Catt, Department of Fair Trading (NSW)
Mr Sitesh Bhojani, Australian Competition & Consumer Commission
Dr David David, Australian Cranio-Facial Unit, Women's and Children's Hospital, Royal Adelaide Hospital

Dr Simon Rosenbaum, Image Centre
Dr Donald R Marshall, Clinical Assoc Prof of Surgery, Clinical and Laser Surgery Institute
Dr Daniel Fleming, Cosmetic and Laser Surgery Institute of Australia
Prof Jim Mienczakowski, Faculty of Education & Creative Arts, Central Queensland University

APPENDIX 4

Submissions to the discussion paper -

Use of lasers for cosmetic procedures

1. Australasian College of Dermatologists, Dr Stephen Lee
2. Australian Nurses Acupuncture Association, Ms Yuri Sawenko
3. Australian College of Cosmetic Surgery, Dr Colin Moore
4. Australian Medical Association (NSW), Dr Craig Lillienthal
5. Australian Society of Plastic Surgeons Inc, Dr Cholm Williams
6. Cleeve, Dr Noel, dermatologist
7. Coherent Surgical, Mr Paul Wardill
8. Cosmetic Physicians' Society of Australia , Dr Sharron Phillipson
9. Environment Protection Authority, NSW, Mr Howard Ackland
10. Equipmed Pty Ltd, Mr Brian Marshall
11. Fleming, Dr Daniel, Cosmetic and Laser Surgery Institute of Australia
12. Hairdressing & Beauty Industry Association, Ms Sandra Campitelli
13. Hanimex Medical Imaging, Mr Andrew Roach
14. Jenkins, Dr David, Southern Vein & Laser Clinic
15. McGeorge, Dr Bruce, dermatologist
16. NSW College of Nursing, Professor Judy Lumby
17. NSW Department of Health, Dr Andrew Wilson
18. NSW Medical Board, Mr Andrew Dix
19. Office of Health Review (WA), Mr David Kerslake
20. Royal Australian College of Ophthalmologists, NSW Branch, Dr Anthony King
21. Royal Australian College of General Practitioners
22. Therapeutic Goods Administration, Ms Shelley Tang
23. United Medical Protection, Dr Richard Tjiong
24. Varcoe, Dr Paul, The Vein & Laser Clinic
25. Walter, Dr James, Neutral Bay Laser & Dermatology Clinic
26. Weinstein, Dr Cynthia, Medical Cosmetic Laser Centre Pty Ltd

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Toolkit for the management of breast implants

March 2022

Surgical Services Taskforce

NSW GOVERNMENT

AGENCY FOR CLINICAL INNOVATION

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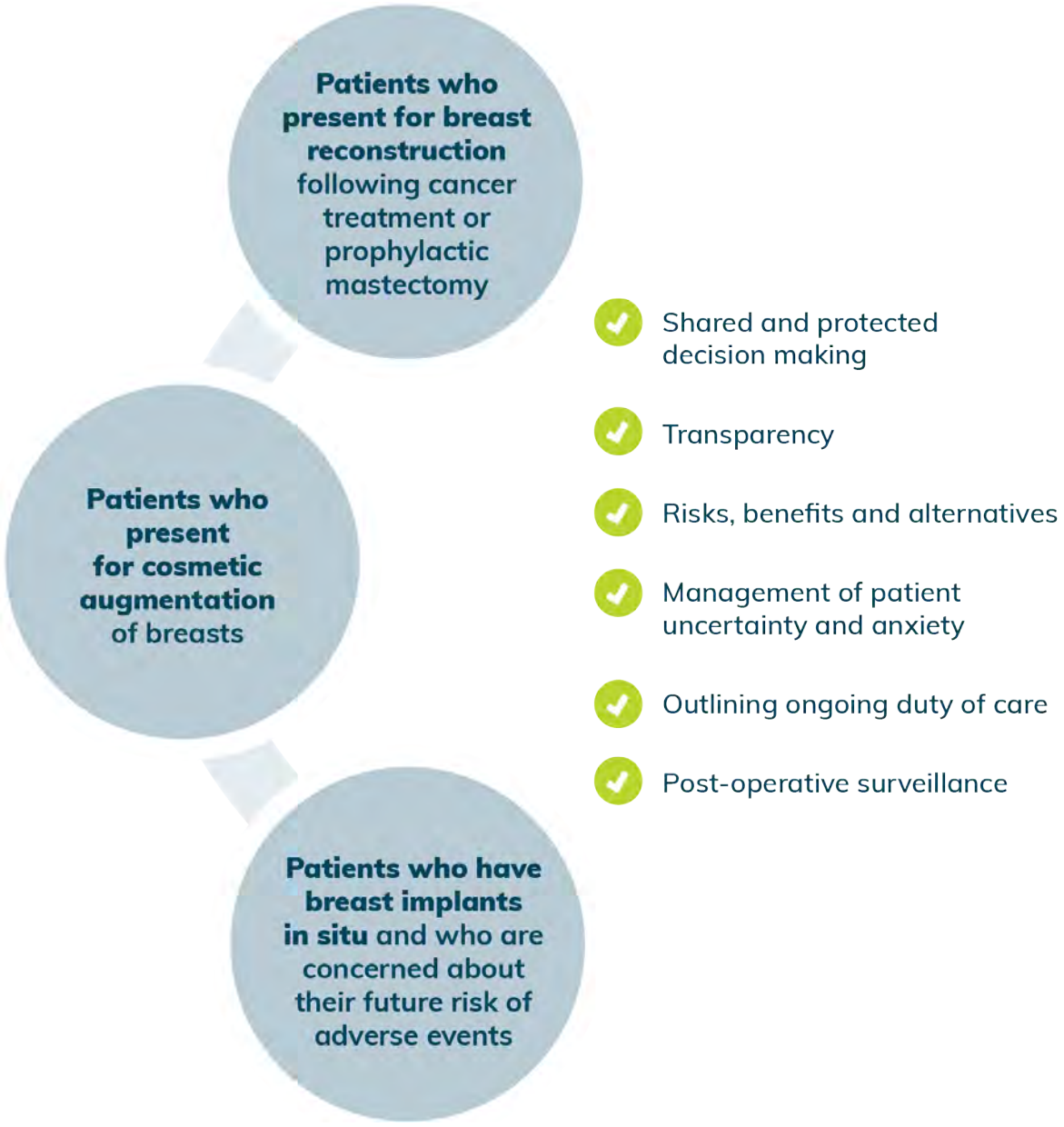
Contents

Management of breast implants at a glance

This toolkit has been developed to inform surgeons who insert breast implants of best practice when caring for patients with breast implants or considering implants. It was developed in response to a safety alert regarding anaplastic large cell lymphoma.[1]



Acknowledgement of contributors

The Surgical Services Taskforce acknowledges the efforts of the following subject matter experts in developing this toolkit:

- Professor Mark Ashton, University of Melbourne
- Dr. Nalini Bhola, Statewide Clinical Director, BreastScreen NSW
- Professor Anand Deva, Macquarie University
- Associate Professor James French, Westmead Breast Cancer Institute, University of Sydney
- Associate Professor Bruno Giuffre, Radiology, Royal North Shore Hospital, University of Sydney
- Associate Professor Mark Magnusson, Griffith University
- Associate Professor Sanjay Warrier, University of Sydney, Royal Prince Alfred Academic Institute

Collaboration with regulatory bodies

Professors Deva, Ashton and Associate Professors Magnusson and Warrier were nominated to be on the breast implant expert working group for the Therapeutic Goods Administration (TGA). The proposal for a breast implant toolkit was first presented to the TGA expert panel meeting and progressed to the TGA consumer forum in October 2019. The Australian Commission on Safety and Quality in Health Care were also consulted as part of the engagement process. The toolkit was then adopted by the Agency for Clinical Innovation (ACI) and presented to the expert panel working on breast implants convened by the Office of the Chief Health Officer, NSW Health. The toolkit was further refined with input from the Surgical Services Taskforce.

Introduction

The TGA issued a safety alert in 2020 regarding an association between breast implants and anaplastic large cell lymphoma.[1] Global regulatory action has taken place to address the safety of breast implants. Guidance is needed about best practice for the clinical use of these devices, both for reconstruction following mastectomy and for cosmetic augmentation.

This toolkit was developed by drawing from clinician groups who are directly involved in the surgical deployment of breast implants and associated devices.

Input was also sought from other related clinical groups including pathology, radiology, consumer advocates, patients who have experienced adverse events related to breast implants and government authorities involved in the administration and regulation of these devices.

This toolkit considers three specific clinical scenarios:

1. Patients who present for breast reconstruction following cancer treatment or prophylactic mastectomy.
2. Patients who present for cosmetic augmentation of breasts.
3. Patients who have breast implants in situ and who are concerned about their future risk of adverse events.

The founding principles that shape these guidelines are:

- Empowerment of patients and encouragement of shared and protected decision making with, where possible, multiple time points for discussion
- Transparency in potential personal and commercial conflicts of interest
- Education of patients on risks, benefits and alternatives of breast reconstruction procedures
- Management of patient uncertainty and anxiety
- Providing options and choice for a variety of treatments
- Outlining ongoing duty of care and post-operative surveillance

NSW Health has published the Consent to Medical and Healthcare Treatment Manual on informed consent procedures relating to healthcare treatment.[2] This is a supporting document for this toolkit.

Where possible, patients should be encouraged to attend consultations with a support person or persons, to ensure that there are multiple opportunities to process information and to provide advocacy and support.

It is also important that any complications or adverse events associated with breast implant procedures are recorded and reported appropriately. This includes compliance with Policy Directive PD2020_047: Incident Management, the Therapeutic Goods Administration online module for adverse event reporting and local hospital or facility policies.[3, 4]

Method

A team of healthcare professionals, technical experts and lay representatives were consulted and undertook the drafting of the clinical scenarios and supported best practice as determined by clinical consensus.

Where required, opinions were sought from relevant specialists (e.g. radiology, regulatory scientists) in relation to these devices. This group was supported by the ACI and the Surgical Services Taskforce, who assisted to harmonise the guidelines with existing NSW Health directives and structure the toolkit in line with other ACI initiatives. The use of prophylactic antibiotics in breast implant surgery was further investigated by performing a literature search. Finally, input was sought from health consumers to ensure that their concerns were addressed and that the language and recommendations were aligned to an appropriate level of health literacy.

Evidence informed	Based on literature search. Literature search of MEDLINE for the terms breast implant, antibiotics, prophylaxis were performed in October 2019, October 2020 and March 2022.
Collaboration	Surgical Services Taskforce Office of the Chief Health Officer Professor Mark Ashton, University of Melbourne Dr. Nalini Bhola, Statewide Clinical Director, BreastScreen NSW Professor Anand Deva, Macquarie University Associate Professor James French, Westmead Breast Cancer Institute, University of Sydney Associate Professor Bruno Giuffre, Radiology, Royal North Shore Hospital, University of Sydney

	Associate Professor Mark Magnusson, Griffith University Associate Professor Sanjay Warrier, University of Sydney, Royal Price Alfred Academic Institute
Currency	Review in 5 years

Implant-based breast reconstruction

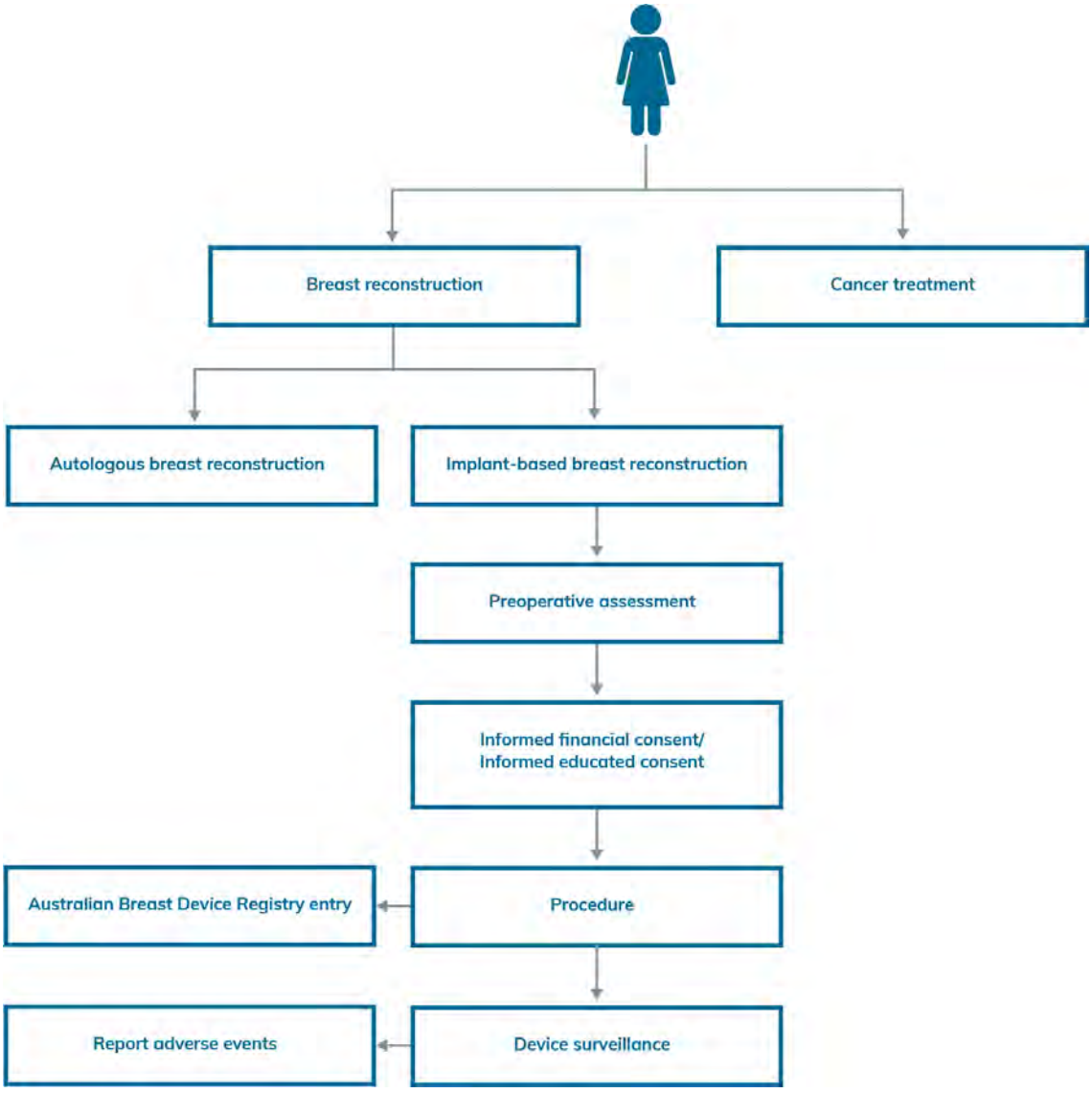
Breast implants, and associated devices such as supporting mesh and dermal matrices, may be indicated for reconstruction of all or part of a breast following mastectomy.

In some cases, there is a period of tissue expansion, usually between six weeks and six months, where soft tissue is prepared prior to the deployment of a permanent implant device. The more immediate priority for such patients is the clinicopathological staging and treatment of the cancer prior to reconstruction planning.

Discussion around options for reconstruction may be constrained by time as well as the impact of the cancer diagnosis.

Figure 1 outlines steps that are recommended for pre, intra and post-operative management of implant-based breast reconstruction.

Figure 1: Steps for implant-based breast reconstruction



Preoperative work up

1. Outline all options for breast reconstruction with the patient, including:
    a. autologous
    b. combined autologous with implant
    c. tissue expander (+/- supporting mesh, acellular dermal matrix) with implant
    d. direct to implant (+/- supporting mesh, acellular dermis matrix).
2. For implant-based reconstruction, outline options for the use of tissue expanders, as well as other associated mesh or acellular dermal matrices and definitive implant(s).
3. Discuss the risks for each implantable device clearly and supported by use of an adverse event checklist, including likely frequency of each complication.
4. Discuss specific risks related to the patient, including any comorbidities, specific anatomy and related cancer treatment, that may impact on the outcome.
5. Present clinical credentials and experience clearly, including the clinicians' track record of patient outcomes.
6. For implant or tissue expander, discuss the range of options and make recommendations supported by sound clinical reasoning.
7. Clear declaration of any industry or personal conflicts related to the device(s).
8. Complete an informed educated consent checklist (see Appendix 1 for an example of this).
9. Obtain informed financial consent.
10. Outline immediate postoperative care plan for the patient.
11. Discuss plans for ongoing and long-term surveillance.
12. Offer a second consultation or telephone conversation, time permitting, prior to undergoing procedure.

Operative procedure

1. The reconstructive procedure must be performed in a fully licensed and accredited facility with established access to high dependency care, if required.
2. Prophylactic intravenous antibiotics are administered at least 10 minutes prior to skin incision.[5-8]
3. Use thorough skin preparation.[9]
4. Apply infection control mechanisms, including steps to prevent bacterial contamination: pocket irrigation, haemostasis, layered closure and sterile surgical technique are essential.[10, 11]
5. Use drains, where required, aiming to remove these as early as practicable.[12]
6. Provide clear postoperative instructions on wound and drain management.
7. Provide postoperative antibiotic prophylaxis as indicated.[13]

8. Entry of the device/s onto the Australian Breast Device Registry.[14]
9. Provide the implant card to the patient with encouragement to enter details to their My Health Record or assist in entering this with administrative support.
10. Document device details in the surgical report or patient notes according to local protocols.
11. Include device details in the patient discharge summary.
12. Communicate operative information, implant information and clinical history to the patient's primary care provider.

Postoperative care

1. Schedule inspection of the surgical site by the treating surgeon (for example at one week, two weeks and six weeks post-operatively).
2. Provide clear, written instructions to the patient as to what to look for in the immediate postoperative period and a contact number in the case of an emergency.
3. Provide a written program of clinical and radiological cancer and implant surveillance to the patient at six to eight weeks post-operatively.[15]
4. Discuss signs and symptoms that should prompt medical review by either treating doctor or general practitioner, including provision of a written information sheet.

Cosmetic breast augmentation

While not generally performed within the NSW public health system, the use of breast implants for cosmetic augmentation remains one of the most commonly performed cosmetic surgical procedures worldwide.[16]

In order to provide a complete picture of the use of breast implant devices, guidance around cosmetic breast augmentation is included in this document. This may also have relevance for general practitioners and public hospitals, as patients can present for an assessment and treatment of adverse events following cosmetic surgical treatment.[17]

There is considerable variation in the clinical delivery of cosmetic breast augmentation. Credentials, training, certification of practitioners and accreditation of facilities where these procedures are undertaken are not strictly regulated outside of the public health system.

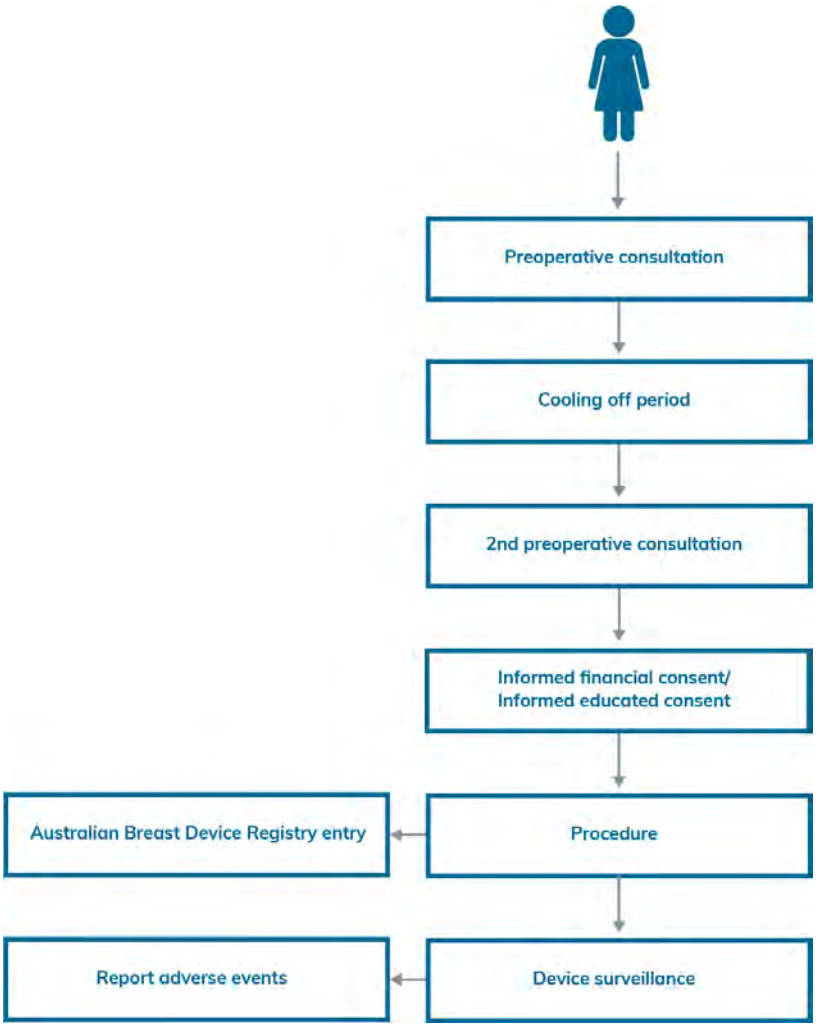
In June 2016, the Private Health Facilities Regulation 2017 was amended to reflect the requirement that all cosmetic surgical procedures (including cosmetic breast augmentation) be undertaken in licensed facilities.[18]

In 2018, NSW Health conducted a review of the regulation of cosmetic procedures.[19] This included recommendations with respect to clearer titling of health practitioners and cooling off periods prior to elective cosmetic surgery. This toolkit seeks to expand on best clinical practice to ensure that patients presenting for cosmetic breast augmentation are given sufficient information and time before they decide to proceed with this elective procedure.

All patients should understand that breast implants are not lifetime devices. They can result in adverse events, which may require further surgical intervention.

Figure 2 outlines steps that are recommended for pre, intra and post-operative management of cosmetic breast augmentation.

Figure 2: Steps for cosmetic breast augmentation



Preoperative work up

1. Present clinical credentials and experience clearly, including track record of performing implant-associated cosmetic augmentation procedures.
2. A minimum of 45 minutes direct face-to-face consultation between the patient and clinician performing the procedure (including patient support persons where appropriate).
3. While telehealth consultations may be offered for patients who are in regional or remote areas, these should not be used a substitute for face-to-face consultation.
4. A thorough clinical assessment of both breasts and axillae and preoperative ultrasound examination and mammography of both breasts and axillae is recommended for all women aged 35 years and older. For women under 35 years of age, a preoperative ultrasound examination of both breasts and axillae in addition to a clinical assessment is recommended.
5. Outline the options for various types of breast implants including shaped, textured or smooth and the options for placement of these implants either above or below the pectoralis major muscle. The clinician should provide the patient with a list of benefits and risks for each option that is offered.

6. Clearly discuss and document the risks associated with breast implants and the need for further surgery as a result of breast parenchymal changes, pregnancy and weight changes.
7. Outline the specific risks related to the patient including any comorbidities, or consideration relating to anatomy and asymmetry.
8. Perform preoperative sizing.
9. Present and discuss the surgeon's operative outcomes and timeframe of achieving these results.
10. Declare any industry or personal conflicts related to the device(s) recommended.
11. Complete an informed educated consent checklist (see Appendix 1 for an example of this).
12. Obtain informed financial consent.
13. Outline immediate postoperative care plan for the patient.
14. Ensure a minimum cooling off period of one week is completed.
15. Ensure a second face-to-face consultation prior to proceeding with surgery, preferably one week prior to the surgical date, to review information again, discuss any radiological findings and confirm treatment plan.

Operative procedure

1. The breast augmentation procedure must be performed in a fully licensed accredited facility.
2. A qualified anaesthetist and appropriately qualified support staff must be present in the operating theatre and appropriately qualified staff must care for the patient in recovery and the postoperative ward.
3. Prophylactic intravenous antibiotics are administered at least 10 minutes prior to skin incision.[5, 6]
4. Use thorough skin preparation.[9]
5. Apply infection control mechanisms, including steps to prevent bacterial contamination: nipple shields, pocket irrigation, good haemostasis, layered closure and sterile surgical technique are essential.[10, 11]
6. Provide clear postoperative instructions on wound management and physical activity following surgery.
7. Entry of the device/s onto the Australian Breast Device Registry.[14]
8. Provide the implant card to the patient with encouragement to enter details to their My Health Record or assist in entering this with administrative support.
9. Include device details in the patient discharge summary.
10. Communicate operative information, implant information and clinical history to the patient's primary care provider.

Postoperative care

1. Schedule an inspection of the surgical site by the treating surgeon (for example at one week, two weeks and six weeks post-operatively).
2. Provide clear, written instructions to the patient as to what to look for in the immediate postoperative period and a contact number in case of emergency.
3. Provide a written program of clinical and radiological cancer and implant surveillance to the patient at six to eight weeks post-operatively.[15]
4. Discuss signs and symptoms that should prompt medical review by either treating doctor or general practitioner, including provision of a written information sheet.
5. Schedule a regular surveillance check at one year postoperatively and then at regular intervals at the discretion of the clinician and patient thereafter. It is recommended that patients are seen at least every two years until 10 years and then yearly thereafter, as adverse event rates accumulate significantly following this.
6. Initiate and incorporate an ongoing screening and surveillance program for breast cancer at an appropriate age. Patients should be instructed to inform imaging staff of the presence of implants to ensure that appropriate care and projections are taken.

Assessment of patients with breast implants in situ

In September 2019, the TGA announced that a number of breast implants were to be suspended and/or cancelled due to the potential risk of a rare cancer associated with textured devices known as breast implant-associated anaplastic large cell lymphoma.[1]

This action has prompted many women to seek a medical review of their implants. This toolkit provides a framework for assessment of these patients. To date, there is no proven benefit in recommending removal of implants that have normal clinical or radiological examination.[20]

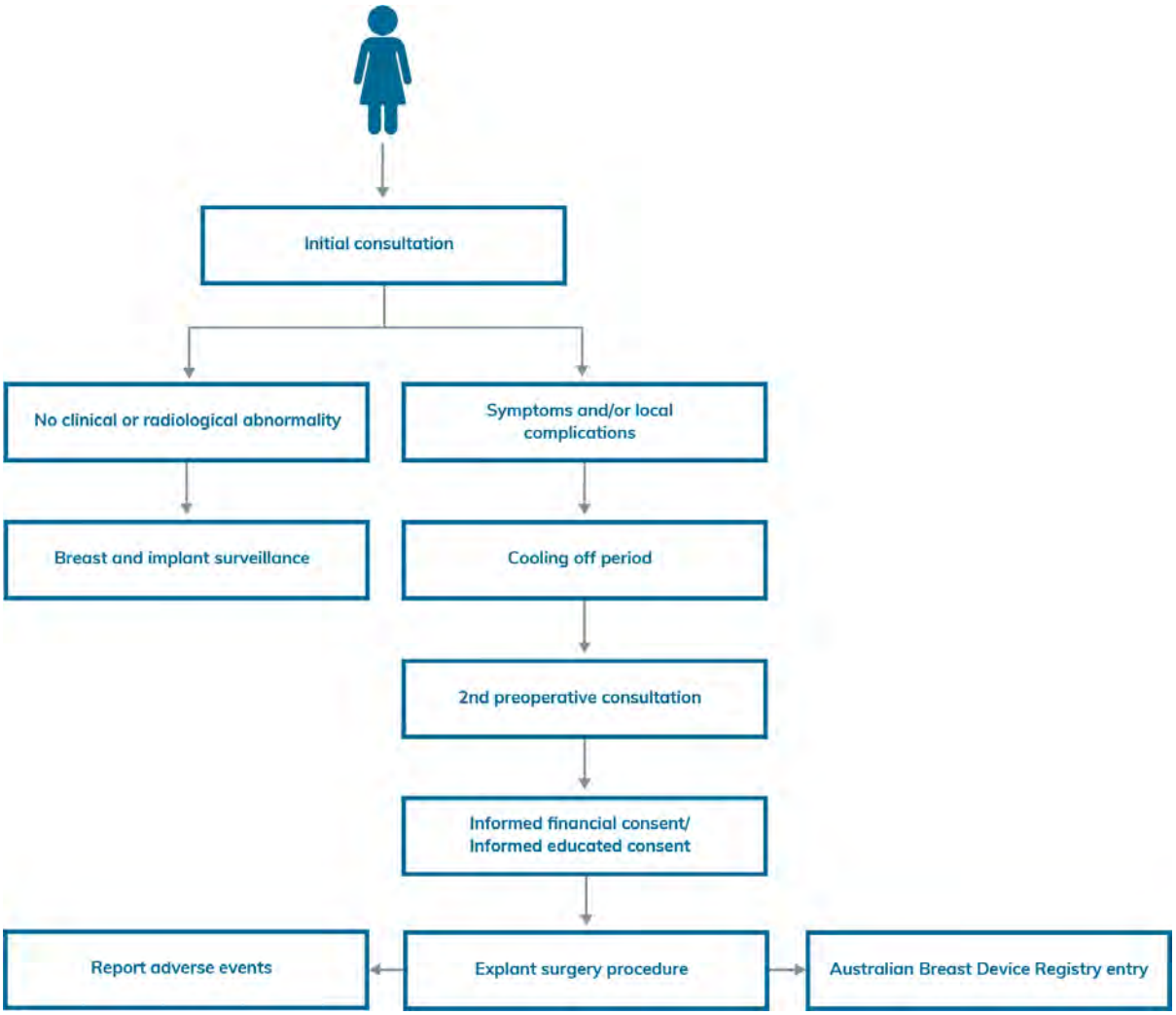
The recommended course of action for people who have no local complications related to their breast implants is to continue with a regular surveillance program.

The clinician plays an important role in completing a comprehensive assessment and providing the patient with information and advice, in relation to breast implant-associated cancer risk.

It is acknowledged that some patients with ongoing concerns about their breast implants may wish to have their implants and/or surrounding capsules removed. In these instances, a clear discussion about the risks compared with benefits of implant and/or capsule removal should be undertaken. The decision to proceed with surgery in these patients should also be made only after at least two clinical consultations, separated by at least a one-week time interval.

Figure 3 outlines steps recommended for patients with breast implants in situ, including consultation and pre, intra and post-operative management of explant surgery, if the the patient proceeds to explant surgery.

Figure 3: Steps for patients with breast implants insitu



Consultation

1. Complete a thorough patient history, history of the implant procedure and identification of the patient's implant type (where possible).[17]
2. Identify any personal or family risk of breast cancer or lymphoma.
3. Document any history of change to the breast in the period since surgery.
4. Review previous pathology and radiology results.
5. Perform a thorough physical examination of implants, breast and draining lymph nodes. Any abnormality warrants further radiological and/or pathological investigation.
6. Consideration should be given to ultrasound examination of the implants to check integrity and exclude any seroma or mass. Any abnormality on ultrasound examination should prompt further imaging with breast MRI and/or biopsy or seroma aspiration to explore pathology.[17]

7. While the treatment of breast implant complications is beyond the scope of this toolkit, if clinical and radiological examination detects implant-associated complications or breast pathology, consider surgical intervention.
8. Should no concerns or issues be identified through this assessment process, conduct regular surveillance and patient education.
9. Should a patient still wish to proceed with explant surgery to remove breast implants, discuss the risks and benefits of implant removal, partial capsulectomy and total capsulectomy. The future risk of breast implant-associated anaplastic large cell lymphoma should also be discussed with respect to removal of part, or all, of the capsule around the implant.

Preoperative work up: Explant surgery

These additional steps are recommended for patients proceeding to explant surgery:

1. Present clinical credentials and experience clearly, including track record performing breast explant procedures.
2. Present and discuss the surgeons' individual operative outcomes and timeframe of achieving these results.
3. Declare any industry or personal conflicts related to the device(s).
4. Complete an informed educated consent checklist (see Appendix 1 for an example of this).
5. Obtain informed financial consent.
6. Outline the immediate postoperative care plan for the patient.
7. Ensure a minimum cooling off period of one week is completed.
8. Ensure a second face-to-face consultation prior to proceeding with surgery, preferably one week prior to the surgical date, to review information again and confirm treatment plans.

Operative procedure: Explant surgery

1. The explant surgery procedure must be performed in a fully licensed accredited facility.
2. A qualified anaesthetist and appropriately qualified support staff must be present in the operating theatre. Appropriately qualified staff must care for the patient in recovery and the postoperative ward.
3. Use thorough skin preparation.[9]
4. Apply infection control mechanisms, including steps to prevent bacterial contamination: pocket irrigation, good haemostasis, layered closure and sterile surgical technique are essential.[10, 11]
5. Provide clear postoperative instructions on wound management and physical activity following surgery.
6. Use drains, where indicated.
7. Use postoperative compression garments, where indicated.
8. Samples must be sent for pathological examination and culture.
9. Send samples and implants to research laboratory, where the patient is enrolled in a prospective study and has provided consent.
10. Provide patient with clear postoperative instructions on wound management and activity following surgery.

11. Enter explanted device details onto the Australian Breast Device Registry.[14]
12. Communicate operative and clinical history to the patient's primary care physician.

Postoperative care: Explant surgery

1. Schedule an inspection of the surgical site by the treating surgeon (for example at one week, two weeks and six weeks post-operatively).
2. Provide clear, written instructions to the patient as to what to look for in the immediate postoperative period and a contact number in case of emergency.
3. Discuss signs and symptoms that should prompt medical review by either treating doctor or general practitioner, including provision of a written information sheet.
4. Consider obtaining a baseline mammogram +/- breast ultrasound one year after explant surgery and review.

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Appendix 1: Patient consent checklist

Before you make a decision about whether to proceed with breast implant surgery, you must ensure you are familiar with the risks associated with using these devices. The risks are reported in clinical trials, scientific literature and patient-reported outcomes.

You should take the time to read through this information and take the opportunity return to your doctor, if necessary, to discuss these further before you proceed.

You should have been given a number of options for treatment, including treatment without the use of implants, by your doctor and they should outline clear reasons why one or more of these treatment options have been recommended for you.

It is also important that you ask for help if you need assistance reading and understanding this information. In addition to this information, your doctor should also provide you with an information booklet or brochure, provided by the manufacturer of the implants to be used in your surgery, which outlines the instructions for their use.

It's important to remember that breast implants are not lifetime devices.

They are associated with a range of risks that can often require further surgery to your breasts.

Underlying health conditions that impact breast implants

Health conditions that prevent the use of breast implants:

If you have any of these conditions, breast implants are not suitable for you**:**

- An active infection such as urinary or respiratory infection
- Cancer in your breast that has not been treated
- You are pregnant or breastfeeding

Health conditions that increase risk of a poor outcome:

If you have any of these conditions, consider the need for breast implants carefully**:**

- Chronic disease that affects healing, e.g. diabetes, autoimmune connective tissue disease
- Active smoker
- Medication that reduces immunity, e.g. steroids, chemotherapy
- Previous radiation treatment to your breast(s) and/or planned radiation treatment after surgery
- Conditions that interfere with blood clotting, e.g. haemophilia, von Willebrand disease

Health conditions that may increase risk of a poor outcome after surgery:

- Autoimmune disease, e.g. rheumatoid arthritis, lupus
- Other implanted products in the breast(s)
- Clinical diagnosis of a mental health disorder, e.g. body dysmorphic disorder, eating disorder, clinical depression

Risks of breast implants

The risks of breast implant surgery may include:

1. Changes to your breast:
    - Breast pain
    - Skin, nipple or areola loss of sensitivity
    - Asymmetry
    - Impact of weight change to size and shape of breasts
    - Impact of pregnancy and breast feeding on the size, shape and position of breasts
    - Infection which may require removal of implant
    - Swelling
    - Scarring
    - Fluid collection (seroma)
    - Bleeding and hematoma
    - Loss of skin and nipple
    - Inability to breastfeed
    - Chronic pain
2. Changes to the implant:
    - Rupture, including silent rupture
    - Leaking of silicone and formation of painful lumps in your breast
    - Visibility and rippling of the implant
    - Capsular contracture, where a hardening of tissue around the implant can cause pain, deformity and may require revision surgery or implant removal
    - Mobility of the implant
    - Malposition or displacement of the implant causing deformity, e.g. double bubble
    - Breast implant associated anaplastic large cell lymphoma (with textured devices)
3. Possible association of systemic symptoms

There are some women that report a variety of systemic symptoms including joint pain, fatigue and ‘brain fog’, which has been labelled as breast implant illness. Whilst the causes of these symptoms remain unclear, more research is needed to further define the cause(s) and outcomes, and to determine whether these symptoms resolve following removal of implants.

Recommended follow up

By proceeding with implant surgery, you are also required to undergo regular follow up with your treating doctor for clinical and radiological assessment of your breast implants. You will require routine and regular surveillance for as long as you have breast implants.

Australian Breast Device Registry

It is strongly recommended that you register your device with the Australian Breast Device Registry. This will allow tracking of outcomes and safety and will allow notification of any important information on the safety of your breast implants to you directly. Please ask your doctor to register your device at the time of surgery.

Checklist for completed clinician/patient discussion

- ☐ Health conditions that can affect breast implants
- ☐ Risks of breast implant surgery
    - ☐ Risk to your breast(s)
    - ☐ Risks of breast implant failure
    - ☐ Risks of systemic symptoms
- ☐ Need for ongoing surveillance
- ☐ Register your device

Signature and confirmation

Patient

I have had the opportunity to ask my doctor about their experience, medical degree and specialty of training and credentials. I acknowledge that I have received and read this information that has been provided to me. I have had time to discuss this information directly with my treating doctor. I have had the opportunity to ask about the benefits and risks of breast implants, given my specific health and indication for surgery. I have considered alternatives to breast implants.

Patient signature and date

Doctor

I acknowledge that I have discussed the benefits and risks of breast implants as described above. I am satisfied that the information has been given in language that the patient can understand. I have provided the patient with the opportunity to return and ask questions and I have addressed these questions. I have informed the patient of the need for ongoing regular surveillance of these devices and the need to report any adverse events related to breast implants and associated breast surgery.

Doctor signature and date

Response template for submissions to the *Independent review of the regulation of medical practitioners who perform cosmetic surgery*

You are invited to have your say about the regulation of medical practitioners (doctors) who perform cosmetic surgery by making a submission to this independent review.

The consultation questions from the consultation paper are outlined below. Submissions can address some or all of these questions, and you can include any evidence or examples that you think are relevant.

Submissions can be emailed to:

Mr Andrew Brown, Independent Reviewer
marked '*Submission to the independent review on cosmetic surgery*' at CSReview@ahpra.gov.au.

The closing date for submissions is 5.00pm AEST 14 April 2022.

Your details

Name	MARK ATTALLA
Organisation (if applicable)	CHELSEA COSMETICS PTY LTD
Email address	[redacted]

Your responses to the consultation questions

Codes and Guidelines

1. Do the current *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures* adequately address issues relevant to the current and expected future practice of cosmetic surgery and contribute to safe practice that is within a practitioner's scope, qualifications, training and experience?	
	1. These could indeed be improved. Currently there is no recognised specialty of Cosmetic Surgery, nor can there be, without a change in the National Law. Therefore no training programme is recognised by the AMC for cosmetic surgery, and the title "cosmetic surgeon" may be used by any medical practitioner. Patients are at risk, because they are unable to identify if the doctor offering cosmetic surgery has the relevant *specific* training and skill. Currently it is impossible to determine if a practitioner is operating within their scope of practice.
2. What changes are necessary and why? What additional areas should the guidelines address to achieve the above purpose?	
	1. The Endorsement model for practitioners performing cosmetic surgery should be adopted to protect the public. Those endorsed medical practitioners who have met a National Accreditation Standard should be on a public register.
3. Please provide any further comment in relation to the use of codes and guidelines relevant to the practice of cosmetic surgery.	
	1. This standard would ensure that practitioners not only have a core surgical competence, but also that they have reached an acceptable level of competence and skill *specifically* in Cosmetic surgery. The practitioners would be required to be part of a recertification programme specific to cosmetic surgery. To ensure patient safety, this model would need to be applied to *all doctors* who perform cosmetic surgery irrespective of their prior backgrounds.

Management of notifications

4. Having regard to Ahpra and the Medical Board's powers and remit, what changes do you consider are necessary to the approach of Ahpra and the Medical Board in managing cosmetic surgery notifications, including their risk assessment process, and why?	
	1- Fast response to the notification. 2- Involving investigators with good specific experience not just general experience in the field. 3- Follow up of the state of compliance with the recommendations and/or restrictions.
5. Please provide any further relevant comment in relation to the management of notifications about medical practitioners involved in cosmetic surgery.	

4- Work on a plan to prevent the occurrence of the incident in the future.

Advertising restrictions

6. Is Ahpra and the Medical Board's current approach to regulating advertising in cosmetic surgery sufficient?
The guidelines are sufficient but there is a noticeable failure in applying these guidelines. There are many cosmetic clinics that do not follow these guidelines and should be approached and notified.
7. What should be improved and why and how?
Closer follow up of the cosmetic clinic advertising and a heavier fines and penalties for the clinics that do not follow the guidelines.
8. Do the current Guidelines for advertising a regulated health service adequately address risks in relation to advertising of cosmetic surgery, or is a more specific regulatory response required?
They are adequate.
9. Does the promotion of cosmetic surgery via social media raise any issues that are not adequately addressed by the advertising guidelines, or that require any specific regulatory response?
Educational videos should be encouraged and advertising videos without mentioning the risks should be stopped.
10. Please provide any further relevant comment in relation to the regulation of advertising.

Title protection and endorsement for approved areas of practice

11. To what extent would establishing an endorsement in relation to the practice of cosmetic surgery address relevant issues of concern in the sector (including patient safety issues)?
. Establishing an endorsement model would essentially protect patients from adverse outcomes. Those practitioners, who are endorsed to practice cosmetic surgery, would have the appropriate training and experience in cosmetic surgery. This would be clear to patients, because there would be an AHPRA administered Cosmetic Surgery Register identifying doctors who are endorsed for cosmetic surgery. Patients could then be rest assured that they are being treated by doctors who are operating within their scope of practice. A title restriction should be linked to a competency-based accreditation Standard/Register as proposed by the

College (ACCSM) by means of the Endorsement pathway provided for in Section 98 of National Law.

12. Would establishing an endorsement in relation to cosmetic surgery provide more clarity about the specific skills and qualifications of practitioners holding the endorsement?
Establishing an endorsement model would provide clarity to the consumer, about the specific skills and qualifications of practitioners holding the endorsement. It would identify those practitioners who have the core surgical training and competence, and *specific* cosmetic surgical training and competence as well as on-going professional education in cosmetic surgery.
13. What programs of study (existing or new) would provide appropriate qualifications?
13. The Australian College of Cosmetic Surgery and Medicine (ACCSM) is a well-recognised college, which has been established well over 30 years ago. This college is well equipped to provide appropriate qualifications for those practitioners to be endorsed in Cosmetic Surgery and Medicine.
14. Please provide any further relevant comment in relation to specialist title protection and endorsement for approved areas of practice relevant to cosmetic surgery.
Specialist title protection is reserved for medical specialists who have been recognised by the AMC. Until this point, Cosmetic surgery and Cosmetic Medicine have not been specialist pathways recognised by the AMC, because there is no burden of disease. Failing being recognised by the AMC as a medical specialty, the endorsement model would be an appropriate way in which to regulate the cosmetic surgical industry. The title 'Cosmetic Surgeon' should be protected for those practitioners who have had specific recognised training in Cosmetic surgery. It is clear that specialist surgeons as recognised by the AMC do not have specific training in Cosmetic Surgery and specialist plastic surgeons qualify with a 'gap' in the area.

Cooperation with other regulators

15. Are there barriers to effective information flow and referral of matters between Ahpra and the Medical Board and other regulators?
N/A
16. If yes, what are the barriers, and what could be improved?
N/A
17. Do roles and responsibilities require clarification?

Yes.
18. Please provide any further relevant comment about cooperating with other regulators.

Facilitating mandatory and voluntary notifications

19. Do the Medical Board's current mandatory notifications guidelines adequately explain the mandatory reporting obligations?
Yes.
20. Are there things that prevent health practitioners from making notifications? If so, what?
1- Concerns about the consequences of the notification and concerns that it could have a negative effect on the practitioner carrier. 2- Concerns that the partitioner can get involved indirectly.
21. What could be improved to enhance the reporting of safety concerns in the cosmetic surgery sector?
Available information about the contact details of the regulating offices and clear rule of each department.
22. Please provide any further relevant comment about facilitating notifications

Information to consumers

23. Do the Medical Board's current codes and guidelines adequately describe the obligations of practitioners who perform cosmetic surgery to provide sufficient information to consumers and obtain informed consent?

The Medical Board's current codes and guidelines do not specifically outline a practitioners training in cosmetic surgery. Currently consumers are left in doubt as to whether their surgeon has had any *specific* training in cosmetic surgery, even if their surgeon is a specialist surgeon as recognised by the AMC.

24. If not, what improvements could be made?

If the endorsement model is adopted for cosmetic surgery, it would allow the public to identify doctors who are trained and competent in cosmetic surgery, provide protection for patients before something goes wrong, facilitate AHPRA taking action more readily against doctors who may be practicing outside of their scope of practice, and by being competency- based and independently set and assessed, be fair to all practitioners and not favour any particular group of doctors on the basis of their non-cosmetic surgical training and qualifications

25. Should codes or guidelines include a requirement for practitioners to explain to patients how to make a complaint if dissatisfied?

Practitioners should have a form to be handled to the patient at the end of the consultation or the service to explain to the patients how to make a complaint and their rights.

26. In the context of cosmetic surgery, does the Ahpra website and public register of practitioners provide sufficient information about medical practitioners to inform consumer choices?

The AHPRA website, and public register of practitioners does not provide adequate information to consumers to safely choose their cosmetic surgeon. There should be a list of endorsed practitioners available for consumers to readily identify those practitioners who are adequately trained in cosmetic surgery.

27. If not, what more could/should Ahpra and the Medical Board do to inform consumer choices?

AHPRA could provide a register of identified practitioners who have the necessary training in cosmetic surgery to perform such procedures safely

28. Is the notification and complaints process understood by consumers?

More information is required to reach the customers and should be available in the cosmetic clinics as a brochure and these brochures has to be handled to the customers.

29. If not, what more could/should Ahpra and the Medical Board do to improve consumer understanding?

30. Please provide any further relevant comment about the provision of information to consumers.
It should be clear to consumers which doctor is trained *specifically* in cosmetic surgery, irrespective of their other previous training.

Further comment or suggestions

31. If you have any further comment relevant to Ahpra's and the Medical Board's regulation of cosmetic surgery including and/or suggestions for enhancements not mentioned in response to the above questions, please provide it here.
It is vital that consumers are made aware of the *specific* experience and qualifications of their cosmetic surgeon, in order for them to make informed choices regarding their surgery and choice of surgeon. I support the proposal for a national competency-based accreditation Standard for *all* doctors performing cosmetic surgery. There should be a register of Endorsement of those who have met, and maintain the national standard. Restriction of the title 'Cosmetic Surgeon' should be applied to those medical practitioners who appear on the Register, administered by AHPRA. Since the Australasian College of Cosmetic Surgery and Medicine is the *only* training body in Australia specifically focused on training practitioners in Cosmetic Medicine and Surgery, this college would be best equipped to train practitioners and enable them to maintain their level of competence and skill.

From: Domit Azar
To: Cosmetic Surgery Review
Subject: Submission to the independent review on cosmetic surgery
Date: Wednesday, 9 March 2022 8:17:05 AM
Attachments: [redacted]

To whom it may concern,

Given my many years of experience in performing cosmetic blepharoplasty surgery, I am of the opinion that only properly trained, surgically trained doctors should perform this procedure. This includes those with the appropriate plastic surgical training who hold a FRACS qualification, or those with eyelid surgical training who hold a FRANZCO qualification. I have had to manage complications following cosmetic eyelid surgery performed by those less qualified who surprisingly are legally-entitled to perform such surgery.

Regards,
Domit Azar

Domit Azar
BSc(Med) MBBS(Hons) MPH(Hons) FRANZCO
MSc (Philosophy, Science, and Religion) Candidate
[redacted]