Australian Health Practitioners Regulation Agency: Consultation – Registered medical practitioners who provide cosmetic medical and surgical procedures

From: Dr Michael Molton

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Adelaide SA 5000

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I do not claim to represent any organisation in this response to the call for public submissions.

### **Executive Summary**

As a full time cosmetic medical practitioner for two decades, and one of two founding doctors of the Cosmetic Physicians Society of Australia (later to become 'of Australasia') prior to the NSW Inquiry in Cosmetic Surgery 1999, I have a continued personal interest in maintaining the medical model in cosmetic procedures and patient advocacy.

Unfortunately there is no specific training in the approved courses of study in undergraduate training for those who become cosmetic medical practitioners. Neither is there a proclaimed medical specialty for cosmetic medical procedures. Nevertheless the principles of the medical practitioners' model when dealing with any patient are unwavering.

- 1. Identify the presenting complaint
- 2. Identify the history of the presenting complaint
- 3. Examination of the system or systems pertinent to the presenting complaint
- 4. Consideration of any special tests relating to the findings of the examination
- 5. Formulation of an assessment, diagnosis and potential alternative diagnoses
- 6. Treatment and follow up.

What has been happening more and more is that these principles, which objectively secure the best interest of the patient are being omitted or exchanged for methods more commonly associated with trade.

The result has incurred a shift away from the patient's best interest to that of the trader's. The patient has become a 'client'. My interpretation of this shift is illustrated by the following proposed definition differences between client and patient.

A 'patient' is a person who presents to a health professional with concerns regarding (biopsychosocial) health with the understanding that the medical practitioner will ensure that the duty of care to the person precedes any benefit to the medical professional.

A 'client' is a person or organisation that engages in a commercial activity not necessarily applicable to the well-being of patient health. The connotations of 'client' are indicative of the process of 'selling to', whether there is a perceived or inherent need by the client to purchase or not, and includes the common law definition of caveat emptor.

Broadly speaking, a patient should not be 'sold to' whether there is a perceived or inherent need by the patient to purchase or not to purchase.

The mechanism that has caused this shift is multifactorial and relates to, but not exclusively, direct payment of procedures by private billing, non-Medicare payment for services, health insurance exclusion of cosmetic procedures and the absence of a recognised specialty of cosmetic medicine.

In the absence of the creation of specialty for cosmetic medical procedures there is little effective peer review and conduct judgement by those best placed to do so. It is therefore no surprise that AHPRA has become embroiled in the complexities of how to protect the public from health practitioners who have become traders who treat patients as 'clients'.

I note that AHPRA is not responsible for this omission.

Secondly, there is the question of *purposeful intent* to shift away from the primary best interests of the patient, to the pecuniary interests of the trader.

On the one hand one could say that some cosmetic health practitioners intentionally use their trusted professional status to disguise their methods of trading, for example the use of terminology regarded as 'holding out' that might mislead the public, engage in advertising scheduled medications using prohibited terms (often by 'implied' mechanisms of 'hidden' or suggestive terms such as 'nicknaming' eg 'Botulinum bacteria', abbreviating terms such as 'BTX', or somehow including the message that the trader is making it known to the public that the trader specifically offers these medications). These actions are purposefully designed to circumvent the Therapeutic Goods Act to advertise scheduled medications which is unlawful.

On the other hand, in some cases I am sure that the switch to monetary profit first and patient welfare second is an unfortunate misunderstanding of how to 'hang the shingle' that the health practitioner is 'open for business' as a cosmetic medical practitioner.

Yet the very fact that we have to design specific codes of conduct and guidelines for medical practitioners practising cosmetic medicine appears to suggest that there is a fundamental difference in the interpretation of what is required as a medical practitioner by some who practice cosmetic medicine and that held and followed by the majority of the health profession.

Note that in this particular instance I make no distinction between cosmetic medicine and 'cosmetic surgery'. It is fact all matters medical and surgical relate to the Medical Board of Australia. We are all medical practitioners under the law whether we are surgeons or non-surgeons.

The proposed guidelines do appear to attempt to differentiate medical (stated as 'low risk') and surgical (which the document attributes a potentially higher incidence of serious risk of injury).

This needs to be fleshed out.

Part of why we find ourselves in the present situation is the generally-held misbelief that cosmetic *medical* procedures that do not involve cutting the skin, are innocuous and/or involve less skill and competency.

Secondly, there is an assumption that the qualification of a surgeon presumes the necessary training, competency and experience has been attained in all cosmetic procedures including cosmetic medical procedures. This is often a false assumption. It is not a requirement to undergo a recognised course of study in cosmetic medical procedures, and it is not common for a surgeon to have voluntarily demonstrated competency in cosmetic medical procedures in modern times which have expanded considerably in a relatively short time and are commonly sought after by the public..

For example, the application of injectable substances has widened extensively. In the words of prominent plastic surgeon Dr Arthur Swift, 'we no longer inject lines and wrinkles. We inject volume....'

Where once surgeons occasionally used cheek implants, and all kinds of other prostheses, now we inject considerable quantities of scheduled medications into all areas of the face instead. And the processes do not end at the face. With this explosion of replenishing lost physiological volume with schedule 4 medications, there has been an emergence of previously ignored complications, recently culminating in international medical fraternities reporting localised skin necrosis, scarring and retinal artery occlusion rand subsequent permanent vision loss (1). Surgical groups have long claimed correctly that the competency of handling of complications be essential to conferring competency in performing the procedure.

Most cosmetic, and many plastic and reconstructive surgeons offer cosmetic medical procedures but permit a registered nurse to perform these procedures. There are established limitations of Scope of Practice (SoP) for the delegation of any treatment, or prescribing of scheduled medications, to nursing staff to carry out. Yet in contradiction that the acquisition of informed consent is more onerous in cosmetic medicine than other fields of medicine, written orders and treatment plans that have been properly delivered by a prescribing doctor who has seen the patient in-person, face-to-face, is commonly found to be absent.

Similarly, variations of the prescribed orders are being made without consultation with the prescribing doctor. In any other field of medicine, should a nurse provide, sell, supply, administer or make

unauthorised variations of prescriptions of scheduled medications, there would be significant consequences sought, and rightly so.

In this way, since there are persons who appear unwilling to recognise the medical model, the status quo would not resolve this problem, and conducting awareness campaigns also falls short of the same.

In summary, medicine is and always will be, about the medical model and preserving the patient's best interest before all else. The abandonment of this model in cosmetic medical procedures is common, both by accidental misunderstanding that when practising cosmetic medicine we must act like a retailer, but also it is exchanged for entrepreneurial tactics that holds profit over patient safety.

It is without doubt that Option 3 is the choice most likely to spell out to those who have misunderstood the importance of maintaining the medical model in cosmetic medicine, and to those who choose to manipulate 'loopholes' in the fundamentals of 'Good Medical Practice – A Code of Conduct for Doctors in Australia'.

### Dr Michael Molton

# Responses to questions

Consultation – Registered medical practitioners who provide cosmetic medical and surgical procedures'

### Q1

I agree with the nature and extent of the problem particularly in relation to cosmetic medicine and the prescribing, selling, supplying, transporting and administration of prescription-only medications.

I would describe the major problems as follows.

- 1. Health practitioners attending one or two day workshops run by entrepreneurial organisations, drug companies and individuals with attendees immediately practising on patients following the workshop.
- 2. Doctors remotely prescribing medications to registered nurses located in other states, when the doctor has little or no training in the procedures being delegated. The doctor receives a small nominal payment per consultation by the entrepreneur who has established a network nurses who also have questionable competency.
- 3.Dentists attending one or two day courses, and then using opportunistic consultations when the patient has attended for dental treatment who may have never considered cosmetic medical procedures to sell and administer extra-oral injections using prescription-only medications approved for use by the TGA for cosmetic medical procedures. The dentists pay significant sums to the entrepreneurial training groups (1) who provide these workshops to achieve 'certification' and claim that the procedures are within the SoP of dentistry(2). The estimated revenue received for one course alone in February 2015 raised in excess of \$60,000 in two days (3).
- 4. There is evidence that Specialist plastic surgeons and 'cosmetic surgeons' are regarded, by both the public and regulators to possess expertise, not only in cosmetic surgery, but also in cosmetic medicine, including the administration of prescription-only medications, laser and pharmacology. In general, the practice of surgery does not require any significant training or experience in procedures involving lasers and scheduled pharmaceuticals, and surgery groups are excluded from consultation groups such as the Australian Pharmaceuticals Advisory Council(4). Surgeons do not manage medications in the community. Most commonly, where cosmetic medical procedures are offered by surgery practices, the surgeon delegates procedures to nursing staff and there is concern over the degree of supervision that can be provided by medical practitioners who are not familiar with the processes of quality use of medication (QUM)(8) or the principles of medication management in the community, which together form the basis of the skilled administration

of scheduled prescription-only medications used in cosmetic medicine, including reporting of adverse events in accordance with professional standards (5).

- 5. Doctors with general registration holding out as surgeons.
- 6. Coupon sales promoting the indiscriminate use of scheduled medications (6)
- 7. Botox parties that trivialize risks, side effects and adverse outcomes
- 8. Risk of multi-use of single use vials (9) and cross-infection of HIV/AIDS and other risks associated with unhygienic environments that lack the protocols set down by the NHMRC(7) and effective risk-management of all manner of incidents such as needle-stick injury.
- 1. Australian Dento-Facial Aesthetics Association website www.aadfa.net
- 2.Communique Dental Board of Australia 2015
- 3. Introductory course in Botox and dermal fillers, WA Branch Australian Dental Association 2015
- 4. Guiding principles in medication management in the community, Australian Pharmaceuticals Advisory Council 2006
- 5. Delegation of procedures Australian Society of Plastic Surgeons
- 6. Website www.cudo.com.au, wwwmydeal.com.au,
- 7. NHMRC guidelines for reconstitution of single use 100 unit vials Botox for multi-use
- 8. The National Strategy for Quality Use of Medicines (see also answer Q3, reference 3) also states:

The six building blocks that support QUM are based on evidence and expert opinion about interventions, regulatory efforts and programs to improve medication use. They are:

- policy development and implementation;
- facilitation and coordination of QUM initiatives;
- provision of objective information and assurance of ethical promotion of medicines;
- education and training;
- provision of services and appropriate interventions; and
- strategic research, evaluation and routine data collection.
- 9. Dept of Health NSW v Davis 1989: Cross-infection of four individuals with HIV involving single use vial
- Q2. The provision of adequate information and rushing into procedures may be a problem in non-medical facilities. Trivialisation of the risks, complications and potential adverse outcomes associated with cosmetic medical procedures may depreciate the process of due diligence and is of major concern.

The practice I work in is an accredited healthcare facility with the Australian Council on Healthcare Services (ACHS). In my experience, patients do not in general rush into cosmetic

medical procedures in modern times. The internet and social media have done much to provide information that the public actively seeks before attending for cosmetic medical procedures. Even then, patients attend to gather information not undergo procedures immediately. In general the majority of the public today may not be as vulnerable or naive as one might imagine when it comes to cosmetic procedures. There are circumstances that produce exceptions.

Procedures performed in non-medical environments such as 'Botox Parties', in hairdressers, beauty salons and by dentists, to name a few, trivialise the risks, complications and side effects of the procedures lowering the threshold that discourages research by the consumer prior to treatment and this may produce the circumstances to undergo a procedure they would not normally consent to.

Trivialisation of risks, side effects and complications also occurs when any consumer who voluntarily attend non-medical facilities for eg leg-waxing, facials and hair treatments that are unrelated to cosmetic medicine and is then 'sold' simultaneous cosmetic medicine procedures when this was not sought by the consumer or self-determined. This trivialisation is instrumental in convincing vulnerable uninformed consumers to undergo cosmetic medical procedures, and represents an unconscionable entrepreneurial and opportunistic advantage that carries risk of injury to the trusting and uninformed consumer.

The incidence and severity of risks of conducting these procedures in non-medical environments are documented. A team of Australian infectious-diseases doctors and epidemiologists warns that the risks of cross-infection in beautician clinics has been documented involving HIV/AIDS, herpes and viral hepatitis (1). Dendle et al report the presentation at Mercy Hospital for Women, Melbourne, of a case of a Streptococcus pyogenes necrotising fasciitis involving a 20 year woman with poorly controlled Type I diabetes who attended for waxing at a beauty salon. The patient required intensive multiantibiotic and anti-viral regimes for this near fatal infection.

The authors stated: (in beauty salons) 'Infecting bacteria can include S. aureus and Pseudomonas aeruginosa, and other potential pathogens include human papilloma virus, molluscum contagiosum, dermatophytes (such as Trichophyton tonsurans) resulting in Majocchi granuloma, and more unusual fungi, such as Sporothrix schenckii,'

The authors also indicated that a previously unknown bacterium specie belonging to the same family as tuberculosis is now found to colonise some salons now named Mycobacterium cosmeticus and there have been concerns regarding the development of antibiotic resistant nosocomial infections of the type that represent significant health issues in hospitals, in these facilities.

The paper closed stating 'The beauty industry is growing at an unprecedented rate, and more invasive and potentially harmful procedures are increasingly available.'

While the case in question resulted from waxing, the absence of principles of proper assessment of a patient, hygiene, cross-infection control measures prior to 'more invasive and potentially harmful procedure(s)' in non-medical facilities is of concern.

Conclusion: There is evidence that patients are more likely to undergo procedures without sufficient knowledge outside of the medical environment. There is an inherent autosuggestion that if these procedures are permitted to be performed in beauty salons, hairdressers, dentists and in groups at private dwellings, the public are entitled to assume that this practice is safe. I do not believe that hasty decisions are common when performed within the medical model. I do receive anecdotal reports from patients often about opportunistic sales outside of the medical model.

- 1.Claire Dendle,1 Sheila Mulvey,3,5 Felicity Pyrlis,2 M. Lindsay Grayson,1,4,and Paul D. R. Johnson1, Severe Complications of a "Brazilian" Bikini Wax: Infectious Diseases Department and 2Endocrinology Department, Austin Health, and Departments of 3Obstetrics and Gynaecology and 4Medicine, University of Melbourne, Melbourne, 5Mercy Hospital for Women, Heidelberg, and Department of Epidemiology and Preventive Medicine, Monash University,
- 2.Johnson et al, Johnson IL, Dwyer JJ, Rusen ID, Shahin R, Yaffe B. Survey of infection control procedures at manicure and pedicure establishments in North York. Can J Public Health 2001; 92:134–7.
- Q3. Limitations of access to factual information exist partly because the TGA prohibitions on the broadcast of factual information about cosmetic medicine hinders the public when seeking treatment that may involve scheduled medications.

The current Therapeutic Goods Act 1989(1) prohibits the use of precise names when referring to schedule 4 medications used in cosmetic medicine. Service providers may only refer to these products as 'anti-wrinkle injections' and 'dermal fillers' in information broadcast to the general public.

For example there are now three formulations of Botulinum Toxin A (BTXA) (2) available on the market. There are differences in these formulations that cannot be broadcast to the public as a result of the Therapeutic Goods Act. There are also many types of dermal filler but none can be named in information to the public or compared. Issues of what dermal fillers have which side effects is variable and the consumer deserves to have access to such information. Presently this knowledge is mostly disseminated by anecdote between members of the public and can be inaccurate and confusing.

Recently, a bulletin issued by the FDA warned of 'counterfeit Botox' in the USA stating that the product could be harmful, recalling all patients who had received this treatment for testing of HIV/Hepatitis and other infections. Such warnings are not permitted to be broadcast by cosmetic medical practitioners as this is determined to be an intent to advertise Botox by the TGA if the information appears on any document that is related to a company that 'sells' this product(3).

Prescribing of medications in Australia is strongly underlined by the Department of Health, as it was known at the time of publication, National Strategy for Quality Use of Medicines (3) (QUM) states:

'The National Strategy endorses the ethical criteria for promotion of medicines developed by the WHO, which urges each country to:
...develop its own appropriate measures to ensure medicinal drug promotion supports the aim of improving healthcare through the rational use of drugs. (WHO 1988)'

However, the prohibition of factual information to the public at large that relates to scheduled medications does not confer an overall benefit to the patient in cosmetic medicine.

It is understood that such deregulation is beyond AHPRA's control but such action would provide the public with more comprehensive information prior to treatment and remove much of the burden on the MBA's resources in deciding on notifications about unlawful advertising of scheduled medications by some medical practitioners.

I am not aware of incorrect information provided to the public, although advertising can be misleading.

Conclusion: Even though there is much information in the electronic media that the discerning patient can evaluate, I do not believe there is enough factual information provided prior to consent by some practitioners and there is concern regarding trivialisation of risks when services are provided outside the medical model.

- 1. Therapeutic Goods Act (Cmwlth) 1989 (current) Section 42DL (1) A person must not publish or broadcast an advertisement about therapeutic goods:
  - (a) that contains a prohibited representation (whether in express terms or by necessary implication) about those goods;
- 2.Botox, Dysport, Xeomin. Botox is indicated for Dysport is indicated for Xeomin is indicated only for glabella,. All other uses are off-label and no studies offered by the manufacturers for approval of use by the TGA
- ${\it 3. National strategy for quality use of medicines in Australia, Cmwlth Dept of Health 2002}\\$

Q4. Yes there is evidence of inappropriate use of qualifications that may mislead consumers. Subjectively at least, I believe this is less wide-spread among doctors with general registration than in earlier years due to actions taken by AHPRA where notifications have been provided.

Much has been made historically of doctors with general registration purporting to be surgeons. I know of only one recidivist in SA who continues to do this despite advice from colleagues.

It is common that surgeons purport to be experts in the administration of scheduled medications in cosmetic medicine, which is not necessarily true, and unlikely to be the norm.

The importance of this point is that cosmetic medicine has developed into a complex set of options and procedures and there is a reasonable case that this may be beyond the scope of practice (SoP) of surgery.

To illustrate the point that the management of medications in the community may require evaluation regarding the present scope of practice of surgery the Australian Pharmaceuticals Advisory Council (APAC) in 2006 (which remains current) produced *Guiding Principles for Medication Management in the Community*(1), as a result of six years consultation with what was considered as every stakeholder involved in prescribing, dispensing, administering and supervising the quality use of medicines in Australia. Surgery groups such as RACS, are absent from the Australian Pharmaceuticals Advisory Council's (APAC) membership list. The exemption of surgeons to participate in this consultation process relied on the basis that surgeons do not manage medications in the community.

The extent of expertise, training, experience and skill that is required to administer schedule prescription-only medications in cosmetic medicine has expanded widely and rapidly in the last five years but not without a comprehensive list of accompanying complications. The most comprehensive and recent account of these complications by an international consensus group headed by Belgian dermatologists De Boulle and Heydenrych (2) also covered 'crucial aspects of patient selection, including absolute contraindications as a well as situations that warrant caution' and declared

'The majority of complications are related to accepting patients inappropriate for treatment or issues of sterility, placement (dermal filler), volume and injection technique'.

Bovine Collagen was the only TGA approved dermal filler available in 1995 now the list of dermal fillers approved for use in Australia comprises many different manufacturers and substances today. The predominant substance is (HA) hyaluronic acid with at least four brands approved for use in Australia all with varying characteristics, applications and methods of administration. Sub-brands of HAs abound varying in consistency, cohesiveness, longevity, carrier protein content, with/without lignocaine and many other differences.

There is a host of non-HA dermal fillers now also including permanent polyacrylamide gel, and Poly-L-Lactic acid which cannot be removed easily.

But of the most importance is that the number of techniques, volumes, delivery systems, and wide anatomical distribution of these products is continuously expanding.

I am not aware of any AHPRA approved study program that provides teaching and performing cosmetic medicine in any specialist qualification. It is assumed this is absent

since it would be inappropriate to permit the practice of cosmetic medicine in the teaching hospital setting. Some surgeons who have acquired competency and expertise and who demonstrate cosmetic medicine procedures to other practitioners. However this is not exclusive to surgeons. There is no requirement for any practitioner to demonstrate competency by way of examination and logbook to perform cosmetic medical procedures. Industry organisations confer diplomas by examination however these are voluntary.

I am also not aware of an approved course of study as a specialist surgeon that contains any substantial content regarding pharmacology, which is the basis of matters relating to scheduled prescription-only medications.

There continues to be an assumption that surgeons automatically become competent in the procedures involving the administration of scheduled prescription-only medications in cosmetic medicine. There appears to be a groundswell of opinion, which I believe to be endemic at state and territory level medical boards that somehow, not only are surgeons competent in the use of prescription-only medications used in cosmetic medicine, but are supremely competent as the benchmark leaders in procedures involving these substances.

As a single example of this misconception, recently I was contacted by a surgeon(3) who had attempted to use a scheduled medication hyaluronidase to 'dissolve' polyacrylamide gel (Aquamid) previously injected into a patient's face. Hyaluronidase is reserved for the treatment to remove hyaluronic acid dermal fillers and is not indicated to 'dissolve' Aquamid and the attempt to use hyaluronidase may cause serious complications in its own right.

Another example is the use of hair removal lasers, although this is not confined to surgery practices that offer this service and delegated to others, upon patients concomitantly taking photosensitive medications (4) which predispose the patient to skin burns, permanent scarring and pigmentation.

Multiple cases of the use of topical local anaesthetic (5) which can be absorbed into the bloodstream and become toxic, with at least two fatalities recorded as another example of the importance of the understanding of pharmacology that is unlikely to be routinely understood by specialist surgeons for the reasons stated earlier. The use of high strength lignocaine gel is commonly applied in advance of many cosmetic medical procedures.

The general assumption that all surgeons are supremely competent and experts in cosmetic medical procedures is clearly misconceived and may mislead the public.

These principles also apply to a new wave of dentists performing cosmetic medical procedures. The current SoP of Dentistry is being challenged by entrepreneurial 'training' organisations for financial gain. Like nurses, dentists have consistently been heralded as one of the most trusted individual professionals by the Australian public. The public is entitled to believe that if dentists who offer cosmetic medical procedures (claiming they are used for

dental purposes and within the SoP of dentistry) that dentists have acquired the necessary training to be competent in the procedures offered. Like surgeons, dentists were not invited to contribute to the development of APAC's guiding principles in medication management in the community, because these principles are not required for dentistry.

Should surgeons (or dentists) ever claim to be competent and benchmark leaders in prescribing antihypertensives or treat patients with asthma with prescription-only medications for example, I would be confident that RACS, AHPRA, RACGP and the AMA would all present valid objections to that practice.

It is hard to understand why this same argument has not been evaluated regarding surgeons being automatically conferred as experts of some supremacy in cosmetic medical procedures involving the use of scheduled prescription-only medications.

Delegation of cosmetic medical procedures to nurses, by surgeons who are unable to demonstrate competence by collegiate examination and logbook of experience in the use of prescription-only medications in cosmetic medicine are unlikely to be familiar with APAC's guiding principles for the management of medications in the community, which is essential knowledge and it is arguable that this may render the use of prescription medicines beyond the SoP of surgery.

The National Strategy for Quality Use of Medicines (see answer Q3, reference 3) also states:

The six building blocks that support QUM are based on evidence and expert opinion about interventions, regulatory efforts and programs to improve medication use. They are:

- policy development and implementation;
- facilitation and coordination of QUM initiatives;
- provision of objective information and assurance of ethical promotion of medicines;
- education and training;
- provision of services and appropriate interventions; and
- strategic research, evaluation and routine data collection.

While the Health practitioners National Law Act does not permit the extension of SoP, the processes of basic training in cosmetic medicine, this does not confer experience on the individual and registrars-in-training in cosmetic medicine usually require two years mentorship before gaining competency.

Not only is it important for prescribers to have competency in prescribing and administering prescription-only medications in cosmetic medicine, it is my belief that it is insufficient for any surgeon to delegate procedures involving QUM to a non-doctor health practitioner, if there has been insufficient relevant post-graduate examination process undertaken by the prescriber, since there does not appear to be any recognized course of study of surgery which includes QUM, APAC's medication management in the community and the in-depth study of the pharmacology for those pharmaceuticals or those that interfere with

medications used in cosmetic medicine. This appears to be very similar to warnings plastic surgeons have issued historically regarding doctors who perform surgical procedures without surgical training.

There is evidence (6) of nurses using titles such as 'aesthetic specialist' and the like. This is misleading for the public.

Conclusion: There four (4) areas of concern regarding misleading qualifications

- 1. Doctors with general registration who hold out as specialist surgeons which has diminished,
- 2. Surgeons who continue to claim, or are assumed by the public to be competent in the use of prescription-only medications, and who have not received specific training and have not acquired logbook recorded competence in those procedures (which are increasingly changing and expanding) and are not members of key advisory panels on medication management in the community, or trained in QUM.
- 3. Nurses who claim to be 'specialists'
- 4. Dentists who claim in the public arena that two days instruction extends SoP of dentistry and provides expertise in cosmetic medical procedures, particularly extraoral injections of prescription-only medications

I recommend that the draft guidelines be amended to include provision that any procedures that have been learned beyond the SoP of any specialty be declared, and that evidence of competency be provided if called upon, in the same way that the declaration by all doctors is required confirming the acquisition of adequate medical indemnity insurance, when renewing registration.

1. Guiding principles for medication management in the community Department of Health and Aging (Cmwlth): 2006 List of contributors.

# Note the absence of consultation with surgical groups

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Aged and Community Services Australia
Alphalink
Australian Council of Community Nursing
Australian Council on Social Service
Australian Divisions of General Practice
Australian Government Department of Health
Australian Government Department of Veterans' Affairs

Australian Medical Association

Australian Nursing Federation

Australian Nursing Homes and Extended Care Association Ltd

Complementary Healthcare Council of Australia

Consumers' Health Forum

Council on the Ageing / National Seniors Australia

Dandenong District Division of General Practice

Department of Health, South Australia

Department of Health and Community Services, Northern Territory

Department of Health and Human Services, Tasmania

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Evans Community Options Project

Federation of Ethnic Communities' Council of Australia

Home Care Services

National Diabetes Strategies Group

guiding principles for medication management in the community

National Prescribing Service Ltd

New South Wales Health

Pharmaceutical Society of Australia

Pharmacy Guild of Australia

Queensland Health

Queensland Nursing Council

Royal Australasian College of Physicians

Royal College of Nursing, Australia

Royal District Nursing Services

- 2.De Boulle K, Heydenrych I, *Patient factors influencing dermal filler complications: prevention assessment and treatment*, Clin Cosm & Investig Derm 2015:8 205-214
- 3. Correspondence (de-identified) regarding treatment of patient with hyaluronidase (encl)
- 4..Molton M Post inflammatory hyperpigmentation in a patient under-going a light-based treatment while taking Amitryptiline: A case study Journal of Cosm Surg Vol 6:1,3 2012
- 5. Sobanko J, Miller C, Alster T Topical anesthetics for dermatologic procedures: A review Dept of Dermatology Derm Surg 2012:38:709-721

6.Google search results 'nu - Clinica		alists' t and cosmetic injecto	or	
a.	Cached			
b.	Similar			
has worked in	n leading plastic	surgery units in <b>Austr</b>	ralia and the United Kingdom.	s experience in all
aspects of plastic and recor	nstructive			
5.		LinkedIn		
a.	Similar			
Adelaide Area, Australia - N	lurse Injector at			
Nurse Injector at	(	Iniversity of	I am also Laser Safety	Certified, is a skin
specialist for Pigmentation	treatments,			
6.	Top 24 Cosmet	ic Nurse Injector prof	iles in Sydney   LinkedIn	
a.	Cached			
Cosmetic Nurs	e Specialist at	9	Sydney and	Canberra. location:

7. Cosmetic Nurse Jobs | Indeed.com

au.indeed.com/Cosmetic-Nurse-jobs

Sydney Area, Australia; industry: Medical ...

- a. Cached
- b. Similar

Jobs 1 - 10 of 33 - Cosmetic Injectors. Australian Skin Clinics - Australia. Submit Your Resume - Cosmetic Injector – REGISTERED NURSE. You must be a ... On going training and mentoring by Specialists and Cosmetic Nurses. Face Forward at ...

Meet our Medical Team |

C. Cached

d. Similar

Australia we have the largest team of Doctors and Nurses of its kind in ... All of our Cosmetic Injectors believe subtle changes that enhance your ... a cosmetic injection specialist since 2007 and a Registered Nurse since 1993.

8. About our Team -

- a. Cached
- b. Similar

She trained as an RN & midwife, working both in **Australia** and the UK where she ... is now a Cosmetic **Nurse** Injector and performs a vast range of ...

Q5. There is evidence that coupon sales continue to promote the unsolicited use of scheduled medications used in cosmetic medical procedures (1) As far as offers of finance, it is at least five years since the clinic I work at has been asked to recommend a source of finance for cosmetic medical procedures. This is significant because the facial rejuvenation procedures I perform are designed as integrated programs involving laser, dermal fillers, PRP, BTXA and other relevant processes. Often these programs will span a period of months and it is not uncommon for such programs to total \$6000-\$9000. I do not believe that there are significant numbers of patients who cannot afford to pay for procedures and who seek finance to do so, and subsequently find themselves in financial difficulties or have used funds reserved for day to day living expenses. Demographics of patients I see are predominantly highly functioning 35-65 years of age women 85%, men 15%.

I do worry however about the lower income and/or younger set, 20-25 yo women. These persons are more likely to choose price as a primary selector but all too often the service will be provided by an unsupervised nurse, or at a clinic that has no doctor on site and who 'Skypes' the 'supervised' nurse. This I believe also to be a much more serious issue of 'rushing' into procedures without the necessary time to consider risks. Even then, it is not so much lack of time to consider the procedure, but the pressures placed upon consumers to proceed using aggressively reduced-price inducements\*. Price inducements expose the intent to attract persons who otherwise may not consider cosmetic medical procedures and risk a lack of warning of potential side-effects and complications which are known risks due to trivialisation and/or omission. Omission may be intentional in the ordinary course of selling the procedure.

Specialist finance companies in my experience have been replaced by the readily available credit card funding. Where once there was Bankcard and MasterCard, and perhaps Diners and AMEX, there are now hundreds of institutions offering credit that could be used unwisely, but this is not limited to cosmetic procedures. Gaming, alcoholism, drug addiction, the sex-wrier industry, and any number of spontaneous uses of trendily available credit could all be found in this dilemma.

# 1.Examples of coupon sales advertised on the internet

Beauty Coupons. Save up t	o 70% on Beauty Coupons with
www.groupon.com.au/cou	pons/beauty
0	Cached
0	Similar
Rating: 5 - 113 reviews	
Save up to 70% with your E	Beauty Coupons or voucher. Don't miss out on fantastic daily Beauty Coupons Deal ends:
31/05/2015   15:59 Buy De	etails
Brisbane Beauty coupons a	and vouchers. Save up to 70% on
www.groupon.com.au/cou	<b>pons</b> /brisbane/beauty
0	Cached
0	Similar
Rating: 5 - 146 reviews	
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Mar 6 2012 She had prov	Similar  viously hought a <b>voucher</b> from the <b>discount</b> website. The clinic has advertised the <b>deal</b>

Mar 6, 2013 - She had previously bought a **voucher** from the **discount** website ... The clinic has advertised the **deal** extensively and, in a recent offer, ... According to the college, in **Australia** genuine **Botox** costs a doctor about \$5.67 a unit

Q6. As an accredited healthcare facility, where I work, protocols exist that require all complaints to be made in writing and investigated. There is a Medical Advisory Committee complete with an independent health facility surveyor, myself as medical practitioner and a senior member of administration. Patients are identified only by their patient ID number. In terms of adverse events, these are required to be entered into an Incident Report Book and audited. Where adverse events involve the administration of scheduled prescription-only medications, these are presented to the pharmaceutical company and, where necessary, the TGA. The numbers do not appear to be disproportionate although indexing against benchmarks has proven to be problematic due to the reluctance of other service providers to share incident records.

Adverse events of note I have seen recently have been delayed hypersensitivity reactions manifested as significant painful swellings lasting several weeks requiring ongoing prescription management in two patients undergoing dermal fillers. I do see on a regular basis, patients attending for consideration of remedial treatment following dysaesthetic outcomes and complications where treatment has been performed outside the medical model. In these cases it is common to subject the patient to injecting substances to dissolve the product, in some one can only wait for the product to be metabolized, or in the case of

permanent dermal fillers, referral is required for surgical removal, potential scarring and the associated surgical risks of intra and post-operative infection.

I have enclosed photographs of recorded complications of dermal fillers.

Q7 Further significance of the problem is that incidence of complications beyond facilities that record and audit them and otherwise evaluate recommendations of preventing further occurrences are few, are not reported to any central agency and many others are hidden. Therefore presently there is no reliable evidence of the magnitude of the problem.

One nurse ex-employee was found to avoid recording adverse events purposely, stating, 'I do not believe in making it known that I have made a mistake'. Fortunately, internal audits revealed this deficiency and was instrumental in separation of the employee from her employment. This view is not consistent with best practice and quality assurance. Non-reporting effectively constitutes avoidance of detection for commercial purposes when procedures using prescription-only medications occur outside the medical model in hairdressers, beauty salons, dentists and spray-tanning booths where many procedures are performed today. (1).

Also it is common for patients to experience guilt and embarrassment when suffering a complication. I have had patients say to me 'it was my own stupid fault, I should have known better' as if somehow the patient had failed to identify an obvious character flaw in the proceduralist's behaviour. Sometimes patients say, 'I can't believe I could be so vain to believe X, Y or Z procedure would get the result I was told I would get', and 'I should have asked more questions about what could go wrong'. Subsequently the patient shuns the idea of lodging a complaint, or even returning to the service provider to discuss the issue because it is interpreted by the patient as potentially too confrontational, embarrassing and self-blamed.

The medical model requires that patients are formally advised of their right to complain to improve service delivery and to assess requirements to change or improve. Importantly complaints provide the additional opportunity to collect previously unavailable data on adverse outcomes and incidents in cosmetic medicine.

# Conclusion:

The incidence of adverse events, and adverse outcomes in Australia in cosmetic medical procedures are unknown and cannot be benchmarked to clinical trials that have established risk profiles of the treatments which have been published in the medical literature and submitted to the TGA when they were approved.

When procedures are performed outside the medical model adverse events and outcomes are less likely to be reported by the service provider because of the perceived priority of commercial reasons and reluctance to complain by the recipient.

Cosmetic medical procedures should be performed in environments where effective infection-control measures, quality assurance and best practice protocols are monitored, audited, where recommendations are assessed to improve performance and reviewed as in accredited health facilities.



Jul 31, 2014 - **Botox**, **cosmetic** fillers and other injectables are increasingly popular for ... If you're thinking about one or more of these **treatments**, what do you need ... says Geoff Lyons, president of the **Australian** Society of Plastic Surgeons. Hair Straightening Treatments - HairSalons.com.au

www.hairsalons.com.au/straightening.htm

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www.gumtree.com.au/s-beauty+salon+botox/k0

Cached

Results 1 - 16 of 16 - Find beauty salon botox ads. Buy and sell almost anything on Gumtree classifieds.

I recommend that cosmetic medicine procedures be prohibited in non-medical environments such as beauty salons, hairdressers, nail salons domiciliary residences.

Q8. The current regulation of medical practitioners who provide cosmetic medical procedures are not specific in what constitutes 'proper assessment' as published in Section 2 Good medical practice- a guide for doctors in Australia. This has provided opportunity to entrepreneurial health practitioners and administrators of some large medical and surgical groups that purposefully and consistently seek ways around the regulations for financial gain and advantage over more ethically compliant health practitioners.

Using the example of electronic consulting (e-consulting) in cosmetic procedures, which is designed to benefit patients who cannot attend the doctor in person, be it mobility and transport difficulties or confined to remote and rural circumstances, in these circumstances, e-consults fulfil an unmet community need. The use of e-consults where the doctor is in Victoria and the nurse and patient is in South Australia attending for cosmetic medical attention at a non-medical facility, does not appear to constitute an unmet community need. There is little likelihood that mobility or transport difficulties exist as the patient has

favourably demonstrated access to the nurse's location. The process is apparently designed entirely to provide a service where the doctor is essentially not required to attend. There is no shortage of supply of the services sought which are located in more favourable environments where the prescribing doctor is present, in-person. Finally the procedures are elective, not as in the case of the elderly, or frail or incapacitated patient living at home in need of ongoing medical care.

The use of e-consulting in cosmetic procedures is at the benefit of the service-provider and there are considerable risks to the patient, and not appreciated by the patient. The acquisition of informed consent has been described as more onerous in cosmetic procedures and among the determinants is the understanding of the procedure, side effects, potential complications and an assessment of the patient's expectations. Many subtle indicators such as rapport with the patient, assessment of the level of health literacy, patient mood and affect all go towards what the lay population calls 'body-language' and doctors examine these systematically in the consultation process. This process and the physical examination itself is hindered by e-consulting\*.

The use of e-consulting for cosmetic procedures was banned by the General Medical Council UK (1) in 2012 on the basis that it was unsafe and inappropriate.

The Australian industry organisations that represent the largest body of doctors who perform cosmetic procedures all recommend that all patients be in the physical presence of the prescribing/treating doctor during consultation and written orders be provided just as in any other healthcare setting. (2,3)

Because of the entrepreneurial mix, e-consulting has been used to manipulate the patient to suit the cosmetic medicine service provider, but the risks of providing an elective procedure that is readily accessible in appropriate medical environments, is not an unmet community need, and when the patient has no mobility issues outweighs any advantage to the consumer.

Many patients express surprise when they are told that it is unlawful for nurses working without supervision performing cosmetic medical procedures offered in shopping centres, beauticians and hairdressers etc so this strongly suggests that the risks of the procedures become trivialized to the patient because of the trust the public has in the nursing profession.

Members of the practice of nursing in Australia have consistently been heralded by public opinion as the number one most trusted professions (4):

Ninety-one percent (up 1% to its highest since 2007) of Australians aged 14 and over rate nurses as the most ethical and honest profession – the  $20^{th}$  year in a row since nurses were first included on the survey in 1994

It could be said the practice of unsupervised administration scheduled prescription-only medications by nurses brings the profession into disrepute.

However, not all blame falls upon the opportunists. The opportunities may have been maximised by inconsistent decisions on notifications provided to the state and territory medical boards and nursing and midwifery boards. I only include the following as an illustration that state and territory boards have struggled to decide upon complex cases that differ dramatically from notifications compared to other areas of medicine.

It is my belief that this is an example of assumption that specialist surgeons are supremely competent in matters pertaining to practices that are not components of the recognized course of study of surgery, IE medication management in the community, and QUM.
In identical circumstances in 2014, the NSW Civil and Administrative Tribunal, HCCC v Piper disciplined the nurse for identical conduct to the notifications in SA with suspension and awarded costs of the proceedings against her.
Here I refer again to APAC's document Guiding Principles for Medication Management in the Community in my response to question 4, this time specifically to Section 11 Standing
Orders
The result of those decisions resonated throughout Australia and created an unfortunate precedence that has been followed throughout the country until HCCC v Piper reversed it in 2014.

Apparently the Medical Board of SA did not consult with the TGA on this question and as a result failed to apply the Health Practitioners National Law Act and discipline an act that appears to be a purposeful opportunistic financially-beneficial tactic to circumvent the regulations.

The cases in SA are not in isolation. Multiple notifications from doctors have received the same responses in other states, particularly Victoria.

It would appear that the application of the regualtions and guidelines is at best inconsistent by state and territory offices of AHPRA and seems to indicate that education regarding the investigation process involving cosmetic medical procedures and the need to consult with the notifier on appeal would be helpful.

It is questionable introducing new guidelines in cosmetic medical and surgical procedures will probably be ineffectual if this is not part of the overall strategy..

- 1. General Medical Council, Unite Kingdom, 2014, Good medical practice
  - 61. You may prescribe only when you have adequate knowledge of the patient's health, and are satisfied that the medicines serve the patient's needs. You must consider:
    - 1. a. the limitations of the medium through which you are communicating with the patient
    - 2. b. the need for physical examination or other assessments
    - c. whether you have access to the patient's medical records
- 2. Cosmetic Physicians Society of Australasia : Protocol for delegated cosmetic S4 injections (current)
- 3. Australian Society of Plastic Surgeons Policy Statement Administration of Botulinum Toxin by Nurses
- 4. Roy Morgan Image of Professions Survey 2014 Nurses still most highly regarded followed by Doctors, Pharmacists & High Court Judges

Q 9. The current regulations are inadequate as outlined in the response to Q8 regarding 'proper assessment for cosmetic medical procedures' as published in Section 2 *Good medical practice a code of conduct for doctors in Australia*. Just as importantly however are

the historical inadequacies of understanding of the current regulations by regional Medical Boards and NMWB on key issues pertaining to the prescribing laws of each region.

It is necessary to reiterate here the historical decisions made by the MBA of SA in regards to unsupervised nurses as cited in the previous question.

As in HCCC v Piper, AHPRA should have arrived at the decision that this conduct was unlawful pursuant to the Controlled Substances Act SA, Part 4 Section 18 1(1) which states:

# 18—Regulation of prescription drugs

- (1) A person must not prescribe a prescription drug (not being a drug of dependence) except as follows:
- (a) a registered health practitioner may prescribe a prescription drug (not being a drug of dependence) for a person if he or she is acting in the ordinary course of the practitioner's profession and—
  - (i) the practitioner is a dentist, medical practitioner or nurse practitioner;

Since the nurses were not nurse practitioners, the conduct I believe is unlawful prescribing which carries a criminal penalty of up to \$10,000 fine or two year imprisonment, and should, as in the case of HCCC v Piper, been referred to the relevant state prosecutor.

Below is the accepted collective health profession's description of what are 'standing orders' and guidance on application of the principles:

# Guiding Principle 11 – Standing Orders

The use of standing orders in the community for the administration of prescription medicines is generally discouraged. However, where standing orders are required in special circumstances, service providers should have policies and procedures in place for their use.

Standing orders provide a legal written instruction for the administration of medicines by an authorised person in situations where a prompt response using a standard procedure will improve consumer care and where a medicine is part of this procedure. A standing order is NOT a 'when required prescription' (PRN) for an individual consumer.

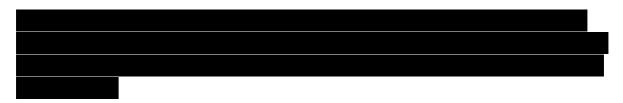
Where standing orders are required, for example in rural and remote areas and some immunisation programs, service providers should develop policies and procedures describing the development, authorisation, use and routine monitoring of the standing order. They must be in accordance with Australian, state and territory legislation and policy, and promote the quality use of medicines.

The decision to use a standing order is a clinical judgement and should be applied following an individual assessment in specific circumstances for an individual consumer.

All standing orders should be linked to a service provider's policies and procedures that are relevant to standing orders. All protocols for the use of standing orders should require that the order:

• is condition specific;

- is supported by or linked to appropriate clinical assessments;
- is clearly written, with the name of the medicine, dosage, route and frequency;
- identifies precisely which patients are to receive the medication;
- clearly states under which circumstances those patients are to be given the medicine, and conditions which are to preclude its administration;
- notes any special observations or care which may be required prior to, or subsequent to the administration;
- is not only signed, but the name of the authorised prescriber is legible;
- is clearly dated;
- is time limited and subject to regular review, that is, the service provider has set a period for review of this type of order where there is no legal time limit;
- is current (within that date);
- identifies who, either by name or by qualification (e.g. RNs), may administer the medicine;
- is supported by appropriate education or training for authorised persons using them.



I bring particular attention to "They must be in accordance with Australian, state and territory legislation and policy' in the APAC guidelines on Standing Orders. Citing the previous excerpt from the SA legislation, there is no provision for 'standing orders' in SA other than a specific 'Standing Drug Order (SDO) which pertains only and specifically to the administration of immunisations by authorised nurses,

And

They must.... 'promote the quality use of medicines' as referred to earlier (QUM).

Q10 See answer to Q9

Q11Yes

Q12 There is one cost that I bring attention to. When considering submissions from others please take into account what vested interests might be involved in those submissions. It is my belief that a number of surgical groups would support the status quo because a number of their members are financially involved in 'delegation' of cosmetic procedures to registered nurses, either remotely or within their own facility. One comment I received during a group discussion on this topic was 'you mean I will have to leave theatre to consult a patient every time my nurse wants to treat someone new with Botox and dermal fillers?' On another occasion, an ACCS member declared that he would not abide by any

requirement for him to make any assessment of patients receiving dermal filler and/or BTXA that his practice nurse was treating. This I believe provides a clear picture of how procedures using scheduled prescription-only medications are viewed by some surgical doctors. The procedures are I believe viewed as a 'sideline' a 'money-spinner' and not as procedures that carry risk and require significant expertise.

Q13 Consumer education material is extremely important and it should be a requirement for the practitioner to ensure this material is available for public viewing. Since most practices providing cosmetic medical procedures use social media and/or web hosting, it should be mandatory for all proceduralists to publish such information along with 'terms and conditions' which detail patients' rights and responsibilities and what protocols to resolve complaints is open to any patient who experiences conduct which may not be satisfactory. In my practice, all patients are provided with this information\* and it is a requirement that before proceeding with any consultation or treatment that the patient and the practice agree on each other's roles, rights, responsibilities and mechanisms of lodging a complaint and any appeal process that the patient is entitled to make to regulators and/or industry associations. In accredited practices, such policies and protocols must be regularly reviewed and updated.

Q14 The industry associations such as the CPSA, ACCS and ASAPs have all produced material that is generic and available for members to use. Recently I attended a neurosurgeon who provided a generic document produced by his association that was descriptive and objective regarding cervical spine surgery. On other occasions I have witnessed many similar documents in general practice, dermatology, audiology etc. So there are already many precedents for this recommendation. How AHPRA can regulate this is undeterminable, however I am of the opinion that should the requirement to publish objective information on procedures is established, a natural course of action would follow for the industry associations to embark upon this strategy, if they have not already done so.

Q15 The members of the industry associations, through those organisations.

Q16. I refer to Q1 regarding the prohibition of information on scheduled medications which severely impedes the public to ascertain factual information about products that are offered by practitioners. This issue continues to represent a significant cost to the consumer which requires the prospective patient to rely on patchy and often inaccurate information in magazines and unreliable sources.

Q17.1 I do not understand the nature of 'minor procedures'. All procedures in the hands of medical practitioners carry some risk, and it should be firmly understood that non-invasive procedures are only declared as such because the incidence of physical complications have been trivialized and true incidence is unknown if it be low or 'minor', however the financial risk should also be considered by the patient. There is a tendency that the paucity of

available information is often confined to the services of a single health practitioner that the patient decides to consult.

This is an important consideration because the patient is deprived of the potential availability of services that may be better than those offered by another practitioner.

A recent similar example outside cosmetic medicine (1) cites the consultation of Urologists who are alleged to provide information on radical prostatectomy and charging up to \$20,000, do not volunteer therapy with Radiation Oncologists which is readily available in the public health system which has demonstrated equal efficacy in the treatment of prostate cancer.

1.Lateline ABC 25/5/2015

Q17.2 yes

Q17.3 Yes, this is fundamental for any doctor and any procedure, cosmetic or otherwise. The skills involved in mental state examination surely are the domain of all medical practitioners. There is a case that purposefully ignoring signs and symptoms that pertain to body dysmorphic disorder (BDD) or traits of this disorder is likely to be regarded as unprofessional, but also extremely unwise as dire circumstances affecting the doctor are known to occur when such patients are accepted for procedures that clearly will not relieve the symptoms of BDD.

Q17.4 In my experience, when I have been confronted with patients who appear to demonstrate extreme reactions to minor blemishes, when this is put to the patient it is common for the patient to acknowledge this over-reaction and willingly accept the recommendation for referral. I believe it is common that many practitioners fear mental disorders and are reluctant to engage patients in conversations about referrals to mental health practitioners. Nevertheless, I am hopeful that part of the training in cosmetic procedures will provide insight and encouragement to be direct regarding these issues with the patient when such situations arise. Cosmetic medical practitioners must be able to identify and confront these concerns with the patient (1).

### 1. Correlates of dysmorphic concern in people seeking cosmetic enhancement

Aust N Z J Psychiatry. 2004 Jun; 38(6): 439-444.

NIHMSID: NIHMS12729

David J. Castle, Professorial Fellow

Mental Health Research Institute and University of Melbourne, 155 Oak Street, Parkville, Victoria 3052.

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Neil J. Preston, Research Psychologist

Fremantle Hospital and Health Service, Western Australia, Australia

Katharine A. Phillips, Director

Body Dysmorphic Disorder Program, Butler Hospital and Brown Medical School, Providence, Rhode Island, USA

Q17.5 I do not believe this should be a unilateral regulation. In my opinion, the practitioner should be competent in deferring treatment and refer only when there are clear indications for referral. The cost of a unilateral requirement to refer such patients will, in my opinion, mar the patient's already poor self-esteem with stigma which immaturity inevitably magnify in the patient's mind. No, this should not be a unilateral requirement.

1. Albertini R, Phillips K Thrty-three cases of Body Dysmorphic Disprder in Children and Adolescents J. Am. Acad. Child Adolesc, Psychiatry, 1999, 38(4):453–459

Q17.6 I cannot recall when last treated or saw someone under 18 years of age. I can tell you of some cases I have treated in this category. The youngest patient I have every treated was a 13 YO girl who had sever sweating of her hands (and feet). This patient was a and recently acquired scholarship to tour.

However, her sweating disorder threatened her playing and she attended myself with her parents. After deferring management on the grounds of a process of consulting with colleagues I agreed to treat her with BTXA, successfully. On another occasion a 19Yo boy pre4sented with parents regarding uncontrolled cystic acne, not responding to Roaccutane or any other treatments. The boy was clearly depressed and treated by his GP for this. Following a series of laser treatments, this patient responded remarkably psychologically, becoming less socially withdrawn and of normal health function.

So, no I do not agree that there should be further restrictions.

Q18 I do not believe there are other considerations in option 3.

Q19. I broadly agree with the stated costs and benefits other than my answers above

Q20 I have not identified other costs and benefits other than my answers above.

Q21. No, the costs are borne by those who should carry them and the benefits broadly are in favour of the consumer.

Q22. My opinion, based on twenty (20) years as a full time cosmetic medical practitioner that benefits of less explicit guidelines as described in Option 4 outweigh the costs.

Q23 The major cost, far outweighing the benefits, in Option 4 is that on previous adaptations of guidelines, entrepreneurial medical practitioners have exploited perceived interpretations to their benefit at a cost to the public. I cite these examples earlier, and I reinforce this concept with the current move of dentists to claim jurisdiction and scope of practice to perform cosmetic medical procedures. Clearly this is an example of financial gain above patient safety. There is not one logical explanation that links cosmetic medical procedures to dentistry and there can be only one reason why dentists are pressing this case, and that is financial motive.

Any attempt to muddy already murky waters is likely to be sought by those health practitioners who are monetarily dissatisfied with the revenue streams associated with their scope of practice or by those practitioners who seek to gain financial advantage over restrained and ethical practitioners.

Bending the law and guidelines has become commonplace in cosmetic medicine by registered nurses, dentists and entrepreneurial marketing groups. It is time for this to stop and the only way I can see this happening is if Option 3 is chosen and properly policed.

Q24 No, see answer Q23.

### Q25 I concur with the estimates

Q26 I would not say there are other viable options. I would say however that one other major issue is yet to be mentioned and that is the financial contribution that cosmetic medical procedures make to the collection of GST. GST is distribute to the States and Territories of Australia for hospitals and public infrastructure.

I fear that many 'back-yarders' do not make their fair share of contributions to this funding.

I would estimate that cosmetic medical and cosmetic surgical procedures produces a GST benefit of approximately \$100M annually, or it should do. In terms of costs to the community, where this figure is diluted, significant State and Territory resources are negatively affected, reducing the ability to provide adequate healthcare to all Australians who rely upon this.

It is my opinion that confining the administration of cosmetic medical procedures to a defined Specialty in Cosmetic Medicine (separating this from Cosmetic Surgery) that revenue streams generated by these procedures will be more accountable, with the result of genuine returns to States and Territories in the form of GST.

Establishing these Specialties will provide better quality control and adherence to ethical guidelines and, as a related benefit, provide Australia with international credibility that will attract overseas visitors seeking high quality cosmetic medical care.

Sadly, research into cosmetic medical procedures by Australian health practitioners is practically non-existent.

Presently I am an Assistant Investigator with an ARC linkage project in partnership with the University of Western Australia developing technology that objectively and quantitatively measures outcomes in cosmetic medicine.

My belief is that it is only recently that authorities have come to accept cosmetic medical procedures as being exactly that, medical. The sooner we all adopt this position unilaterally, the sooner Australia can claim world leadership and become the international destination for quality cosmetic medical procedures.

It is my firm belief that this journey of a thousand steps begins with Option 3.



# Guiding principles for medication management in the community

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Aged and Community Services Australia

**Alphalink** 

**Australian Council of Community Nursing** 

Australian Council on Social Service

**Australian Divisions of General Practice** 

Australian Government Department of Health

Australian Government Department of Veterans' Affairs

**Australian Medical Association** 

**Australian Nursing Federation** 

Australian Nursing Homes and Extended Care Association Ltd

Complementary Healthcare Council of Australia

Consumers' Health Forum

Council on the Ageing / National Seniors Australia

**Dandenong District Division of General Practice** 

Department of Health, South Australia

Department of Health and Community Services, Northern Territory

Department of Health and Human Services, Tasmania

Department of Human Services, Victoria

**Evans Community Options Project** 

Federation of Ethnic Communities' Council of Australia

**Home Care Services** 

**National Diabetes Strategies Group** 

National Prescribing Service Ltd

New South Wales Health

Pharmaceutical Society of Australia

Pharmacy Guild of Australia

**Queensland Health** 

**Queensland Nursing Council** 

Royal Australasian College of Physicians

Royal College of Nursing, Australia

**Royal District Nursing Services** 

St Luke's Nursing Service

# Introduction

Australia's **National Medicines Policy** aims to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved.<sup>1</sup> The policy has four central objectives, including the quality use of medicines (QUM). QUM means selecting management options wisely, choosing suitable medicines if a medicine is considered necessary, and using those medicines safely and effectively.<sup>2</sup>

The term 'medicine' includes prescription and non-prescription medicines, including complementary health care products.<sup>1</sup>

The National Medicines Policy advocates a partnership approach to promoting its objectives, recognising that governments—Australian, state and territory—health educators, health practitioners, and other health care providers and suppliers, the medicines industry, health care consumers, and the media have accepted a shared responsibility in this endeavour.

While medicines make a significant contribution to the treatment and prevention of disease, increasing life expectancy and improving the quality of life, they also have the potential to cause harm. It has been shown that inappropriate or incorrect use of medicines can have an adverse effect on health. The quality use of medicines can have a positive impact on health and can improve quality of life.

<sup>&</sup>lt;sup>1</sup> Commonwealth Department of Health and Ageing (2000). *National Medicines Policy*.

<sup>&</sup>lt;sup>2</sup> Commonwealth Department of Health and Ageing (2002). The National Strategy for Quality Use of Medicines.



## Background

The Australian Pharmaceutical Advisory Council (APAC) is a consultative forum that brings together key stakeholders from the medical, nursing and pharmacy professions, as well as industry, consumers and government, to advise the Australian Government Minister for Health and Ageing on medicines policy. APAC's mission is to develop, promote, influence and assist in the implementation of the National Medicines Policy in Australia, using a partnership approach to do so.

APAC has been addressing matters related to medication management for older people for some years. In 1997, APAC released guidelines for medication management in residential aged care facilities to address concerns in the residential aged care setting. The first two editions of APAC's *Integrated best practice model for medication management in residential aged care facilities* raised awareness about the quality use of medicines in residential aged care facilities and how a multi-disciplinary approach can improve health outcomes for residents. The 2002 review of these guidelines saw them renamed as *Guidelines for medication management in residential aged care facilities*.

After the third edition of the guidelines was disseminated in 2003, and in line with APAC's mission, APAC agreed that similar guidelines were needed for medication management in the community. It established the APAC Community Care Working Party to develop *Guiding principles for medication management in the community*. The working party included representatives from the medical, nursing and pharmacy professions, consumers, the Department of Health and Ageing, state governments, and the aged and community care industry.

Users of these Guiding principles for medication management in the community should be aware of the links with APAC's recently revised *Guiding principles to achieve continuity in medication management* and the *Guidelines for medication management in residential aged care facilities* and refer to them as needed.

#### Purpose and scope

Consistent with the approach of the National Medicines Policy, these guiding principles recognise that partnerships are important when support is being provided to consumers at home. They should include a range of health and community care providers.

The guiding principles aim to:

- promote the quality use of medicines and better medication management in the community
- assist service providers in developing or evaluating policies and procedures
- support those involved in assisting consumers

- support consumers in managing their medicine(s)
- guide health care professionals in developing and evaluating professional standards.

Health care professionals and care workers have a 'duty of care' to the people they support, care for, or advise. They must act reasonably to avoid foreseeable risk of injury, whether or not there are policies, guidelines or protocols relevant to the circumstances. When determining whether there has been a breach in duty of care, the standard of care that should have been provided will be considered.

Employers should be aware of their employees' levels of skill and knowledge, and provide the necessary training to ensure duty of care is met. They should not expect employees to perform tasks beyond their knowledge, skills, experience and training.

Employees should consider their own skills, experience, knowledge and limitations and inform employers if they do not understand or feel competent in performing any procedures.

Guiding principles for medication management in the community setting are essential, given the increasing numbers of people on complex medication regimens in their own homes. The guiding principles focus on older people as they are the greatest users of medicines, and more older people are living in the community.

These guiding principles are **intended only as a guiding document**. They are not prescriptive. The document sets out recommended parameters and procedures for medication management in the community. These guiding principles do not replace existing State or Commonwealth legislation. Service providers and health care professionals should refer to government, organisational and relevant health care professional policies on medication administration.

The guiding principles target paid health and community care service providers who support older people in managing their medicines in their home and in the community. They could also be used by other community-based services, such as those supporting people with disabilities or chronic disease.

The guiding principles could also be used by the following groups:

- consumer organisations
- service providers, including community care providers
- · health care professionals
- professional organisations, including regulatory authorities
- educational organisations
- governments Australian, state, territory and local
- consumers, carers and volunteers.

It is recommended that community-based services such as respite centres and transitional care facilities use APAC's *Guidelines for medication management in residential aged care facilities*.

These guiding principles may not be applicable in all rural and remote settings as they may not address the complexities in these settings. However, the guiding principles are broad and could help in establishing best-practice policies and procedures for medication management in these settings. Specific references have been made to Aboriginal and Torres Strait Islander health in some of the guiding principles. For example, Aboriginal Health Workers, Torres Strait Islander Health Workers and Aboriginal Medical Services are mentioned with respect to preparation of Dose Administration Aids (Guiding Principle 3), and Aboriginal Health Workers are recognised as having an important role in the administration of medicines (Guiding Principle 4).

When developing policies and procedures, service providers should consider the needs of people from Culturally and Linguistically Diverse (CALD) backgrounds.

## Consent to medical treatment, decision-making and impaired capacity.

It is important that everyone involved in the health care of a person is aware of the relevant Australian, state or territory legislation and/or standards that deal with substitute decision making. Legislation on substitute decision making, for example, guardianship, provides the means to involve a substitute decision maker in personal and health care decisions made on behalf of consumers who do not have the capacity to make decisions for themselves.

#### **Privacy principles**

A consumer's privacy is protected by the professional, ethical and legal obligations of health care professionals. Everyone involved in the health care of another person should be aware of their responsibilities in relation to privacy rights of that person.

In accordance with relevant legislation, service providers should develop policies and procedures that address the principles of substitute decision-making and privacy principles.

#### **Future directions**

Systems are being developed to assist consumers and those involved in their health care.

Health*Connect* is an overarching national change management strategy to improve safety and quality in health care by establishing and maintaining a range of standardised electronic health information products and services for health care providers and consumers.<sup>3</sup>

The strategy is a partnership between the Australian, State and Territory Governments which aims to leverage e-health systems in different parts of the health sector through a common set of standards so that vital health information can be securely exchanged between health care providers such as doctors, specialists, pharmacists, pathologists and hospitals and so on.

Privacy, security, consent and timeliness of information flows to improve the delivery of health services to all Australians are the hallmarks of this strategy.



## **Guiding Principles**

### Guiding Principle 1 – Information resources

All health care professionals and care workers should have access to current, accurate and balanced information about medicines. This will assist health care providers and care workers to provide consumers with appropriate information, including Consumer Medicine Information (CMI), and advice about medicine use, in a timely manner.

### Guiding Principle 2 – Self-administration

Consumers should be encouraged to maintain their independence for as long as possible, including managing their own medicines in a safe and effective way.

## Guiding Principle 3 – Dose Administration Aids

Dispensed medicines should be retained in the original manufacturers' or other dispensed packaging unless a Dose Administration Aid (DAA) could help to overcome specific problems that a consumer or care worker might face.

# Guiding Principle 4 – Administration of medicines in the community

Health care professionals, care workers and service providers all play an important role in making sure that consumers who live at home receive suitable information and/or assistance so that they take their medicines correctly.

## Guiding Principle 5 – Medication lists

Consumers should be supported in maintaining a current list of all their medicines. This list should be available and easily accessible to the consumer and all those involved in the consumer's care.

### Guiding Principle 6 – Medication review

Consumers are encouraged to have their medicines reviewed by members of the health care team. These reviews should follow the relevant professional guidelines.

## Guiding Principle 7 – Alteration of oral formulations

Some consumers might need to have oral formulations altered, for example, tablets broken or crushed to aid administration. However, some medicines cannot be altered and the consumer might need alternative formulations or different medicines instead. These consumers should be given the help they need to guarantee their medicines are managed safely and effectively.

## Guiding Principle 8 – Storage of medicines

Consumers using medicines in the community should be encouraged to store their medicines in a manner that maintains the quality of the medicine and safeguards the consumer, their family and visitors in their home.

## Guiding Principle 9 – Disposal of medicines

Consumers and/or their carers should be encouraged to return any unwanted, ceased or expired medicines to their local community pharmacy for safe disposal.

# Guiding Principle 10 – Nurse-initiated non-prescription medicine

Service providers should develop policies and procedures about the safe practices related to nurse initiation of non-prescription medicines.

## Guiding Principle 11 – Standing orders

The use of standing orders in the community for the administration of prescription medicines is generally discouraged. However, where standing orders are required in special circumstances, service providers should have policies and procedures in place for their use.

## Guiding Principle 12 – Risk management in the administration and use of medicines in the community

Health care professionals, care workers, service providers, and consumers and/or carers should work together to manage risks and incidents associated with medicine use in the community.



## Implementation Guide

This section provides some of the underlying rationale for the Guiding Principles as well as strategies for implementing them. It does not describe the resources needed to implement them. Each setting will be responsible for identifying and developing suitable resources, taking into account factors such as the needs of consumers and the size and the location of the service.

The Guiding Principles are worded so that they can be applied in a range of settings. It is expected that each setting will need to develop suitable strategies that reflect individual needs, resources and constraints. It is therefore possible that implementation plans will vary from setting to setting. Implementation strategies might also need to be placed in context, depending on the needs of individual consumers and the nature of the episode of care.

It should be noted that the Working Party intended that users of this document read the document as a whole, as some of the guiding principles contain information relevant to other guiding principles.

The documents referenced within these Guiding Principles are provided as references only and have not been endorsed by APAC (with the exception of those documents issued by APAC).

### Guiding Principle 1 – Information resources

All health care professionals and care workers should have access to current, accurate and balanced information about medicines. This will assist health care providers and care workers to provide consumers with appropriate information, including Consumer Medicine Information (CMI), and advice about medicine use, in a timely manner.

Health care professionals and/or care workers should establish the consumer's level of understanding of their medication including how to take it and what would happen if they don't. This should take into account the consumer's literacy and language skills, their cultural background and their medication regime. The following resources provide information about prescription and non-prescription medicines and complementary health care products. They are listed alphabetically within each section. Care workers and service providers who are supporting older people in the community and require further information about medicine(s) should consult the consumer's pharmacist and/or doctor.

#### 1. Resources for consumers, care workers and service

The resources listed below are either available for downloading from the website provided, or information on how to obtain the resource is available at the website or telephone number provided.

Examples of available resources for consumers, care workers and service providers include:

#### **Adverse Medicine Events Line**

The Adverse Medicine Events Line allows consumers to report or receive advice on adverse medicine events.

Telephone 1300 134 237

#### Australian Council for Safety and Quality in Health Care - 10 Tips for safer health care

The **10 tips for Safer health care booklet** has been produced by the Safety and Quality Council to assist people to become more actively involved in their health care. It explains how and why things can go wrong, and how consumers can work in partnership with their health care professionals to get the best possible care. The booklet also:

- gives 10 tips for improving health care, which include questions consumers might like to ask their health care professional
- outlines what consumers can expect from their health care professional
- lists some sources of information for consumers to find out more about their condition and how to manage medicines
- explains what consumers can do if they have concerns about their health care.

«---www.safetyandquality.org/index.cfm?page=publications#10tips----

#### **Consumer Medicine Information (CMI)**

CMI is designed to inform consumers about prescription and pharmacist-only medicines. CMI leaflets are brand specific and are produced by the pharmaceutical company that makes the particular medicine. They might be included in the medicine package, but can always be requested from the pharmacist or doctor. A CMI guide is available, which provides information about how CMI can be used by consumers and health care professionals to build better relationships to achieve the quality use of medicines. Refer to:

#### Health*Insite*

Health*Insite* is an Australian Government initiative, funded by the Department of Health and Ageing. It aims to improve the health of Australians by providing easy access to quality information about human health. Go to:

www.healthinsite.gov.au

**Medicines Line** 

*Medicines Line* gives consumers access to independent, accurate, up-to-date and specific information about medicines, provided by experienced medicines information specialists and clinical pharmacists.

Telephone 1300 888 763.

Medicines Talk

Medicines Talk is produced by consumers, for consumers, to encourage and promote quality use of medicines, especially among people who use multiple medicines.

Medicines Talk can be downloaded in PDF format from the NPS web site:

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«---www.nps.org.au/site.php?content=/resources/content/cons_medtalk.html----
Telephone (02) 8217 8700
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Medimate

Medimate is a brochure produced by the National Prescribing Service (NPS) to help consumers find, understand and use information about medicines. Medimate encourages consumers to do this in partnership with their doctors, pharmacists, and other health care professionals. Medimate covers prescription medicines, non-prescription medicines and complementary health care products. It includes advice about keeping healthy with and without medicines, how to use medicines safely, and using multiple medicines safely. Medimate also includes a special medicines list in which consumers can list their medicines and keep notes.

Available at:

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---www.nps.org.au---->, telephone (02) 8217 8700
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Medimate is available in the following languages:

- Chinese
- Greek
- Italian
- Vietnamese
- English

#### **Veterans' MATES**

Veterans' MATES (Medicines Advice and Therapeutics Education Services) is a Department of Veterans' Affairs program designed to address medicines usage by veterans and war widows and to reduce medicines misadventure. The Department works closely with the University of South Australia, Quality Use of Medicines and Pharmacy Research Centre, which has formed a consortium with the National Prescribing Service, Drug and Therapeutics Information Service, Australian Medicines Handbook, University of Adelaide Department of General Practice and Public Health, and the Pharmacy Department of Daw Park Hospital, for delivery of the program.

Veterans' MATES uses prescription data to identify veterans who may be at risk of medication misadventure and provides information which may assist in improving their medication management. GPs are provided with feedback on their veteran patients and information detailing current clinical guidelines through mailout. The program also provides educational materials to veterans and their carers to assist in improving medication management at home.

Veterans' MATES will deliver ten modules targeting specific clinical and therapeutic topics over the next three years. The modules will include material for GPs, other health care professionals and veterans.

#### 2. Selected additional resources for health care

#### **Adverse Drug Reactions Advisory Committee (ADRAC)**

The ADRAC encourages reporting of all suspected adverse reactions to medicines, including suspected reactions to new medicines, suspected interactions of medicines, and suspected reactions causing death, admission to hospital or prolongation of hospitalisation, increased investigations or treatment, or birth defects. The ADRAC produces the *Australian Adverse Drug Reactions Bulletin* six times a year. The bulletin lists current drugs of interest to ADRAC, and referenced information on drugs that are the subject of reports to ADRAC. Contact the ADRAC Secretariat:

Telephone 1800 044 114, email adrac@health.gov.au or refer to www.tga.gov.au/adr/index.htm

#### Australian Drug Information for the Health Care Professional (AusDI)

AusDI is a comprehensive, authoritative, unbiased source of drug and therapeutic information developed for Australian pharmacists, doctors, nurses and other health care professionals. It is a database of single and family generic drug information monographs, including the most commonly used complementary health care products. Information is available at:

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#### **Australian Medicines Handbook (AMH)**

The AMH provides a source of readily accessible, concise, up to date independent drug information to facilitate effective, rational, safe and economical prescribing. Available at:

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«---www.amh.net.au----», telephone (08) 8303 6977, email amh@amh.net.au
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#### Australian Medicines Handbook (AMH) Drug Choice Companion: Aged Care

This contains independent drug information that promotes safe and rational use of medicines in older Australians. Available at:

#### Australian Pharmaceutical Formulary (APF)

The APF and Handbook (APF) is designed to assist pharmacists in providing pharmaceutical services that promote optimal health outcomes through the quality use of medicines. APF-19 provides core information on therapeutics and standards of practice. Available at:

#### **Australian Prescriber**

Australian Prescriber is an independent publication providing readily accessible information about drugs and therapeutics. Available at:

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www.australianprescriber.com

telephone (02) 6282 6755,
email info@australianprescriber.com
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#### **Australian Prescription Products (APP) Guide**

The APP Guide contains a comprehensive listing of prescription product information approved by the Therapeutic Goods Administration (TGA) and compiled specifically for pharmacists. Available at:

## Central Australian Rural Practitioners Association (CARPA) Standard Treatment Manual

CARPA developed this manual as a guide to standard treatment for those working in remote and rural communities in Central and Northern Australia. Available at:

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www.carpa.org.au

telephone (08) 8950 4800

telephone (08) 8950 4800

www.carpa.org.au

telephone (08) 8950 4800

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#### MIMS Annual

MIMS Annual is a comprehensive, up-to-date drug reference system. It is classified by therapeutic class, fully indexed, and contains complete, detailed, approved prescribing information for over 2000 prescription and non-prescription drugs. Available at:

«---www.mims.com.au----», telephone 1800 800 629

#### **National Prescribing Services (NPS)**

The NPS is a not-for-profit Australian organisation established to provide a source of evidence-based information about medicines. The NPS is independent of government and the pharmaceutical industry. Available at:

Contact the NPS: telephone (o2) 8217 8700, email info@nps.org.au, facsimile (o2) 8217 7578, or refer to <a href="https://www.nps.org.au-----">www.nps.org.au------>

#### **RADAR (Rational Assessment of Drugs and Research)**

NPS RADAR provides timely, independent, evidence-based information on new drugs, research and PBS listings. It's published by the National Prescribing Service (NPS) for general practitioners, specialists, pharmacists, other health care professionals and consumers.

RADAR can be accessed over the internet, either by registering online to receive email alerts, or by simply logging on to the website. RADAR can also be accessed using one of the major prescribing software packages, or by emailing a request for a hard copy to:

info@nps.org.au or refer to <---www.npsradar.org.au---->

#### **Schedule of Pharmaceutical Benefits**

The Schedule of Pharmaceutical Benefits provides information about the arrangements for doctors and participating dental practitioners to prescribe pharmaceutical benefits, and the supply of pharmaceutical benefits by approved pharmacists, approved doctors and approved hospital authorities. Available at:

#### The Primary Clinical Care Manual (PCCM) 3rd Edition 2003

The PCCM is a major clinical reference and policy document developed by Queensland Health and the Royal Flying Doctor Service (Queensland Section). The PCCM is intended for use by Aboriginal Health Workers and Torres Strait Islander Health Workers, registered nurses and medical practitioners engaged in collaborative practice in rural hospitals, isolated practice areas and sexual health programs throughout Queensland.

The PCCM can be obtained from the Team Leader, Workforce Improvement, North Queensland Workforce Unit, PO Box 902, Cairns Qld 4870.

Telephone (07) 4050 8923, fax (07) 4031 0133.

#### **Translating and Interpreting Services (TIS)**

The Australian Government, through the Department of Immigration and Multicultural and Indigenous Affairs, provides a Translating and Interpreting Services (TIS) for people who do not speak English and for English speakers needing to communicate with them.

TIS is Australia's only national service and is available to any person or organisation in Australia requiring interpreting services. TIS is available 24 hours a day, 7 days a week, and is accessible from anywhere in Australia for the cost of a local call.

#### Telephone 131 450

The Doctors Priority Line is a fee-free service for eligible doctors or specialists to help them communicate with patients who do not speak English. It provides a prompt telephone interpreting service for medical practitioners and their eligible patients, and is also available 24 hours a day, 7 days a week, anywhere in Australia for the cost of a local call.

Telephone 1300 131 450

#### Therapeutic Advice and Information (TAIS) Line

The National Prescribing Service provides a Therapeutic Advice and Information Service (TAIS) for health care professionals. For the cost of a local call, the TAIS provides immediate access to independent drug and therapeutics information.

Telephone 1300 138 677, email tais@nps.org.au, web site <---www.nps.org.au---->

#### **Therapeutic Guidelines**

Therapeutic Guidelines are disease-oriented guidelines for prescribing. They provide clear, practical and succinct recommendations for therapy, derived from the best available scientific evidence. Available at:

Telephone 1800 061 260, email sales@tg.com.au, web site <---www.tg.com.au---->

3. Other useful web sites

Pharmacist-relevant sites (for links to medicine information resources). Go to:

#### Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)

The SUSDP and its amendments contain the decisions of the National Drugs and Poisons Schedule Committee regarding the classification of drugs and poisons into schedules for inclusion in the relevant legislation of the states and territories. Refer to:

#### State and territory drugs and poisons legislation

**Queensland** Health (Drugs and Poisons) Regulation 1996, available at

**Victoria** Drugs, Poisons and Controlled Substances Regulations

1995, available at \\ www.dms.dpc.vic.gov.au \\ \

**Western Australia** *Poisons Regulations 1965*, available at

**New South Wales** Poisons and Therapeutic Goods Regulation 2002, available

at \(\times\)www.health.nsw.gov.au/public-health/psb\(\times\)\)

**South Australia** *Controlled Substances (Poisons) Regulation 1996*,

**Tasmania** Poisons Regulation 2002, available at

Northern Territory Poisons and Dangerous Drugs Act 1983, available at

Australian Capital Territory The Drugs of Dependence Act 1989, available at

#### **Therapeutic Goods Administration (TGA)**

The TGA is a unit of the Australian Government Department of Health and Ageing. The TGA carries out a range of assessment and monitoring activities to make sure that therapeutic goods available in Australia are of an acceptable standard, with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances. Refer to:

Take care when sourcing information from the Internet. Health care professionals and care workers are responsible for accessing and providing accurate, up-to-date, independent information from an objective source, for example, Health*Insite*, or the National Prescribing Service. Information sourced from the Internet should not be used as a substitute for medical or professional health care advice and should not be used to diagnose, treat, cure or prevent any disease. Before relying on information found on websites listed in this document, users should carefully evaluate its accuracy, currency, completeness and relevance for their purposes, and should obtain any appropriate professional advice relevant to their particular circumstances. APAC can not assume any liability for the content of Web sites listed in this document.

### Guiding Principle 2 – Self-administration

Consumers should be encouraged to maintain their independence for as long as possible, including managing their own medicines in a safe and effective way.

Consumers should be encouraged to self-administer their medicines (including prescription and non-prescription medicines and complementary health care products). It is important that all health care professionals and care workers respect the need for consumers to maintain their independence with the administration of their medicines. Consumers might want to administer only some of their medicines (for example, consumers could take oral medicines, but might require an authorised health care professional to administer injections). Health care professionals and care workers should support consumers in their choice of self-administering their medicines.

As a team approach to addressing issues regarding self-administration of medicines is an advantage to the consumer, health care professionals and care workers should communicate with each other and the consumer/carer. To enhance the quality use of medicines, if consumers use more than one prescriber and dispenser, they should share information about their medicines with the other prescribers and dispensers.

Health care professionals and care workers should encourage consumers to talk to their prescribers and pharmacists about all of their current medicines. In particular, prescribers should talk to consumers about the safe and effective use of all their medicines, including prescription and non-prescription medicines, and complementary health care products, and the potential interactions between these.

If there is doubt that a consumer is able to safely administer and store their medicines (refer to Guiding Principle 8 – Storage of medicines), a health care professional, in consultation with those involved in the consumer's care, should conduct a formal assessment (for example, Home Medicine Review (HMR), Enhanced Primary Care (EPC) Care Plan and or Case Conference or other self-administration assessment tools). Should a care worker or carer find that a consumer is having difficulty in administering their medicines, the care worker should alert their supervisor to the need for a formal assessment by a health care professional. Carers should be encouraged to discuss the problem with the care worker who can discuss this with their supervisor.

All support strategies should be trialled with consumers, carers and/or care workers before a health care professional is engaged to manage medicines. Strategies might include the provision of Dose Administration Aids (DAAs) or engaging a nurse or care worker to help with aspects of administering medicines (refer to Guiding Principle 4 – Administration of medicines in the community). Any strategies in use should be documented in the consumer's record. Provision of Consumer Medicine Information (CMI) and organising a HMR might help a consumer to administer medicines safely and in a way that suits their needs (refer to Guiding Principle 6 – Medication Review).

The situation should be reassessed as necessary, for example, when the consumer, carer, or those involved in the consumer's care (such as nurses and care workers) notice that the consumer's ability to manage their own medicines has lessened. If the assessment is that the consumer is unable to continue administering their own

medicines, for example, due to physical or cognitive impairment, a strategy for future medication management should be discussed with the consumer and/or carer, nurse, doctor, pharmacist or care worker as necessary, and agreed upon by the consumer.

Attention should be paid to a consumer who is returning home from hospital and who might need extra support to administer their medicines for a time (see APAC's Guiding principles to achieve continuity in medication management).

Documentation on self-administration should show whether a consumer is administering their own medicines, any potential problems, and any strategies in place to make sure the consumer is administering and storing medicines safely and in compliance with the instructions. Information regarding possible adverse health outcomes that could be caused by a potential medicines interaction, or possible adverse effects, should be made available and/or discussed with the consumer and documented.

Provided that the chosen method is safe, nurses, Aboriginal Health Workers and Torres Strait Islander Health Workers or care workers should support the consumer's chosen method of self-administration and to remain independent. Such a method might include the use of a dose-administration aid (refer to Guiding Principle 3 – Dose Administration Aids). The health care professional should continue to provide information to the consumer about their medicine management.

Health care professionals are responsible for discussing with the consumer any other options for administering medicines (such as pump delivery systems, patches or inhalation devices) that can help a consumer to self-administer medicine or ensure that a carer is able to administer medicines at home. The nurse and/or Aboriginal Health Workers / Torres Strait Islander Health Worker and/or doctor and/or pharmacist are to give the consumer and/or their carer information to ensure that they understand how to use such administration systems properly.

Where possible, in situations where palliative care or complex pain management is required and a syringe driver device or other system cannot relieve 'break-through pain', it might be necessary for an authorised health care professional to prepare a syringe (for either break-through medicines or reloading a syringe driver) for a consumer or their carer to administer when the nurse is not available. The regulations and legislation that apply to the preparation and labelling of syringes and the possession of Schedule 8 substances differ between jurisdictions.

Service providers should have clear policies and procedures for these circumstances, including who is authorised to prepare syringes, documentation, and storage and infection control. Where a nurse prepares a syringe for a consumer or carer to use, as per the prescriber's orders, a detailed label should be placed on the syringe. The label should be fixed to the immediate container and state the:

- consumer's name
- · date and time of preparation
- indications for use
- consumer's date of birth and Unit Record Number (if applicable)

- name of medicine and where necessary dilution fluid/diluent
- dose of medicine (total amount of drug being delivered, for example, in mg) and, if applicable, total volume of solution (containing the dose) being delivered (mL).
- total volume of solution being delivered (in mL), as applicable
- start and finish time of infusion, as applicable
- · "discard by" date and time

The label should also include provision for the nurse's signature, name and designation, and any appropriate warnings, such as **KEEP OUT OF REACH OF CHILDREN**.

It is recommended that service providers use pre-printed labels to meet these requirements and to ensure legibility.

The relevant health care professional should provide clear instructions to the consumer and/or carer in accordance with the prescription. Reviews of medication management should continue in order to streamline medication management for consumers and carers in their home.

Where a consumer has ordered an overseas medicine to be self-administered and used for their personal use, and the medicine is not registered in Australia, the nurse, carer or care worker should follow the service provider's policies and procedures on managing overseas medicine, or contact the pharmacist or a medicine information service for relevant information, including monitoring for possible signs of side effects. In such cases, the consumer should be encouraged to consult their relevant health care professionals.

If a consumer or their carer is unsure about the administration of any medicines, the consumer's doctor, pharmacist or nurse should use resources such as CMI to explain the medicine's purpose, use and administration. Care workers should refer consumers to their doctor, pharmacist or nurse for advice on questions about medicines (refer to Guiding Principle 4 – Administration of medicines in the community).

## Guiding Principle 3 – Dose Administration Aids

Dispensed medicines should be retained in the original manufacturers' or other dispensed packaging unless a Dose Administration Aid (DAA) could help to overcome specific problems that a consumer or care worker might face.

A DAA is a device or packaging system for organising doses of medicines according to the time of administration. Different types of DAAs include blister or bubble packs, compartmentalised boxes, and compliance packs such as those provided by automated medication dispensing systems. A DAA is a tool to be used in a coordinated approach to medication management.

There are safety limitations to the use of DAAs. They might be difficult to label with medicine information or cautionary labels unless they have been specifically designed for such labelling, and they might not be tamper-evident. DAAs might not be suitable for all consumers and their use should be considered carefully. Some consumers might find it difficult to use a DAA, for example, a person with rheumatoid arthritis or other physical disability. The cost of a DAA might also make it an unsuitable aid for some consumers. It is important that consumers or their carers are supported in making informed decisions about the aid that most suits their needs.

The legislation and service provider policies applying to DAAs will differ between states and territories.

#### Assessment

Assessments to identify consumers that may potentially benefit from the use of DAAs could be conducted by a health care professional upon the request of the consumer or a carer or another health care professional. Carers, families, care workers, community pharmacists, community nurses, doctors and other health care professionals all share a role in identifying any concerns about a consumer's ability to manage their medicine.

Consumers who are using DAAs should be monitored in the same way as all other consumers to make sure that they continue to administer medicines safely (refer to Guiding Principle 2 – Self-administration).

#### Preparation

DAAs should be packed and fully labelled either by a pharmacist or under the supervision of a pharmacist, in accordance with professional guidelines.<sup>4</sup> The pharmacist should sign off that the correct medicine(s) have been packed into the DAA, in accordance with professional standards and guidelines.<sup>5</sup> In some states and

Pharmaceutical Society of Australia (1999) Dose Administration Aid Guidelines. July 1999. —www.psa.org.au/media/ACF9EF4.pdf—

<sup>5</sup> Pharmaceutical Society of Australia (2002) Dose Administration Aid Standards. Version 2.

territories, a health care professional other than a pharmacist, that is, a registered nurse or Aboriginal Health Worker or Torres Strait Islander Health Worker, might fill a DAA. Nurses and Aboriginal Health Workers and Torres Strait Islander Health Workers should refer to relevant legislation, guidelines and service provider policies for when this may occur.

Only solid oral medicines can be packaged in a DAA.

The following should not be placed in a DAA with other medicines:

- · medicines administered on an 'as required' basis
- solid dose cytotoxic preparations
- medicines unsuited to this form of storage due to their instability if exposed to heat, light, air or moisture, for example, effervescent, dispersible, buccal and sublingual tablets, and significantly hygroscopic (moisture absorbing) preparations
- medicines that might be affected when the backing of a DAA is heat-sealed, for example, soft gel caps.

If the pharmacist is not packing the DAA, information about medicines that might be unstable in a packaging system should be sought from a pharmacist, medicine information service or product information before the system is packed.

A consumer might want to have complementary health care products and non-prescription medicines included in the DAA. The pharmacist should check for potential interactions and other considerations and with the consumer's consent, inform the prescriber.

The DAA should be returned to the pharmacist for repackaging if there are any changes to the consumer's medicines. It is the responsibility of the prescriber to notify the pharmacist, carer, health care professional and/or care worker of any changes, with informed consent from the consumer and/or carer (refer to Guiding Principle 5 – Medication lists).

#### **Procedures**

The pharmacist should verify a medication order with the prescriber where necessary. Communication protocols should be set up between the prescriber, the pharmacist, carer and care worker or nominated responsible person.

Pharmacists should keep a master copy of each consumer's medication profile and should only make changes according to written or direct communication from the prescriber. These communications should be recorded and stored according to professional guidelines.

#### Labelling

The DAA should be clearly labelled with:

- · details of the person packing the medicine(s) in the DAA
- the name, strength and form of all medicines supplied in the DAA, to enable identification of individual medicines
- · directions for the use of each medicine
- date of filling
- date and day of week the medicine is to be administered
- any specific instructions about the use of the medicine, including cautionary and advisory labels, including KEEP OUT OF REACH OF CHILDREN, and information about alteration of the dosage form where appropriate (refer to Guiding Principle 5 Medication lists)
- any other details as required by relevant Australian, state and territory legislation
- an indication in a prominent position that other medicines are contained in another DAA pack/s and are to be administered (e.g. 1 of 2 DAAs) as applicable.

The print font used should be of a size and type easily readable by the consumer.

Labelling should include both the brand and the active ingredient names, reference to the colour, shape and size of the medicines, as well as manufacturer's marks that have been made on each product.

All or part of a consumer's medication regimen might be provided in a DAA. Where medicines are ordered for a defined short-course treatment, or in a complicated regimen, or where there are specific requirements regarding timing of administration in relation to meals and other medicines, such medicines should be in their original container or unit dose packs. Prompts should be given on DAA labels that the consumer is taking other medicines.

#### Role of care workers

A care worker should only physically assist a consumer in using their DAA if the consumer is responsible for their own medication management, and where agreement has been reached between the consumer and service provider in accordance with relevant Australian, state or territory legislation.

The care worker might remove medicines from a DAA or prompt a consumer to remove and take the medicine. Care workers should have competency-based training in accordance with organisational policy and Australian, state or territory legislation. Care workers should monitor medication management by consumers and be guided by their organisations' medication management policies and procedures if there are any suspected adverse medicine events.

#### Provisions for registered nurses

#### **Preparation**

All efforts should be made to have a DAA packed by a pharmacist. A registered nurse should only pack or re-pack a DAA if a pharmacist is unable to do so, if a consumer will self-administer medicines, and if the consumer's health and welfare is at risk if the registered nurse does not do so. This practice should be restricted to 'special circumstances' and should comply with relevant Australian, state or territory legislation, as some states restrict the re-filling of DAAs by registered nurses, as well as being in accordance with organisational policy. Before packing a DAA, the nurse should liaise with the doctor and dispensing pharmacist to obtain all relevant information.

A carer or another nurse cannot administer medicines contained in a DAA that has been packed by a registered nurse.

A registered nurse packing a DAA should document this activity in the consumer's clinical record or notes. Labelling of the DAA by the registered nurse should also be in accordance with organisational policy.

#### Administration

It is preferred that a registered nurse administer medicine from the container in which the medicine was originally dispensed, however, if a consumer has been supplied with a DAA (which has not be packed by a registered nurse), a registered nurse should only administer these medicines if they have a prescriber's order and the medicines can be clearly identified from labels that state the name, colour, shape and details of manufacturers' marks. A registered nurse cannot administer medicines that are not clearly identifiable.

#### Quality assurance

#### Safety and quality

The DAA should contain features that will show if the container has been tampered with before the medicine has been administered, depending on the individual requirements of the consumer receiving the medicines. If a care worker is to help a consumer use their DAA and it is evident that the DAA has been tampered with, it should be returned to the pharmacist for repacking.

In the event of a dosage or medicine change where the consumer is self administering medicine from a DAA, the DAA should be returned immediately to the pharmacy or Aboriginal Medical Service for re-packing and re-delivery. The registered nurse, care worker or community care provider should liaise with the consumer about returning the DAA to the pharmacy and arrange alternate supply where necessary.

Quality assurance activities should be implemented to make sure packing processes are audited regularly.

#### Consumer Medicine Information (CMI)

Even when medicine is supplied in a DAA, CMI should be provided, in accordance with professional guidelines.

# Guiding Principle 4 – Administration of medicines in the community

Health care professionals, care workers and service providers all play an important role in making sure that consumers who live at home receive suitable information and/or assistance so that they take their medicines correctly.

Communication and coordination between health care professionals, care workers and service providers providing care for a consumer living in the community are essential elements for safe and effective medicines administration. This becomes particularly important when a consumer is unable to take responsibility for their own medicines and /or their carer needs help in managing and/or administering the consumer's medicines.

Many consumers may have a family member or other person involved in their day to day care. Carers should be involved in medication administration and /or management as appropriate in individual circumstances, for example, care of children.

State and Territory legislation varies in the extent to which it regulates the administration of medication once it has been prescribed and dispensed for an individual. However, legislation regulating professional groups (such as Nurses Acts) and the guidelines for government funded programs (such as HACC program) may set out rules controlling the circumstances in which different groups of professionals and other care workers may administer medicines.

For the majority of people living at home with functional disabilities arising from frailty or other causes, their doctor is their health care manager and the main provider of health care services. Where they are unable to manage their own medicines due to physical or cognitive limitations, decisions need to be made about the most suitable worker or person such as a family member to assist them.

Pharmacists can assist by dispensing medicines with labelling and packaging that facilitates their use by persons with functional disabilities (for example, alternative closures to child resistant closures, larger print on labels, labels in another language in addition to English).

#### The role of service providers

All relevant legislation and guidelines should be taken into account by service providers in determining their own policies, guidelines, protocols and training for the administration of medicines to people living in the community, including the recording of information relating to the administration of medicines, for example, medication charts. Service providers should have policies that identify those circumstances when the service provider does not authorise staff to administer.

Service providers should ensure that an up-to-date record of the consumer's medicine is kept on the consumer's file. There should be clear instructions on a consumer's care plan about what steps the care worker will take to support a consumer and/or their

carer in the administration of medicine. All care workers should be guided by their organisation's policies and procedures for the administration of medicine.

Employers should be aware of their employees' levels of skill and knowledge, and provide the necessary training to ensure duty of care is met. They should not expect or require employees to perform tasks beyond their knowledge, skills, experience and training.

#### Administration of medicines by nurses

Nurses are authorised to administer medicines according to the relevant state or territory legislation, and policies. Service providers should have policies that identify those medicines the service provider does not authorise staff to administer.

Delegation of the administration of medicines by registered nurses should be in accordance with policies and guidelines of relevant nurse regulatory authorities and state or territory legislation and regulations.<sup>6</sup>

As part of their role, registered nurses are required to understand the therapeutic action of medicines, including the reason for their use and the effects of use. Registered nurses use clinical judgement to assess if medicines should be administered or withheld in view of a consumer's clinical status. If a dose is not taken for other than predetermined or prescribed reasons, such as refusal, the registered nurse must consult the prescriber. Registered nurses also have a role in educating carers about the safe and appropriate administration of medicines.

In addition, registered nurses need to use the following professional standards to assist in administering medication: the right medicine must be administered to the right person in the right dose at the right time via the right route. All medication administration should be documented.<sup>7</sup>

Registered and authorised enrolled nurses can administer medicines only when an authorised prescriber has prescribed the medicine. Australian, state and territory legislation, together with organisational policies, define some medicines as potential nurse-initiated medicines. These medicines can be administered by a registered nurse without authorisation by an authorised prescriber. They include some Schedule 2 and 3 medicines (refer to Guiding Principle 10 – Nurse-initiated non-prescription medicine).

The practice of registered and enrolled nurses is bound by Nurses Acts in each state and territory and nurse regulatory authorities set up pursuant to those Acts and regulations.

<sup>&</sup>lt;sup>7</sup> Forrester K and Griffiths D (2001) Essentials of law for health care professionals. Harcourt, Australia p.328.

#### Administration of medicines by Aboriginal Health Workers

Aboriginal Health Workers play a unique and pivotal role in the health care of Aboriginal people in the community. They are recognised as an integral part of the primary health care provider team.

Some states and territories have made legislative provision for Aboriginal Health Workers to administer some medicines such as immunisations and antibiotics. To be able to administer medicines, Aboriginal Health Workers must be authorised to do so according to legislative provisions and service provider policies and guidelines.<sup>8</sup>

#### Role of care workers in supporting the administration of medicine

Care workers should refer to organisational policies on the administration of medication.

Most states and territories have legislation that provides for some care workers to administer medicines, for example, disability workers in Tasmania. A trained and competent care worker can therefore help when a consumer or their carer requires physical assistance to administer the consumer's medicines (refer to Guiding Principle 3 – Dose Administration Aids).

Care workers in some jurisdictions are generally able to help consumers who are responsible for managing their own medicines, by unscrewing bottle lids, removing tablets from dose administration aids. It is important that all care workers are educated and competent to assist the consumer with medication management. Some care workers have completed a vocational education course, such as an Australian Qualifications Framework Certificate III in community services or its equivalent. There is a unit of competency that prepares community care workers to physically assist consumers in the community with their medicines.<sup>9</sup>

Care workers should only provide services that are consistent with their level of training and competence. The delivery of care will depend on the consumer and their health care needs. Care workers are not authorised to make any decisions about whether the medicine should be administered and should seek assistance from their supervisor if they have any concerns about medication management.

Where a consumer runs out of their current supply of medicine, care workers should seek the advice and/or assistance of the consumer's doctor, pharmacist, registered nurse, or the usual source of supply, for example, Aboriginal Medical Service, as dictated by the particular circumstances.

See, for example, the Northern Territory Poisons and Dangerous Drugs Act 1983

<sup>9</sup> See <---www.cshta.com.au--->

## Guiding Principle 5 – Medication lists

Consumers should be supported in maintaining a current list of all their medicines. This list should be available and easily accessible to the consumer and all those involved in the consumer's care.

All consumers are encouraged to keep a list of all of their current medicines, including prescription and non-prescription medicines, and complementary health care products. Health care professionals, care workers and carers should actively encourage this practice regardless of whether medicines are being self-administered or administered with assistance. This list should be updated by the consumer and/or carer, with assistance from a health care professional if required. Consumers might choose the prescriber-generated list or alternate forms such as *Medimate*<sup>10</sup> or Medilist<sup>11</sup>.

At a minimum, the medication list should include:

- The consumer's complete name, address and date of birth.
- The name and contact details of the consumer's doctor/prescriber and pharmacy.
- Details of all medicines the consumer is currently taking, including brand name and active ingredient, strength and form, dose, frequency, route, duration and indication.
- Any allergies and previous adverse drug reactions that the consumer has experienced.
- Details of any vaccinations the consumer has received.

The health care professional, care worker or carer should confirm with the consumer that they understand any changes to their medication regimen (including brand substitution) and the need to update the medication list accordingly.

The medication list should indicate whether the consumer is receiving assistance with the administration of any of their medicines (refer to Guiding Principle 4 – Administration of medicines in the community).

The medication list should be kept with the consumer's medicines and be accessible at all times to the person responsible for administration of these medicines. It should be available to all involved in the consumer's care so that it can be easily produced for reference by other health care professionals or health services, for example, in an emergency.

Informed consent to share information on the consumer's medication list with others involved in the consumer's care, for example health care professionals and providers,

<sup>10 &</sup>lt;---www.nps.org.au---->

<sup>11</sup> Available from most pharmacies

should be obtained from the consumer. It is recommended that the consent be obtained in writing and include the following information about the consumer:

- full name
- date of birth
- what the consumer is consenting to, for example, sharing of information on the consumer's medication list with other services.

The consent should be signed and dated by the consumer or the carer and a witness. The consumer should be given a copy of the signed consent.

If a medication management review is conducted and there are changes to the medication regimen, the medication list should be updated accordingly (refer to Guiding Principle 6 – Medication review).

When a consumer returns home from hospital, an outpatient appointment or another health care facility, the consumer and/or carer, the health care professional or care worker should compare details of the medication list with the medication details provided by the hospital or facility, and update the list accordingly. If there are any changes to the previous medication regimen, the community pharmacist and doctor or authorised prescriber should be contacted for further instructions before medication is administered by the consumer or the health care professional, care worker or carer. (Further information is available in *APAC's Guiding principles to achieve continuity in medication management*).

### Guiding Principle 6 – Medication review

Consumers are encouraged to have their medicines reviewed by members of the health care team. These reviews should follow the relevant professional guidelines.

As part of good quality care, it is essential that all medicines be reviewed regularly. A comprehensive medication management review should be undertaken in accordance with the relevant professional guidelines. <sup>12</sup> Reviews should involve collaboration between the consumer and/or carer and appropriate members of the health care team, for example, doctor, pharmacist, nurse, other health care professionals, Aboriginal Health Workers and Torres Strait Islander Health Workers and care workers.

Home Medicines Review (HMR), (also known as Domiciliary Medication Management Review), is a service to consumers living at home and is a formalised medication review carried out within an agreed process. The goal of HMR is to maximise an individual consumer's benefit from their medication regimen, and prevent medicine-related problems. HMR is based on a team approach that involves the consumer's general practitioner and preferred community pharmacy, and other relevant members of the health care team such as nurses, Aboriginal Health Workers, Torres Strait Islander Health Workers or care workers. It uses the specific knowledge and expertise of each of the health care professionals involved. When a consumer's general practitioner believes that the consumer would benefit from HMR, the general practitioner can arrange the review with the consumer's consent. A consumer's general practitioner can also arrange a HMR following a request from a pharmacist, nurse, Aboriginal Health Worker, Torres Strait Islander Health Workers, consumer and/or carer, or other health care professional. It is preferable to conduct the HMR in the consumer's home.

During the HMR, an accredited pharmacist will comprehensively review the consumer's medication regimen (including prescription and non-prescription medicines and complementary health care products). The pharmacist will discuss with the consumer how the consumer takes his or her medicines and any difficulties or uncertainties about them. The pharmacist will then talk to the general practitioner about the results of the home visit, and the general practitioner and the consumer and/or carer will then agree to a Medication Management Plan. The consumer and/or carer, and the general practitioner, are central to the development and implementation of this plan.

It is recommended that service providers have access to the Medication Management Plan and identify any need for further support. As these plans are the property of the consumer, the health care professional or care worker should request access to the document so that they are aware of the results of the review.

Following are the eligibility criteria for such a review as agreed by the Australian Government Department of Health and Ageing<sup>13</sup>:

The review can be offered to any (consumer) for whom the GP feels it is clinically necessary to ensure quality use of medicines or address (consumers) needs. Some examples of risk factors known to predispose people to medication-related problems include:

- currently taking 5 or more regular medications
- taking more than 12 doses of medication/day
- significant changes made to the medication regimen in the last 3 months
- Medication with a narrow therapeutic index or medications requiring therapeutic monitoring
- symptoms suggestive of an adverse drug reaction
- sub-therapeutic response to treatment with medicines
- suspected non-compliance or inability to manage medication related therapeutic devices
- (consumers) having difficulty managing their own medicines because of literacy or language difficulties, dexterity problems or impaired sight, confusion/dementia or other cognitive difficulties.
- (consumers) attending a number of different doctors, both general practitioners and specialists
- recent discharge from a facility/hospital (in the last 4 weeks)

It is recognised that there might be additional risk factors that should be considered, including:

- health conditions or lifestyle practices that significantly affect pharmacodynamics and pharmacokinetics (e.g. alcohol, tobacco, illicit drugs or restricted diets)
- the use of non-prescription medicines and/or complementary health care products with other medicines or treatment.

A consumer brochure has been developed to provide consumers with practical information about the Home Medicines Review Medicare item and how a consumer might benefit from this service. Home Medicines Review—helping to manage your medicines at home is available at \(\cdot\text{---www.health.gov.au/epc/pdf/homereview.pdf----}\). It has been translated into many languages, available at \(\cdot\text{---www.health.gov.au/epc/transl.htm---}\).

Other resources for medication review include:

- The National Prescribing Service (NPS) guidelines for medication review, which
  primarily target general practitioners, but are applicable to a wider audience.
   Available at <---www.nps.org.au----->
- Medimate, published by the NPS to assist consumers in managing their medicines.
   Available at <a href="www.nps.org.au">www.nps.org.au</a>
- The Society of Hospital Pharmacists of Australia (SHPA) Standards of Practice for Clinical Pharmacy August 2004. J Pharm Pract Res 2005; 35 (2): 122-46
- The Pharmaceutical Society of Australia (PSA) book entitled Medication review: a process guide for pharmacists. Available at <a href="www.psa.org.au">www.psa.org.au</a>

## Guiding Principle 7 – Alteration of oral formulations

Some consumers might need to have oral formulations altered, for example, tablets broken or crushed, to aid administration. However, some medicines cannot be altered and the consumer might need alternative formulations or different medicines instead. These consumers should be given the help they need to guarantee their medicines are managed safely and effectively.

Wherever possible, alteration of formulations should be avoided. However, where alteration may be required, advice from a pharmacist should be sought before any formulation alteration is considered. There are references under the further reading resources list on this issue that readers may find useful.

Altering solid dosage forms by means such as crushing tablets or opening capsules can make it easier to administer a medicine to a consumer who has difficulty in swallowing. As some consumers will not report difficulties in swallowing, all consumers should be given advice about all medicines that should not be altered. It would be useful if health care professionals and care workers routinely asked consumers whether they have any difficulties swallowing medicines, and respond to any reported or noted difficulties, especially if there is advice that the medicine should not be altered.

When a consumer finds it difficult to swallow, the consumer and/or carer who helps to administer the consumer's medicines should be given information about altering oral formulations at the time of prescribing and dispensing. For example, the information could be in the form of verbal instruction, Consumer Medicine Information, and/or labelling the medicine container.

Service providers should provide their staff with access to current information about alteration of oral formulations, including the organisation's policies and procedures and medicine information resources such as the *Australian Medicines Handbook*, AusDI, APF-19 or *MIMS Annual*.

Care workers should not alter a medicine without instruction from a prescriber or other relevant health care professional. They should check the dose administration aid or medicine container for any instructions about altering the oral formulation (e.g. 'do not crush or chew') before helping the consumer. Care workers who are asked to alter oral formulations against the advice of pharmacists or organisations should refer the matter to their supervisor. Care workers should be guided by their organisation's policies and procedures on medication management.

Medication management reviews, including Home Medicines Reviews (HMRs), are an excellent means of identifying consumers who are having difficulties in swallowing, as the consumer is interviewed about the medicines that they are taking and how they are taking them. Perceived or actual swallowing difficulties might trigger such a review. Information about any difficulties, such as swallowing, that might result in consumers altering oral formulations should be sought, with the consumer's permission, from those helping them to manage their medicines, for example, carers, health care

professionals, and care workers. Consumers experiencing increasing difficulty in swallowing might require further assessment by the doctor and this would be included in the pharmacist's recommendations (refer to Guiding Principle 6 – Medication review).

HMRs provide an opportunity to assess the needs of consumers who might be altering formulations in spite of advice from the pharmacist. Where consumers are altering formulations, the pharmacist might need to consult the prescriber (in the case of HMR, a doctor) about a change in formulation or the use of another medicine.

This advice also applies to non-oral formulations such as topical patches.

### Guiding Principle 8 – Storage of medicines

Consumers using medicines in the community should be encouraged to store their medicines in a manner that maintains the quality of the medicine and safeguards the consumer, their family and visitors in their home.

Health care professionals and care workers should advise consumers that it is important to store medicines properly and in accordance with any instructions on the medicine label.

Generally, medicines should be stored in their original container in a cool, dry and secure place. The stability/effectiveness of some medicines depends on storing them at the correct temperature, for example, those medicines requiring refrigeration.

Consumers who need help in managing their medicines might also need help in storing them safely, for example, away from children and people who might be unable to read or understand labels.

When a consumer needs to take their medicines out of the home, the health care professional should give them information about suitable storage and transport of their medicines, for example, medicines that are normally stored in the fridge can be put in a small insulated lunchbox. The health care professional should advise the consumer to keep medicines in their original packaging and to observe the directions on the label for safe storage. Care workers should seek further advice from a community nurse, pharmacist or a consumer's doctor if they have concerns about transporting a consumer's medicine.

Where there is a major risk of medicine misuse, such as accidental overdose by consumers who are diagnosed with confusion or dementia, the service provider (in conjunction with other family members if appropriate/available) might need to take a lead role in making sure that the medicines are appropriately secured. In such cases, medicines should be stored out of the consumer's reach and sight, while still being accessible to those assisting in medication management. For example, medicines could be stored in a locked box in the top of the pantry or kitchen cupboard.

Particular care must be taken to ensure that sharp objects such as syringes are stored safely.

There is an increasing trend for consumers to have cytotoxic therapy in their own homes. In such cases, the health care professional is responsible for making sure that the consumer, carers or other care workers are provided with the necessary information to ensure the health and safety of everyone in the consumer's home. Such information should reflect Australian Government, state and territory legislation and include home storage of medicines and management of cytotoxic waste, including secure storage of cytotoxic waste and precautions when transporting waste containers.<sup>14</sup>

<sup>&</sup>lt;sup>14</sup> Reference may be made to jurisdictional work cover and occupational health and safety documents.

### Guiding Principle 9 – Disposal of medicines

Consumers and/or their carers should be encouraged to return any unwanted, ceased or expired medicines to their local community pharmacy for safe disposal.

To avoid accidental poisoning, medicine misuse and toxic releases into the environment, the safe disposal of unwanted and expired medicines is a priority of the Australian Government.

The National Return and Disposal of Unwanted Medicines Program, funded by the Australian Government, uses the national community pharmacy network to collect expired and unwanted medicines from consumers. <sup>15</sup> This program allows consumers to return their unwanted medicines to a community pharmacy for disposal, at no cost. The medicines are destroyed in an environmentally-friendly way using high-temperature incineration. This disposal method avoids the significant environmental health hazard posed by inappropriate disposal through the sewerage system and landfill.

It is important that sharp objects such as needles are not collected under this program, due to the danger of needle stick injuries to workers. Service providers should have policies and procedures in place about the safe disposal of medicines and related equipment, such as sharp objects and cytotoxic products. If a consumer does not have access to and / or dispose of sharps in an appropriate container, the care worker or health care professional should discuss access and use of an appropriate container in accordance with the service provider's policies and procedures.

Where a Home Medicines Review is being conducted for a consumer, disposal of expired and unwanted medicines should occur with the consumer's permission.

If care workers or health care professionals identify the need for disposal of medicines, this should only occur once consent has been obtained from the consumer and/or their carer.

Following the death of a consumer, the carer or their family should be encouraged to return all of the deceased consumer's medicines to their community pharmacy for safe disposal.

# Guiding Principle 10 – Nurse-initiated non-prescription medicine

Service providers should develop policies and procedures about the safe practices related to nurse initiation of non-prescription medicines.

Consumers and/or their carers occasionally ask nurses or care workers about minor conditions that could result in the use of commonly used non-prescription medicines.

As nurses require appropriate authorisation from service providers to administer non-prescription medicines, service providers should consider whether there is a need for the administration of commonly used non-prescription medicines by nurses within their service. Not all service providers will approve nurse-initiated non-prescription medicines. Care workers should refer such inquiries to their supervisor.

Where service providers do approve nurse-initiated non-prescription medicines, they should develop policies and procedures to assist nurses in safely initiating these medicines. These should include a list of medicines for treating minor conditions that nurses can initiate for consumers in their home. These medicines will be administered in consultation with the consumer and/or carer.

This list must comply with Australian, state and territory legislation and guidelines and be developed in consultation with doctors and pharmacists. This consultation can occur via clinical governance committees, Divisions of General Practice, or individual doctors and pharmacists. The list should provide information about each medicine, including indications for use, dosage ranges, precautions and contra-indications. The list of nurse-initiated medicines should be reviewed regularly.

When considering initiating a medicine for a consumer the nurse should consider any known allergies or previous adverse medicine events / adverse drug reactions experienced by the consumer. All adverse medicine events / adverse drug reactions should be reported in accordance with the service provider's policy (refer to Guiding Principle 12 – Risk management in the administration and use of medicines in the community). The policy should also specify that any doses of nurse-initiated medicine administered to a consumer should be recorded in a document that is accessible to other health care professionals and care workers.

Service providers should distribute the list to all authorised prescribers who refer consumers to the nursing service. If the use of a nurse-initiated medicine becomes routine, the authorised prescriber should review the consumer's use of this medicine.

### Guiding Principle 11 – Standing orders

The use of standing orders in the community for the administration of prescription medicines is generally discouraged. However, where standing orders are required in special circumstances, service providers should have policies and procedures in place for their use.

Standing orders provide a legal written instruction for the administration of medicines by an authorised person in situations where a prompt response using a standard procedure will improve consumer care and where a medicine is part of this procedure. A standing order is NOT a 'when required prescription' (PRN) for an individual consumer.

Where standing orders are required, for example in rural and remote areas and some immunisation programs, service providers should develop policies and procedures describing the development, authorisation, use and routine monitoring of the standing order. They must be in accordance with Australian, state and territory legislation and policy, and promote the quality use of medicines.

The decision to use a standing order is a clinical judgement and should be applied following an individual assessment in specific circumstances for an individual consumer.

All standing orders should be linked to a service provider's policies and procedures that are relevant to standing orders. All protocols for the use of standing orders should require that the order:

- is condition specific;
- is supported by or linked to appropriate clinical assessments;
- is clearly written, with the name of the medicine, dosage, route and frequency;
- identifies precisely which patients are to receive the medication;
- clearly states under which circumstances those patients are to be given the medicine, and conditions which are to preclude its administration;
- notes any special observations or care which may be required prior to, or subsequent to the administration;
- is not only signed, but the name of the authorised prescriber is legible;
- is clearly dated;
- is time limited and subject to regular review, that is, the service provider has set a period for review of this type of order where there is no legal time limit;
- is current (within that date);
- identifies who, either by name or by qualification (e.g. RNs), may administer the medicine;
- is supported by appropriate education or training for authorised persons using them.

## Guiding Principle 12 – Risk management in the administration and use of medicines in the community

Health care professionals, care workers, service providers, and consumers and/or carers should work together to manage risks and incidents associated with medicine use in the community.

Consumers have the right to be protected against products, production processes and services that are hazardous to health or life.<sup>16</sup>

Service providers are responsible for having systems in place that meet legislative responsibilities and result in a safe system for medication management in the community. These systems are covered in the previous sections of this document.

This guiding principle provides advice on systems that can reduce or eliminate the risk of medication errors and incidents. It focuses on the processes that should be in place when a medication incident occurs or where a medication incident has been averted (referred to as a 'near miss'), and on risk management systems to minimise the likelihood of medication errors and prevent their reoccurrence.

Medication errors and other medication incidents can occur at numerous points, from the prescription or selection of a medicine to its ingestion. There are formal and informal safety and quality checks at many points along this path, for example, the prescriber using electronic prescribing information, the pharmacist dispensing the prescription, the consumer reading the Consumer Medicine Information, and the health care professional administering the medicine.

All staff are responsible for their own actions and should report any medication incidents or near misses as outlined in their organisational policy and professional codes of conduct. Responding to medication incidents and near misses should be included in a medication incident management policy that outlines the steps to be taken following a medication incident or near miss.

#### Risk assessment

Risk assessment should take place at regular intervals, when a change in process is implemented, and when an adverse incident or near miss occurs.

Risks associated with medicines should be managed within a continuous, quality improvement (CQI) framework.<sup>17</sup> A CQI program is consumer-focused, active, peerbased, and provides feedback about quality of care and services, as well as appropriate

The Consumers' Health Forum of Australia's Charter of Health Consumer Rights —www.chf.org.au/public\_resources/consumer\_rights.asp—>

<sup>&</sup>lt;sup>17</sup> CQI is generally used to describe the process of systematically reviewing and improving existing operational systems and processes.

changes in practice resulting in maintaining and improving quality of care. Principles that underpin a CQI approach include:

- improvement oriented towards meeting the needs of consumers and communities
- decisions to improve systems and processes driven by analyses and data
- a multidisciplinary team approach to problem solving and quality improvement.

Health care professionals and care workers use CQI processes to measure and compare their performance against professional standards.

#### Continuous quality improvement tools

Service providers should use or develop quality improvement tools which health care professionals and care workers should be familiar with and use. Various tools are used in the CQI process. These might include improvement forms, continuous improvement plans, incident forms, cause and effect diagrams, Pareto charts and run charts. Root Cause Analysis (RCA) is another risk management tool that is used when investigating a medication incident or near miss. Additional information on RCA is available from the Australian Council for Safety and Quality in Health Care (ACSQHC).<sup>18</sup>

Managing incidents and near misses is outlined in the ACSQHC's national standard on open disclosure. While the standard is primarily designed for use in public and private hospitals, it can be modified for use by community health care providers. The preface notes that the standard 'aims to provide guidance on minimising the risk of recurrence of an adverse event through the use of information to generate systems improvement and promotion of a culture that focuses on health care safety'. <sup>19</sup>

#### Reporting mechanisms

A medication incident reporting document starts an investigation process and provides information on possible trends in relation to adverse incidents or near misses. This documentation system can be part of a comprehensive incident reporting system. Alternatively, a generic medication incident reporting tool can be modified for use. This document should include the consumer identifying information, the person reporting the incident, details of the actual incident, who was notified of the incident, and the outcome of the investigation, including the name of the investigator (refer to APAC's *Guiding principles to achieve continuity in medication management*).

It is recommended that service providers collect and analyse the medication incident data relating to their own organisations. Organisations should also use systems that provide a benchmark for measuring their performance, that is, an incident reporting system such as the Australian Incident Monitoring System (AIMS) or Incident Reporting to Improve Systems (IRIS).<sup>20</sup>

ACSQHC (Australian Council for Safety and Quality in Health Care) (2003) Patient safety: towards sustainable improvement. Fourth report to Australian Health Ministers' Conference, 31 July 2003. At —www.safetyandquality.org—

ACSQHC (2003) Open Disclosure Standard: A national standard for open communication in public and private hospitals, following an adverse event in healthcare, July 2003. At —www.safetyandquality.org

<sup>20 &</sup>lt;---www.apsf.net.au/products.html---->

The Adverse Medicine Events (AME) line, an initiative of the ACSQHC, has been established as an interactive service through which consumers can report adverse events associated with medicines or seek information about them.<sup>21</sup> The phone-in service is available for consumers who suspect they have experienced an adverse medicine event. Consumers can telephone 1300 134 237 between 9am and 6pm (AEST), Monday to Friday.

Consumers can report any reaction serious enough to have caused them concern, made them reluctant to continue using medication, or caused them to seek additional help, including admission to hospital. Errors with medicines can also be reported, whether or not they resulted in injury. The AME service sends reports of suspected adverse events to the Adverse Drug Reactions Advisory Committee (ADRAC).<sup>22</sup>

The Adverse Drug Reactions Unit of the Therapeutic Goods Administration receives reports of suspected adverse reactions to prescription medicines, vaccines, non-prescription medicines and complementary health care products. All reports are reviewed by professional staff. Those reports involving serious reactions or recently marketed drugs are reviewed by the ADRAC.

<sup>&</sup>lt;sup>21</sup> <---www.safetyandquality.org/index.cfm?page=ACTION#consumer----->

<sup>22 &</sup>lt;---www.tga.gov.au/adr/index.htm---->

# **GLOSSARY**

Aboriginal Health Worker and Torres Strait Islander Health Worker A person who has completed the nationally accredited Certificate 3 in Aboriginal Health Work.

**Accredited pharmacist** 

A registered pharmacist who has undertaken specialised training and credentialing to conduct medication reviews.

**Active ingredient** 

The therapeutically active component in a medicine's final formulation that is responsible for its physiological or pharmacological action.

Administration

The process of giving a dose of medicine to a consumer or a consumer taking a medicine.

**Adverse drug reaction** 

A response to a drug or medicine which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function (ACSQHC 2002).

Adverse *medicine* event

A particular type of adverse *medicine* event where a drug or medication is implicated as a causal factor in the adverse event. This encompasses both harm that results from the intrinsic nature of the medicine (an adverse drug reaction) as well as harm that results from medication errors or system failures associated with the manufacture, distribution or use of medicines (ACSQHC).

**Buccal tablets** 

Tablets that are taken by allowing them to dissolve in the mouth cavity beside the cheek.

Care plan

A plan outlining the needs and support to support a consumer in the community.

#### Care worker

Paid workers supporting people to live the community. Examples include Aboriginal Health Workers and Torres Strait Islander Health Workers, assistants in nursing, personal care assistants, community support workers, HACC (Home and Community Care) Workers.

#### Carer

Carers are usually family members who provide support to children or adults who have a disability, mental illness, chronic condition or who are frail or aged. Carers can be parents, partners, brothers, sisters, friends or children.

#### Collaboration

In the context of medication management, collaboration is a process whereby consumers and health care providers share their expertise and take responsibility for decision making. Accomplishing collaboration requires that individuals understand and appreciate what it is they, and others, want to contribute to the 'whole'.

#### **Community**

A specific group of people, often living in a defined geographical area, who share a common culture, values and norms and who are arranged in a social structure according to relationships the community has developed over a period of time. The term "community" encompasses worksites, schools and health care sites.

#### **Community care provider**

Provider of a health and community care service in the community.

# Complementary health care products

Includes vitamins, mineral, herbal, aromatherapy and homoeopathic products, also known as 'traditional' or 'alternative' medicines.

#### Compliance

A quantitative measure of how closely a consumer follows the intentions and recommendations of a prescribed course of treatment, regardless of their personal beliefs and capabilities. Failure to comply generally has a negative connotation despite the fact that deliberate non-compliance might be a positive expression of the consumer taking control of his/her own actions.

#### Concordance

Concordance is an agreement reached between a patient and a health care professional that fully respects the beliefs and wishes of the patient in determining whether, when and how medicines are to be taken. This includes consideration of timing, dosage and consumer memory and dexterity.

#### Consultation

Consultation occurs when people seek information or advice and take into consideration the feelings and interests of all of the members of the medication management team.

#### Consumers

People who use or are potential users of health services, including their family and carers (DH&AC 1998). Might include patients, clients and carers. (Lynne 2003, p9)

# Consumer Medicine Information (CMI)

Brand-specific leaflets produced by a pharmaceutical company in accordance with the Therapeutic Goods Regulations to inform consumers about prescription and pharmacist-only medicines. Available from a variety of sources, for example, enclosed within the medication package, supplied by a pharmacist as a leaflet or computer printout, provided by a doctor, nurse or hospital, or available from the pharmaceutical manufacturer.

#### **Cytotoxic**

Toxic to cells, cell-toxic, cell killing. Any agent or process that kills cells. Chemotherapy and radiotherapy are forms of cytotoxic therapy. (Webster's Medical Dictionary)

#### **Dispensing**

The (1) assessment of the medicine prescribed in the context of the patient's other medication, medical history and the results of relevant clinical investigations available to the pharmacist; (2) selection and supply of the correct medicines; (3) appropriate labelling and recording; and (4) counselling of the patient on the medicine(s).

#### **Doctor**

A registered medical practitioner, such as a general practitioner, medical specialist, consultant medical practitioner or hospital medical officer.

#### Domiciliary Medication Management Review

See Home Medicines Review.

#### **Dose Administration Aids (DAA)**

A device or packaging system where doses of one or more solid oral dosage forms of medicines can be organised according to the time of administration.

#### **Enrolled nurse**

A person who is enrolled and registered to practise by an Australian nurse regulatory authority. In Victoria this refers to a registered nurse (Division 2).

#### **Formulation**

The form in which a medicine is presented e.g. tablet, capsule, lozenge, syrup, mixture.

#### Generic medicine

A generic medicine is defined in the Therapeutic Goods Regulations as a medicine that, in comparison to a registered medicine:

- (a) has the same quantitative composition of therapeutically active substances, being substances of similar quality to those used in the registered medicine;
- (b) has the same pharmaceutical form;
- (c) is bioequivalent;
- (d) has the same safety and efficacy properties.

#### Health care professionals

Persons who have professional qualifications in all health care settings, e.g. doctors, pharmacists, nurses, occupational therapists, dieticians.

#### **Home Medicines Review (HMR)**

A service to consumers living at home in the community. The goal is to maximise an individual consumer's benefit from their medication regimen. The reviews involve a team approach including the general practitioner, the consumer's preferred community pharmacy and an accredited pharmacist, with the consumer as the focus. A HMR might also involve other relevant members of the health care team, such as nurses in community practice or carers. The review allows the patient the opportunity to have a pharmacist, in collaboration with their general practitioner, comprehensively review their medication regimen in a home visit and to be central in the development and implementation of an agreed medication management plan.

#### Hygroscopic

Denoting a substance capable of readily absorbing and retaining moisture. (Stedman's Medical Dictionary)

#### Medication

A drug or medicine. (Webster's Medical Dictionary)

#### **Medication chart**

Used by medical practitioners to record medication and treatment orders, and by nursing staff to record and monitor the administration of such medications and treatment. Medication charts need to satisfy state or territory regulations and other requirements of the Poisons Acts in each jurisdiction.

#### **Medication error**

An error can be defined as failure in the (drug) treatment process that leads to, or has the potential to lead to, harm to the (consumer) and includes an act of omission or commission. Errors rarely occur as the result of the actions of a single individual. They are usually the result of a series of system failures. (ACSQHC 2002)

#### **Medication incident**

An incident associated with medication. (ACSQHC 2002)

#### **Medication Management Plan**

Written medication management plan as part of a Home Medicines Review (HMR).

The medication management plan should:

- take account of the needs outlined in the pharmacist HMR report
- map the proposed management and expected outcomes of the consumer's medication regimen
- specify who is responsible for any further actions and future follow up and/or monitoring, the timeframe in which these should be completed, and the expected outcomes for the consumer
- identify any other relevant members of the health care team whose involvement is necessary to the implementation of the plan, including any role expected of the consumer's carer.

#### **Medication list**

A list of all medicines currently used by a consumer, including prescription, non-prescription (over-the-counter), and complementary.

#### **Medication review**

A structured, critical examination of a consumer's medicines with the objective of reaching an agreement with the consumer about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste.

#### **Medicine**

A substance given with the intention of preventing, diagnosing, curing, controlling or alleviating disease or otherwise enhancing the physical or mental welfare of people. Includes prescription and non-prescription medicines, including complementary health care products, irrespective of the administered route.

#### Non-prescription medicine

Medicine available without prescription. Examples are cough mixtures, simple analgesics and antacids. Some can be sold only by pharmacists or sold in a pharmacy, others can be sold through non-pharmacy outlets.

#### Nurse

See enrolled nurse / registered nurse.

#### **Nurse practitioner**

A registered nurse educated to function autonomously and collaboratively in an advanced and extended clinical role. The nurse practitioner role includes assessment and management of clients using nursing knowledge and skills and may include, but is no limited to, the direct referral of patients to other healthcare professionals, prescribing medications, and ordering diagnostic investigations. The nurse practitioner role is grounded in the nursing profession's values, knowledge, theories and practice and provides innovative and flexible healthcare delivery that complements other health care providers. The scope of practice of the nurse practitioner is determined by the context in which the nurse practitioner is authorised to practice.

#### **Partnership**

Refers to a relationship where there is a sharing of expertise and responsibility among doctors, nurses, pharmacists, care workers and consumers for a person's wellbeing. It requires consultation between individuals and collaborative decision-making.

#### **Performance indicators**

Provide a set of criteria for monitoring the implementation, effect and outcomes of the medication management continuum.

#### **Pharmacist**

A registered pharmacist practising in a variety of settings including community, hospital, facilities, etc.

#### **Pharmacodynamics**

The study of uptake, movement, binding, and interactions of pharmacologically active molecules at their tissue sites of actions. (Stedman's Medical Dictionary)

**Pharmacokinetics** The study of the movement of drugs within

biologic systems, as affected by absorption, distribution, metabolism and excretion; particularly the rates of such movements.

(Stedman's Medical Dictionary)

**Prescriber** A health care professional who is authorised

by legislation to issue a prescription for the supply of medicines. Usually refers to a medical practitioner (doctor) but might include a nurse practitioner, dentist

or optometrist.

**Registered nurse** A person who is registered and licensed to

practice by an Australian nurse regulatory authority. In Victoria this refers to a registered

nurse (Division 1).

**Root Cause Analysis** A systematic process whereby the factors that

contributed to an incident are identified.

**Service provider** Provider of a health and/or community care

service in a community setting.

**Standard of care** The law requires professionals to take all

reasonable care in carrying out their work and to ensure that appropriate standards of care are met. The appropriate standard of care is assessed on what action a reasonable person

would take in a particular situation.

**Sublingual tablets** Tablets that are taken by allowing them to

dissolve under the tongue.

**Substitute decision maker** Someone a person chooses to make personal

or lifestyle decisions, including health care decisions, when they are a no longer capable of doing so. The appointing person usually chooses the types of decisions or functions they want the substitute decision maker to make. This process differs in detail across the different State and Territory jurisdictions.

# FURTHER READING AND RESOURCES

The documents referenced within these Guiding Principles are provided as references only and have not been endorsed by APAC, with the exception of those documents issued by APAC. Please note that any questions about a document should be directed to the relevant organisation or author.

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artoooo2

# STATE AND TERRITORY CONTACTS FOR REGULATORY AND POLICY ADVICE

#### **NEW SOUTH WALES**

Duty Pharmaceutical Adviser Pharmaceutical Services Branch

Department of Health

PO Box 103

**GLADESVILLE NSW 1675** 

Telephone: (02) 9879 3214 Fax: (02) 9859 5165

Website: www.health.nsw.gov.au/public-health/psb

#### **QUEENSLAND**

Medicine policy issues

Director

**Medicines and Pharmacy Services Unit** 

Queensland Health Building

GPO Box 48

BRISBANE Qld 4001

Telephone: (07) 3234 1167 Fax: (07) 3234 0773

Legislation issues

Principal Advisor Drugs, Poisons and Therapeutic Goods

Environmental Health Unit Queensland Health Building

GPO Box 48

**BRISBANE Qld 4001** 

Telephone: (07) 3234 0960 Fax: (07) 3234 1480

Website: www.health.qld.gov.au

Health information and documentation of relevance to consumers, industry and health care professionals in Queensland:

Website: www.health.qld.gov.au/healthyliving

#### **VICTORIA**

**Duty Officer** 

**Drugs and Poisons Unit** 

**Department of Human Services** 

GPO Box 1670N

MELBOURNE Vic 3001

Telephone: 1300 364 545 Fax: 1300 360 830

Website: www.health.vic.gov.au

#### **SOUTH AUSTRALIA**

**Drug Policies and Programs Branch** 

Department of Health

PO Box 6

**RUNDLE MALL SA 5000** 

Telephone: (08) 8274 3432 Fax: (08) 8274 3440

Website: www.health.sa.gov.au

#### **WESTERN AUSTRALIA**

**Pharmaceutical Services** 

Department of Health

PO Box 8172

PERTH BC WA 6849

Telephone: (08) 9388 4980 Fax: (08) 9388 4988

Website: www.health.wa.gov.au

#### **TASMANIA**

**Pharmaceutical Services** 

Department of Health and Human Services

GPO Box 125B

**HOBART Tas 7001** 

Telephone: (03) 6233 2064 Fax: (03) 6233 3904

Website: www.dhhs.tas.gov.au/publichealth/pharmaceuticals

#### **AUSTRALIAN CAPITAL TERRITORY**

**Pharmaceutical Services** 

**ACT Health** 

Locked Bag 5

WESTON CREEK ACT 2611

Telephone: (02) 6205 0996, (02) 6205 0998

Fax: (02) 6205 0997

Website: www.health.act.gov.au

#### NORTHERN TERRITORY

**Poisons Control** 

Department of Health and Community Services

PO Box 40596

CASUARINA NT 0811

Telephone: (08) 8922 7341

Fax: (08) 8922 7200

Website: www.health.nt.gov.au

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## IDEAS AND INNOVATIONS

## Blindness Caused by Cosmetic Filler Injection: A Review of Cause and Therapy

Jean D. A. Carruthers, M.D. Steve Fagien, M.D. Rod J. Rohrich, M.D. Susan Weinkle, M.D. Alastair Carruthers, M.D.

Vancouver, British Columbia, Canada

Summary: Vascular occlusion causing blindness is a rare yet greatly feared complication of the use of facial aesthetic fillers. The authors performed a review of the aesthetic literature to ascertain the reported cases of blindness and the literature reporting variations in the vascular anatomy of the human face. The authors suggest a small but potentially helpful addition to the accepted management of the acute case. Cases of blindness, mostly irreversible, from aesthetic filler injections have been reported from Asia, Europe, and North America. Autologous fat appears to be the most frequent filler causing blindness. Some cases of partial visual recovery have been reported with hyaluronic acid and calcium hydroxylapatite fillers. The sudden profusion of new medical and nonmedical aesthetic filler injectors raises a new cause for alarm about patient safety. The published reports in the medical literature are made by experienced aesthetic surgeons and thus the actual incidence may be even higher. Also, newer injectors may not be aware of the variations in the pattern of facial vascular arborization. The authors present a summary of the relevant literature to date and a suggested helpful addition to the protocols for urgent management. (Plast. Reconstr. Surg. 134: 1197, 2014.)

Blindness after the facial injection of particulate materials was first reported in 1963.<sup>1</sup> The recent remarkable growth in the popularity of the cosmetic filler market has caused a dramatic increase in the number of cases of blindness reported.<sup>2-7</sup> Furthermore, this review shows that, although rare, the affected individual seldom recovers vision.

This review is intended to highlight causative factors and to address prevention and therapy. Our hope is that this information will assist every injector of three-dimensional fillers in enhancing patient safety.

All of the commonly used filling agents have been responsible for embolic events. In one large study, approximately 50 percent of the patients were blinded with cosmetic injections of autologous fat. The equipment and injection technique used for the injection are often not recorded in the article because the authors are the doctors to whom the affected patient was referred rather than the injector who caused the embolus.

In 2010, Sung et al.<sup>2</sup> reported unilateral loss of sight in a young man who desired cosmetic

From the University of British Columbia. Received for publication December 16, 2013; accepted May 7, 2014.

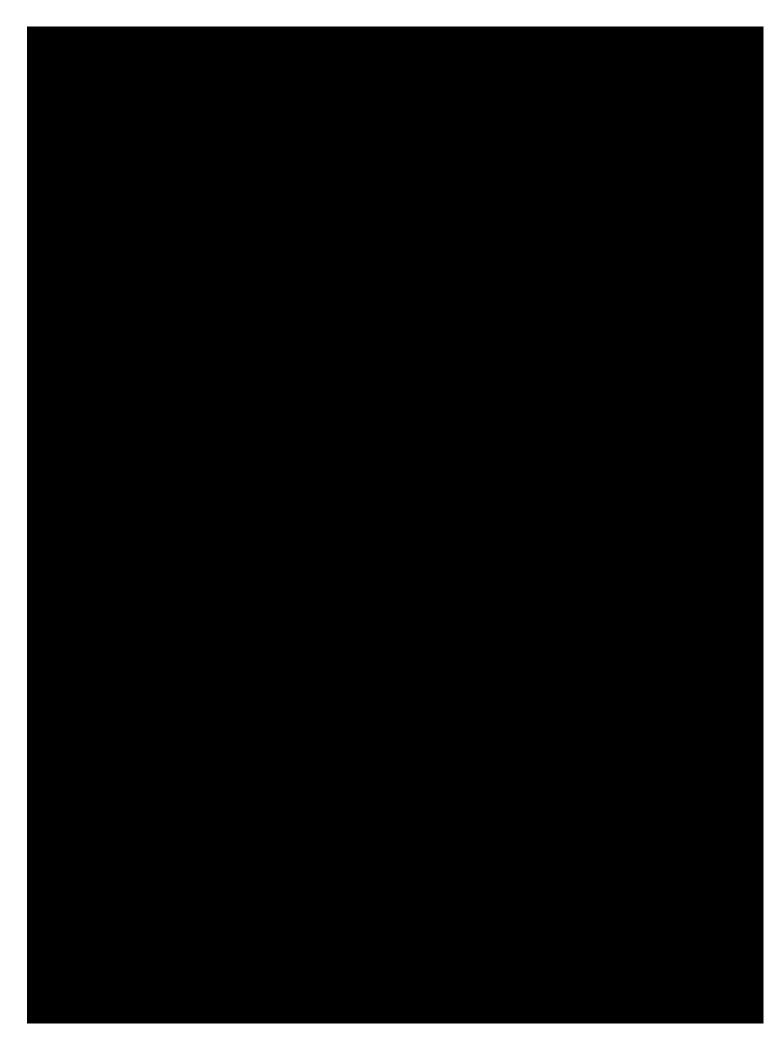
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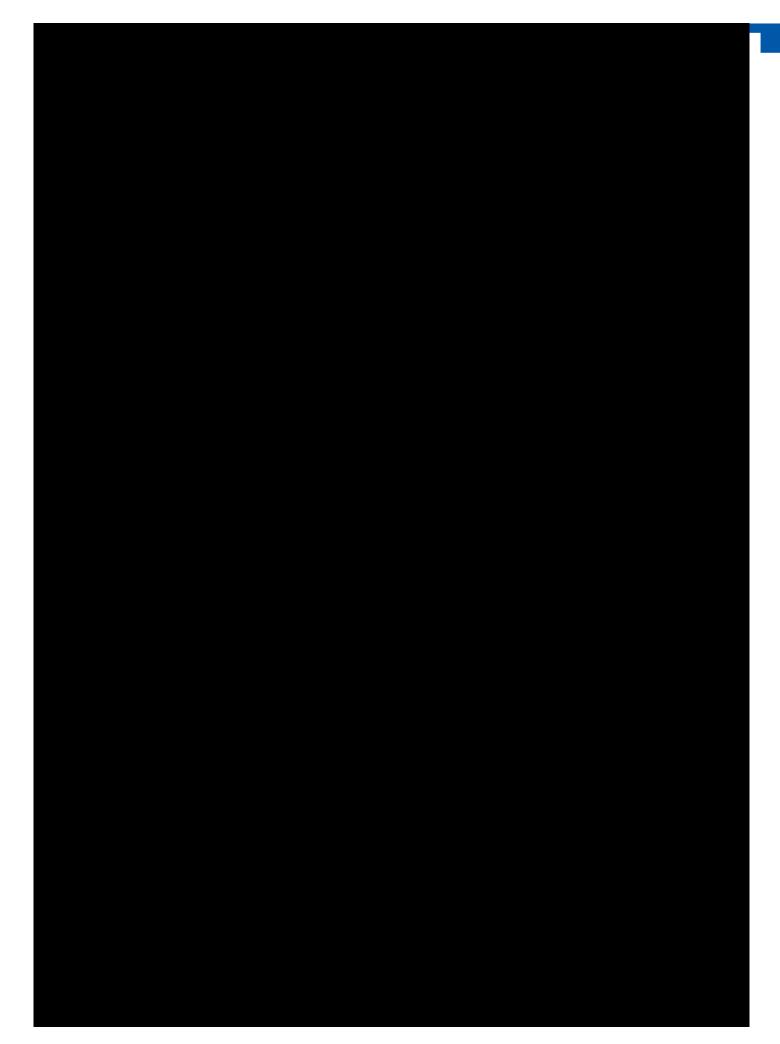
DOI: 10.1097/PRS.0000000000000754

augmentation of his nasal bridge and was treated with calcium hydroxylapatite. Shortly after treatment, he suffered sudden unilateral blindness and excruciating pain in the right eye. He also had right ophthalmoplegia, a fixed dilated pupil, and calcium hydroxyl apatite filler material visible in his conjunctival and retinal vessels on the right side. Fortunately, after 3 months, his visual acuity returned to 20/20 with pinhole, and his necrotic skin healed, but he had retinal damage in his nasal retina.

In 2012, in a European study, Lazzeri et al.³ published the results of their search of the MED-LINE and Cochrane databases, Google and Google Scholar, Current Contents, and PubMed. They found 29 articles representing 32 cases of post–cosmetic filler vascular occlusion causing blindness. Fifteen of 32 cases were diagnosed with blindness following fat injection of the face for cosmetic reasons. None of the fat-injected subjects recovered any sight. The second group included

**Disclosure:** Dr. Rohrich receives instrument royalties from Micrins Instruments and book royalties from Quality Medical Publishing. He received clinical research grant support from Neodyne Biosciences, Inc., for participation in a clinical trial. No funding was received for this article. The other authors have no financial information to disclose.









Aboriginal and Torres Strait Occupational therapy Islander health practice Optometry Chinese medicine Osteopathy
Chiropractic Pharmacy
Dental Physiotherap Medical

Nursing and Midwifery

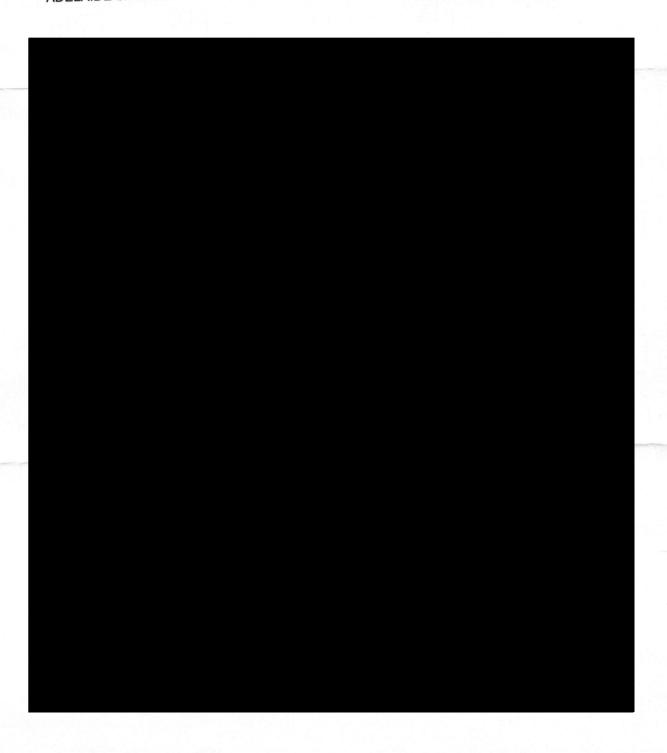
Physiotherapy Medical
Medical radiation practice
Nursing and Midwifery
Podiatry
Psychology

Australian Health Practitioner Regulation Agency

### Private and Confidential

24 October 2013

Dr Michael Molton 245 Wakefield Street ADELAIDE SA 5000





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Optometry Osteopathy Pharmocy Physiotherapy Podiatry

Australian Health Practitioner Regulation Agency

#### **Private and Confidential**

14 August 2013

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# POLICY STATEMENT ADMINISTRATION OF BOTULINUM TOXIN BY NURSES

#### I. Introduction

Botulinum Toxin is commonly prescribed by doctors for the purpose of cosmetic treatments. It may be lawfully administered by either the doctor, or a nurse acting under the supervision and instruction of a doctor, and in accordance with a written order provided by the doctor.

#### 2. The Role of Nurse Injectors

Adequately qualified and properly supervised nurse injectors can provide a valuable and appropriate service to patients undergoing cosmetic treatments, provided proper procedures are in place to ensure the required standard of care is met.

Supervising doctors must be satisfied that the nurse has adequate qualifications, training and expertise for the duties performed. Whilst it may be the nurse who administers the Botulinum Toxin, the doctor remains responsible for ensuring the treatment is provided safely and appropriately.

The doctor should be immediately contactable in order to respond to a nurse or patient's concern in a timely manner.

#### 3. Regulatory Requirements for Schedule 4 Substances

Botulinum Toxin is a Schedule 4 substance. The precise legal requirements for the possession, use, storage and disposal of Schedule 4 substances vary between States and Territories. It is the responsibility of the prescribing doctors to be aware of the legal requirements in their jurisdiction and ensure they are complied with.

#### 4. Premises for Injection

Botulinum Toxin should only be administered in an appropriate setting with adequate equipment and protocols in place. The premises must be properly equipped to deal with anaesthetic toxicity effects and potentially life threatening anaphylactic reactions. The premises must provide facilities and procedures for all healthcare workers to adhere to infection control principles, including safe injection practices and aseptic technique for the preparation and administration of all injectable medications.

#### 5. Initial Consultation

The doctor's initial consultation with a patient considering Botulinum Toxin treatment should include a proper clinical history and examination, as well as a complete discussion of the realistic potential benefits, side effects and possible complications.

The treating doctor should always be satisfied of the indication for the proposed treatment, the patient's medical suitability for Botulinum Toxin and that full and informed consent has been obtained.



Remote consultations (i.e. via telephone or 'Skype') are not recommended, and may, in the opinion of the Australian Society of Plastic Surgeons, unnecessarily hamper the doctor's ability to undertake a proper patient assessment.

#### 6. Written Instruction for Administration

The doctor must provide written instructions for the administration of Botulinum Toxin for the patient including directions on the dose, treatment frequency and area. These instructions may remain valid for a period of up to 12 months. A nurse must never administer Botulinum Toxin without a valid order from a doctor.

#### 7. Review of Treatment Plan by Doctor

The patient and/or administration instructions should be reviewed by the doctor as necessary, including if:

- I. There is a material change in the patient's general medical condition; or
- II. The patient wishes to see the doctor for any reason whatsoever; or
- III. The nurse is concerned or unclear about the written instructions for any reason; or
- IV. An unexpected side effect, complication or result of treatment has occurred.
- V. In such cases, the doctor should personally review the patient to determine whether the treatment plan remains appropriate, and no further treatment should be given until this review has taken place.

Approved by ASPS Council: September 2012

Review Date: September 2013

Dear Dr Molton

Advertising Unit Recalls and Advertising Section Office of Product Review

From: Michael Molton < drawlton@epiclinic.com.au >

To: "TGA.Advertising@tga.gov.au" <TGA.Advertising@tga.gov.au>,

Date: 20/08/2013 03:36 PM

Subject:

#### PROTOCOL FOR DELEGATED COSMETIC S4 INJECTIONS

Suitably-trained registered nurses may administer S4 medicines for cosmetic purposes after a doctor has consulted in person, face-to-face with a patient and formulated a written treatment plan:

- 1. to cover a time period no greater than 1 year
- 2. stipulating the areas to be treated
- 3. stating which medications are to be used
- 4. setting the maximum number of procedures
- 5. stating the maximum dosages of the medications to be administered.

The patient and treatment plan would be reviewed:

- 1. at the expiration of the set time period
- 2. if unexpected side effects or complications occurred
- 3. if the patient or nurse were unhappy with the results
- 4. if new indications for the ordered medications were contemplated
- 5. if other medications were considered for the original or new indications
- 6. if the original presentation were altered by eg. surgery, trauma, pregnancy or other procedures for which the original treatment plan did not cater.

If the patient is taking new medications the nurse would need to check with the supervising doctor prior to the procedure to ensure there were no contraindications to proceeding with the treatment plan.

The doctor should ensure that the nurse is fully competent and capable to carry out all injections that are delegated to him/her. The supervising doctor must be capable of performing these procedures him- or herself and should perform those procedures which are outside the nurse's capabilities him- or herself.

Suitably-trained registered nurses may perform such procedures at adequately-equipped premises, distant from the doctor's rooms, if treatment plans for all patients had previously been formulated by the supervising doctor, following an in person, face-to-face consultation. The doctor should be readily contactable but need not be on site.

After each instance where S4 medicines are taken away from the doctor's rooms, an inventory must be performed. The amount of stock returned must be reconciled with the amount taken away, that recorded as injected and the monetary return.

It is not acceptable for a doctor to onsell S4 medications to a nurse or other person to then administer these to patients, regardless of any prior order for the administration of said medications.

Registered nurses performing such procedures must:

- 1. have current national registration
- 2. be covered by the practice insurance policy, or in the case of an independent contractor have his or her own policy
- 3. have had adequate training in the particular procedure/s
- 4. have been certified as competent where certification exists, or deemed competent by a trainer approved by the supervising doctor.

The CPSA does not endorse the use of injectors whose qualifications or experience is less than that stated above and is vehemently opposed to injections being given by non-paramedical persons such as beauty therapists.

All members should ensure there are no additional requirements pertinent to their own state or territory which must be fulfilled.



# Severe Complications of a "Brazilian" Bikini Wax

Claire Dendle, Sheila Mulvey, 5 Felicity Pyrlis, M. Lindsay Grayson, As and Paul D. R. Johnson, 4

<sup>1</sup>Infectious Diseases Department and <sup>2</sup>Endocrinology Department, Austin Health, and Departments of <sup>3</sup>Obstetrics and Gynaecology and <sup>4</sup>Medicine, University of Melbourne, Melbourne, <sup>5</sup>Mercy Hospital for Women, Heidelberg, and <sup>6</sup>Department of Epidemiology and Preventive Medicine, Monash University, Clayton, Victoria, Australia

A 20-year-old Australian woman with poorly controlled type 1 diabetes presented with life-threatening *Streptococcus pyogenes* and *Herpes simplex* infection of her external genitalia following a routine perineal "Brazilian" bikini wax. Extensive pubic hair removal is now common among young adults in Australia and elsewhere. However, the infectious risks of these practices, particularly among immunosuppressed individuals, are often underappreciated.

A 20-year-old Australian woman presented to our emergency department (Austin Health; Melbourne, Australia) with high fever and swelling of the external genitalia. She had poorly controlled type 1 diabetes mellitus as a result of nonadherence with insulin therapy, had a history of frequent episodes of diabetic ketoacidosis, and had a glycosylated hemoglobin level of 11.9%.

Two weeks before presentation, the patient had undergone a "Brazilian" bikini wax at a beauty salon that involved removal of all hair from her mons pubis, vulva, and anus with hot wax. The patient experienced significant pain and some vulval bleeding during the procedure, which was performed by a trainee beauty therapist.

During the subsequent 4 days, worsening vulval swelling, redness, and pain were noted, as well as a copious vaginal discharge. On the day of presentation, the patient reported excruciating perivulval pain, severe dysuria, fever, and a diffuse erythematous rash.

The patient's last normal menstrual period finished 4 days

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DOI: 10.1086/519425

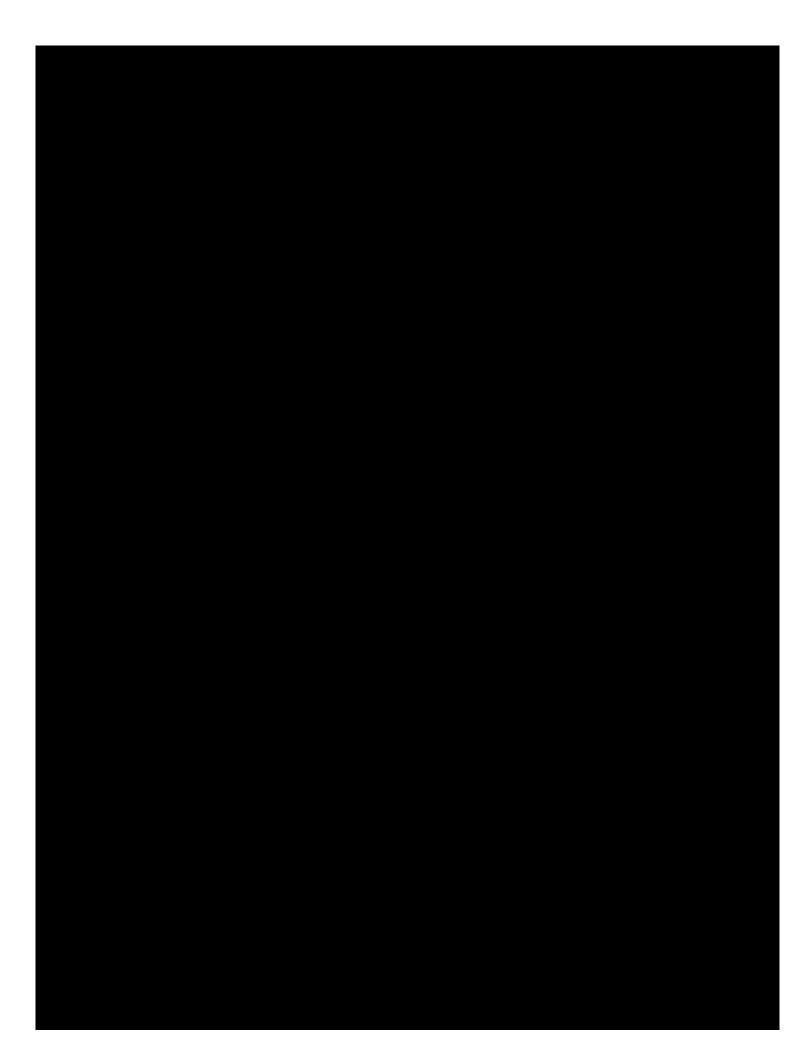
before presentation, and there was no history of tampon use or of a foreign body in the vagina. She had 1 male sexual partner with whom she had been having unprotected sex for several months. There was no history of previous infective episodes or vaginal trauma.

At presentation, the patient was found to be febrile (temperature, 38°C), hypotensive (blood pressure, 90/60 mm Hg), and tachycardic (heart rate, 100 beats/min), and she looked very unwell. There was an erythematous rash over the patient's chest and neck. The external genitalia were grossly swollen particularly the vulva, the labia majora and minora, and the clitoris—with the urethra displaced inferiorly and cellulitis extending from around the vulva up onto the abdominal wall. The distribution of the cellulitis was consistent with the area onto which the wax had been applied. There was a copious, purulent vaginal discharge and prominent white exudate on the vulva. Examination was difficult because of the extreme swelling, but no vesicular lesions or ulcers were seen. Neither speculum nor bimanual vaginal examination was able to be performed because of severe pain. The findings of the rest of the physical examination were unremarkable.

Laboratory investigations revealed normal findings of a complete blood examination, as follows: hemoglobin level, 126 g/ L (normal range, 115–165 g/L); WBC count,  $8.7 \times 10^9$  cells/L (normal range,  $4.0-11.0 \times 10^9$  cells/L); platelet count,  $257 \times 10^9$ platelets/L (normal range, 150-400 × 10° platelets/L); albumin level, 21 g/L (normal range, 36-48 g/L); bilirubin level, 11 mmol/L (normal value, <18 mmol/L); alanine transaminase level, 428 U/L (normal value, <34 U/L); alkaline phosphatase level, 182 U/L (normal range, 32–91 U/L); and  $\gamma$ -glutamyltransferase level, 246 U/L (normal value, <38 U/L). The patient's glucose level was 20.9 mmol/L with no ketoacidosis, but her blood urea nitrogen level and electrolyte levels were within the normal range. The patient's coagulation profile was normal. Serological test results were negative for hepatitis A, B, and C and for HIV infection; subsequent urinary PCR test results were negative for Chlamydia trachomatis.

Gram stain of vaginal discharge samples demonstrated profuse polymorphs, profuse gram-positive cocci, scanty gram-positive bacilli, and scanty gram-negative bacilli; culture grew a pure growth of *Streptococcus pyogenes*. Culture of a midstream urine sample demonstrated  $>500 \times 10^6$  leukocytes/L and grew *S. pyogenes*. No organisms were isolated from 3 sets of blood cultures. Herpes simplex virus multiplex PCR of vaginal fluid samples had results positive for herpes simplex virus type 1.

The initial differential diagnosis was severe perineal strep-





MEDIA RELEASE June 2014

# CPSA reminds doctors & nurses to practice within the law when using anti-wrinkle injections

In the wake of a recent decision by the NSW Civil and Administrative Tribunal to suspend a nurse, the Cosmetic Physicians Society of Australasia (CPSA) reminds both doctors and nurses of the protocols that should be followed when using anti-wrinkle injections.

In its decision on 12 June 2014, the NSW Civil and Administrative Tribunal found a nurse "guilty of unsatisfactory professional conduct and serious misconduct" for the practice of:

- 1. supplying Schedule 4 medication to patients at a practice and/or day spa contrary to the *Poisons and Therapeutic Goods Act 1966* (NSW)
- 2. administering the substance in the absence of any:
  - i) consultation, review or assessment of the patients by a medical practitioner
  - ii) prescription from a medical practitioner;
  - iii) written instructions or written orders from a medical practitioner;
  - iv) supervision by a medical practitioner.

Dr Catherine Porter, spokesperson for the CPSA said: "We don't think this is an isolated event, the CPSA is concerned that this type of illegal practice occurs with worrying regularity. That is why we have developed a 'Protocol for Delegated Cosmetic S4 Injections' to assist both medical practitioners and nurses,"

"The CPSA strongly recommends that doctors and nurses working in the area of cosmetic medicine obey the law and follow the protocols that are in place for these types of treatments, as this type of malpractice endangers patient safety and increases the likelihood of adverse and undesirable result" said Dr Porter.

Anti-wrinkle and other cosmetic injections are classified Schedule 4 medicines by the Therapeutic Goods Administration. Under Australian law and Medical Board guidelines, nurses are not permitted to administer such treatments, unless supervised by a doctor. The order for such administration may only be given after the doctor has completed a full medical history and examination of the patient and then prescribed the treatment.

In 2009 the CPSA released a *Protocol for Delegated Cosmetic S4 Injections*, which reinforces these guidelines and provides a framework for cosmetic medical practitioners on how to appropriately delegate procedures to ensure that patient safety remains paramount.

Patients that want to locate a doctor whose focus is the provision of cosmetic medicine, can visit <a href="https://www.cosmeticphysicians.com.au">www.cosmeticphysicians.com.au</a> to find a local practitioner.

#### **END**

#### **About the CPSA**

The CPSA represents the largest body of doctors who perform non- or minimally-invasive cosmetic medical treatments in Australia. Incorporated in 1997, the Society works to uphold and improve standards in cosmetic medicine and aims to ensure patients can access safe non- or minimally-invasive cosmetic treatments.

#### For further information please contact:

Angela Koutoulas - akoutoulas@respublica.com.au (02) 8297 1514



REVIEW

# Patient factors influencing dermal filler complications: prevention, assessment, and treatment

Koenraad De Boulle Izolda Heydenrych2

On behalf of the Consensus Group

Aalst Dermatology Group, Aalst, Belgium; <sup>2</sup>Cape Town Cosmetic Dermatology Centre, Century City, South Africa



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Abstract: While rare, complications do occur with the esthetic use of dermal fillers. Careful attention to patient factors and technique can do much to avoid these complications, and a well-informed practitioner can mitigate problems when they do occur. Since cosmetic surgery is usually an elective process, requested by the patient, clinical trials are complex to organize and run. For this reason, an international group of practicing physicians in the field of esthetics came together to share knowledge and to try and produce some informed guidance for their colleagues, considering the literature and also pooling their own extensive clinical experience. This manuscript aims to summarize the crucial aspects of patient selection, including absolute contraindications as well as situations that warrant caution, and also covers important considerations for the pre- and posttreatment periods as well as during the procedure itself. Guidance is given on both immediate and long-term management of adverse reactions. The majority of complications are related to accepting patients inappropriate for treatment or issues of sterility, placement, volume, and injection technique. It is clear that esthetic practitioners need an in-depth knowledge of all aspects of treatment with dermal fillers to achieve optimal outcomes for their patients.

Keywords: dermal fillers, complications, prevention, assessment, treatment, patient factors

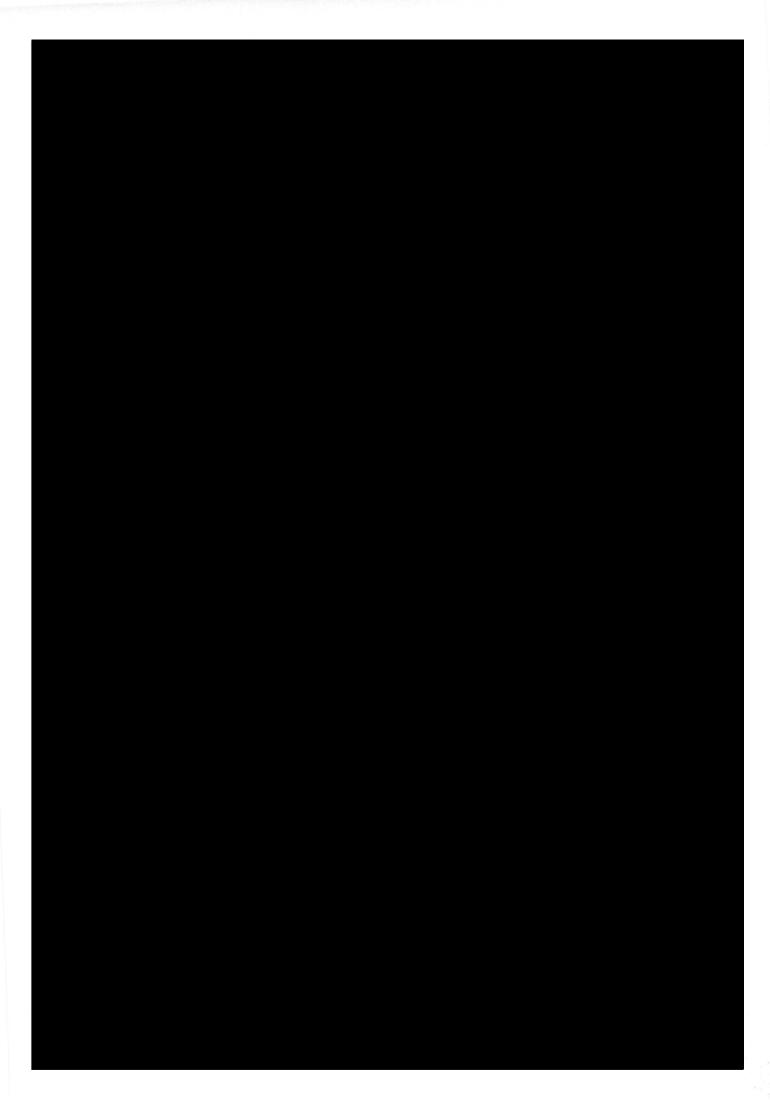
#### Introduction

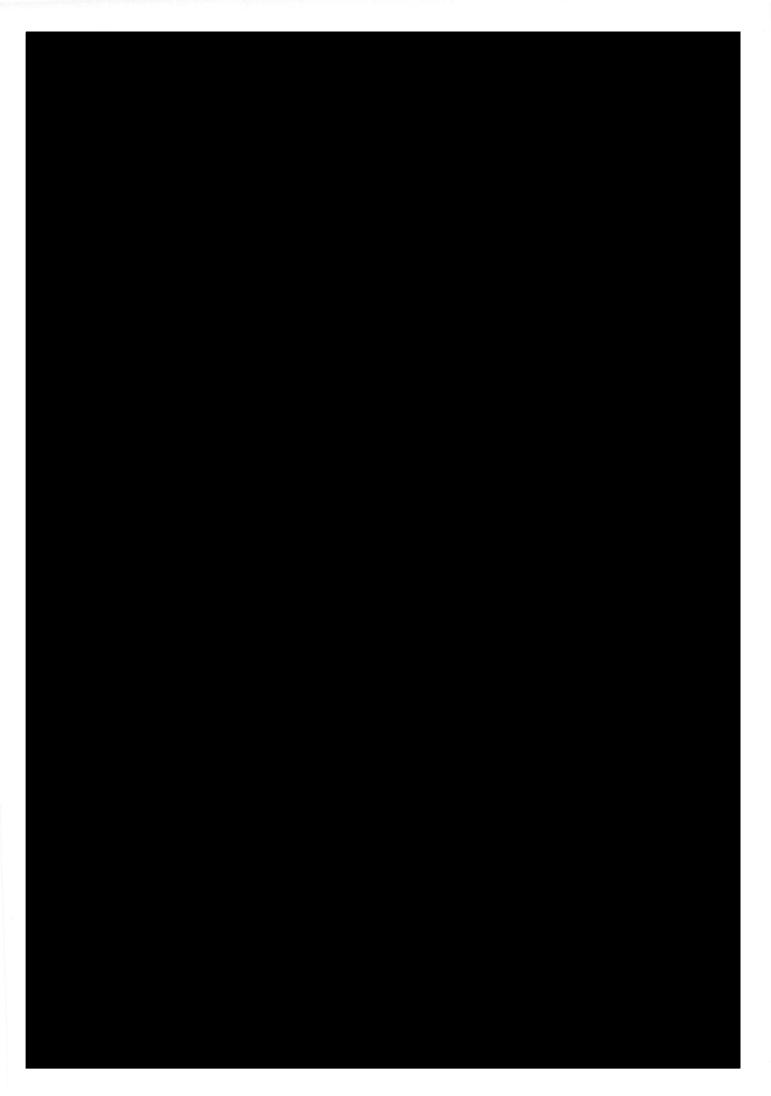
A wide range of dermal fillers is now available for use in facial esthetics.1 All are potentially capable of causing complications,23 but fortunately, serious occurrences are rare, although probably underreported. Careful attention to patient selection, education, and injection technique can minimize the incidence of complications, and an understanding of the early signs of complications and their proactive management can decrease their impact.

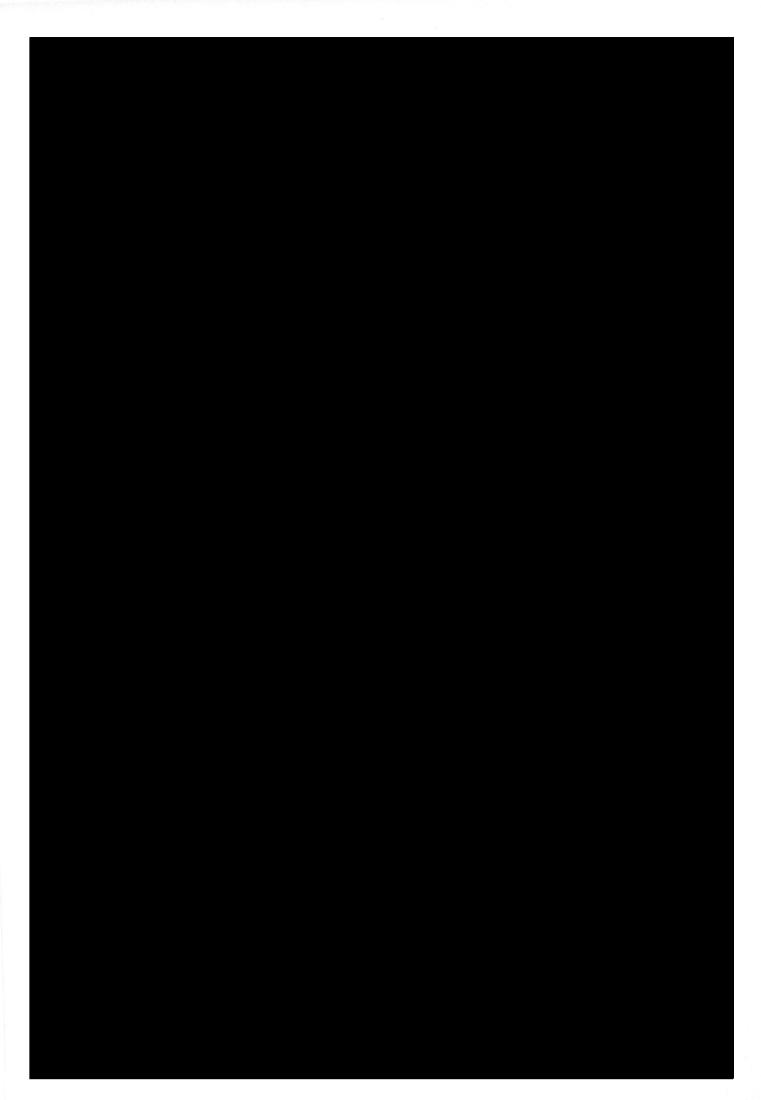
Selecting appropriate patients, or perhaps more importantly, not treating inappropriate patients, is the first and a crucial step in avoiding complications with dermal fillers. This review considers the factors that should be borne in mind when assessing a patient for suitability for dermal filler treatment. It aims to give the practitioner an overview of contraindications, preventative measures, recognition of events, and appropriate treatment options. There remains, however, no consensus on the best treatment for adverse reactions, and each treatment option with its advantages and disadvantages should be carefully considered and discussed with the patient.4

Cosmetic surgery is usually an elective process, requested by the patient. As such, clinical trials are complex to organize and conduct. For this reason, an international group of practicing physicians in the field of cosmetic surgery came together to share









# ADA WA CPD 2015

### **Introductory Course in Botox & Dermal Fillers**





#### DATE

Friday & Saturday 20-21 February

#### TIME

9am-5pm

#### **VENUE**

The Rose Medical Ctr Lvl 1, 78 Stirling Hwy North Fremantle (Parking available on site)

#### FEE

\$2,900.00 (inc GST) Limit: 20 (includes all supplied materials, catering and patients)

#### **CONVENOR**

Dr Jenny Ball

CPD HOURS: 14



#### Presented by Dr Kate Morlet-Brown and Scott McLennan

The Dental Board of Australia has reviewed its Policy on the use of Botulinum toxin and dermal fillers. The Board has taken a transitional measure by withdrawing the previous Interim Policy. In the absence of a finalised Policy, the Board now appears to allow for the provision of these treatments, very much subject to the specific conditions set out in the DBA communique issued on 5th November 2014. The overriding principle is that like all treatment provided by a dentist, these treatments must be within the practice of dentistry.

This limited attendance two day introductory course in botulinum toxin and dermal fillers will cover foundation principles eg. facial anatomy, the science of facial ageing, facial aesthetics, the science and pharmacology of the products being used, basic indications and injection techniques, complications, prevention and management - in the form of didactic training/lectures. The demonstration of surface and applied anatomy, product management and injection techniques will be in the form of hands-on training with supplied live patients so that you can start injecting on the course. A full variety of products available on the market will be discussed. The use of the products outside the approved indications will not be covered. It will be necessary to pass a written exam before moving onto the hands-on component of the course.

(OMS) from the Royal College of Dental Surgeons. Her private practice is in North Fremantle, WA and focuses on traditional Oral & Maxillofacial Surgery along with contemporary cosmetic medicine. Dr Morlet-Brown speaks at major Australian and International cosmetic meetings and regularly attends international events. Dr Morlet-Brown has been training medical practitioners for over 8 years in Australia, New Zealand, and many countries in Asia by way of lecturing, workshops and one-on-one specialist training sessions.

Scott McLennan is a highly trained and experienced consultant in Aesthetic Dermatology, including clinical applications & treatments, and the training & education of numerous other specialists around the world. Scott regularly presents at international conferences and workshops keeping his skills attuned to the latest nonsurgical aesthetic trends whilst also presenting his unique perspective on ageing and utilising the different products available. After completing his studies at the University of Sydney, Scott has worked in various clinical settings, including the Australian Army and numerous hospitals, before settling in Aesthetic Medicine, where he has been working since 2002. Scott is the Head of the Regional Centre of Excellence for Galderma based in Hong Kong, working and leading a variety of multi-disciplinary teams locally and globally.

#### About the Presenters:

ADA WA CPD 2015 Registration Form - DENTIST ONLY

I am a member of the ADA - WA / SA / VIC / NSW / QLD / TAS / NT Branch (please circle)

**Dr Kate Morlet-Brown** is an Oral & Maxillofacial Surgeon based in Perth, WA. Kate holds degrees in Dentistry and Medicine from UWA and Specialist

A multiple course Registration Form may be downloaded from the ADA website at www.adawa.com.au in the CPD area.

Course Name:	Course Date://			
Please use block letters when filling in your details.				
Title: (Prof/Dr/Other)				
Given Name:				
Surname:				
Postal Address:				
State:	Postcode:			
Work Phone: Mobile Phone:				
Email Address:				
Additional Participants: (Names)  Special Dietary   Vegetarian   Gluten Free				
Requirements:   Lactose Free	☐ Other:			
Payment: Total Amount: \$ (includes GST)				
Please Note: Non ADA Members add 50% to course fee (members of other ADA branches exempt)				
□ Credit Card: □ Mastercard □ Visa □ AMEX □ Diners				
Card Number: Expiry Date: /				
Cardholder Name: Signature:				
Fax completed form to ADA WA Branch (08) 9321 1757 or email to adawa@adawa.com.au or cpd@adawa.com.au				
☐ Cheque: Make cheque payable to ADA WA Branch Inc and post to PO Box 34, West Perth WA 6872 with	your Registration Form.			

Bookings, Course & Payment Enquiries: ADA Office (08) 9211 5600.

Other Enquiries: Dr Jenny Ball 0419 044 549.

Please note: Your registration for these events indicates acceptance of the CPD Terms and Conditions contained in the ADA WA CPD 2015 Course Book.

No Certificate of Attendance will be issued. A receipt/tax invoice will be provided showing the course name and CPD hours for your records.