Major surgery in melanoma patients

Guideline for wound care in Epidermolysis Bullosa

European guideline for cutaneous lupus erythematosus

European guideline on topical steroids in pregnancy

AAD guideline for acne vulgaris

Recommendations for acne fulminans

Upgraded PI warning for actinic keratosis gel

Update from the Global Burden of Disease Study

Improving patient care with teledermatology

Need to know more about multi-item billing?

New Medicare Benefits Schedule listings for Mohs surgery

New SAS Category C for unapproved goods

New ACD abstracts website

Etanercept biosimilar Brenzys PBS listed

PBS listing of adalimumab for hidradenitis suppurativa

PBAC recommendations

Welcome to the 4th issue of Dermatology Practice Review.

This new Review covers news and issues relevant to clinical practice in dermatology. It will bring you the latest updates, both locally and from around the globe, in relation to topics such as new and updated treatment guidelines, changes to medicines reimbursement and licensing, educational, medicolegal issues, professional body news and more. On the back cover you will find a summary of upcoming local and international educational opportunities including workshops, webinars and conferences.

We hope you enjoy this new Research Review publication and look forward to hearing your comments and feedback.

Kind Regards,

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Clinical Practice

New practice-changing research will reduce the need for major surgery in many melanoma patients

New findings from a large international clinical trial published in the New England Journal of Medicine are likely to change the way melanoma is managed in many patients by reducing the need for major surgery and its associated morbidity and cost. Many Australian patients participated in this trial and Melanoma Institute Australia was the top recruiting centre in the world.

National and international melanoma management guidelines currently state that patients who are found to have melanoma deposits in a sentinel lymph node should undergo immediate completion lymph node clearance. However the initial results of the second Multicenter Selective Lymphadenectomy Trial (MSLT-II) indicate that there is no difference in survival for sentinel-node positive patients who undergo immediate lymph node clearance compared to those who are closely monitored with ultrasound to detect disease progression.

MSLT-II study results

The three-year melanoma-specific survival was 86% ± 1.3% in 824 patients who had a completion lymph node dissection versus 86% ± 1.2% in 931 patients who were monitored after a median follow up of 43 months. The rate of disease-free survival was slightly higher in the dissection group than in the observation group (68% vs 63%; respectively; p=0.05) at 3 years, based on an increased rate of disease control in the regional nodes at 3 years (92% vs 77%; p<0.001); these results must be interpreted with caution. Nonsentinel-node metastases, identified in 11.5% of the patients in the dissection group, were a strong, independent prognostic factor for recurrence (HR 1.78; p=0.005). Lymphoedema was observed in 24.1% of the patients in the dissection group and in 6.3% of those in the observation group.

According to the study authors, these results are going to change treatment recommendations for sentinel-node positive patients most of whom will avoid the short-term and long-term morbidity that may follow a complete lymph node dissection. Only those who are found to have disease in their lymph nodes during the course of follow-up – about 20% – will ultimately require full regional lymph node dissection. This change in treatment recommendation is likely to improve the quality of life for many patients. In particular this will make a big difference to patients who have disease of the lower limb by reducing the rate of lymphoedema.

An initial sentinel lymph node biopsy of the primary melanoma site needs to be discussed as it provides further information about prognosis and may be needed to enter trials.

The management of regional lymph nodes has long been controversial in the treatment of many solid tumours particularly melanoma. This trial provides robust evidence to change the current practice guidelines to improve the management of patients with melanoma.

N Engl J Med 2017; 376:2211-2222
Press release

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International guideline for wound care in Epidermolysis Bullosa

The International Best Practice Guideline for Skin and Wound Care in Epidermolysis Bullosa has recently been updated, developed in close association with DEBRA International. The guideline has been developed to aid all clinicians who manage the skin and wound care of patients with the genetic skin fragility disorder Epidermolysis Bullosa (EB). Management strategies for wounds or wound complications are suggested for patients of any age diagnosed with any form of this genetically inherited disorder. It is a tool that can be used globally and includes advice for practitioners who have limited access to wound care materials. A variety of options for managing EB wounds are presented.

Download the full guideline [here](#).

European guideline for treatment of cutaneous lupus erythematosus

This paper reported on a European subcommittee’s guidelines for cutaneous lupus erythematosus (CLE), guided by the European Dermatology Forum and supported by the European Academy of Dermatology and Venereology. The 16 European participants included in this project agreed on the following recommendations:

1. Topical corticosteroids remain the mainstay of treatment for localised disease, with additional topical agents (e.g. calcineurin inhibitors) listed as alternative first- or second-line options;
2. Antimalarials are recommended as first-line and long-term systemic treatment in all patients with CLE who have severe and/or widespread skin lesions, particularly those with a high risk of scarring and/or the development of systemic disease;
3. Systemic corticosteroids added to antimalarials are recommended as first-line treatment in highly active and/or severe CLE;
4. Second- and third-line systemic treatments are methotrexate, retinoids, dapsone and mycophenolate mofetil or mycophenolate acid; and
5. Thalidomide use should be limited to selected therapy-refractory patients, preferably in addition to antimalarials. Several new therapeutic options (e.g. B-cell- or interferon-α-targeted agents) require further evaluation in clinical trials.

*J Eur Acad Dermatol Venereol* 2017;31(3):389–404

European guideline on topical corticosteroids in pregnancy

These authors reported updated evidence-based guidelines from a subcommittee of the European Dermatology Forum for the use of topical corticosteroids during pregnancy. The current best evidence, which is from 14 observational studies (n=1,601,515), suggests no significant association between topical corticosteroid use at any potency during pregnancy and mode of delivery, birth defect, preterm delivery or foetal death. This is reassuring to mothers and it should be pointed out that there is less risk when compared with systemic corticosteroids.

However, use of potent/very potent topical corticosteroids during pregnancy, especially in large amounts, does increase the risk of low birthweight. As with any topical corticosteroid, there are more risks when large areas are treated, used in areas with high absorption and where the skin barrier is impaired and under occlusion. There are no data available to determine whether newer lipophilic topical corticosteroids (mometasone furoate and methylprednisolone aceponate) are associated with less risk of low birthweight, although on theoretical grounds they may be safer.

*J Eur Acad Dermatol Venereol* 2017;31(3):761–73

AAD guideline for the management of acne vulgaris

This paper by the American Academy of Dermatology (AAD) is a good reference point as a ‘big picture view to acne treatment’. These guidelines are evidence based and are an update from the 2007 guidelines. They provide strength of recommendation, level of evidence and comprehensive referencing for classification, investigation as well as topical and oral treatments for acne. It is a good refresher and one can easily skip sections to gain an insight into the area of interest.

The guideline addresses important clinical questions associated with the management of acne vulgaris, including review of issues of acne grading and topical and systemic management. It is the result of work done by a group of 17 recognised acne experts, one GP, one paediatrician and one patient, and a review of 242 papers. The full 62-page paper with all recommendations can be accessed by clicking the link below.


Evidence-based recommendations for the management of acne fulminans and its variants

A panel of physicians with expertise in severe acne vulgaris convened and comprehensively reviewed the literature with the aim of improving the definition of acne fulminans and its variants, devise optimal therapeutic approaches and identify areas of future research. The final recommendations were limited by a lack of evidenced-based data and prospective studies on the treatment of acne fulminans.

Commenting on the recommendations, Dr Warren Weightman from Queen Elizabeth Hospital, Adelaide, said that most dermatologists would agree with the main recommendation of oral prednisolone 0.5–1.0 mg/kg for acne fulminans. Prednisolone should be continued until the crusted lesions have healed and then low-dose isotretinoin
(0.1 mg/kg/day) can be added. Systemic corticosteroids need to be continued for 3–4 months or longer if the acne is not settling. Isotretinoin can be gradually increased as control is achieved. High-dose doxycycline (100 mg twice daily) or minocycline 100 mg twice daily can be given as alternatives to isotretinoin if it is contraindicated. There are no specific data regarding the use of biologicals in acne fulminans, but TNF inhibitors have been used successfully to treat isotretinoin-resistant acne conglobata and also in treating acne in PAPA (pyogenic arthritis, pyoderma gangrenosum and acne) and PAPASH (pyogenic arthritis, pyoderma gangrenosum, acne and hidradenitis suppurativa) syndromes, and TNF blockers could be options in severe cases. Alternative immunosuppressive agents such as cyclosporin and dapsone have been successful in a small number of cases. Pulsed-dye laser is effective in improving wound healing, acne scarring and excess granulation tissue.


**Upgraded PI warning for hypersensitivity reactions, herpes and eye injury when using actinic keratosis gel**

The Product Information (PI) for Picato gel (ingenol mebutate) has been updated to warn against the risk of hypersensitivity reactions, herpes zoster and ophthalmic injury.

The TGA investigated safety concerns relating to ingenol mebutate following reports of severe allergic reactions, herpes zoster, ophthalmic injury and local skin reactions in the United States. Some of the cases were associated with the medicine not being used in accordance with its directions for use.

The TGA investigation found that the risk of local skin reactions was well-communicated in the PI, however this did not address the potential adverse events of hypersensitivity/anaphylaxis, herpes zoster reaction or ophthalmic injury. Based on this, the TGA worked with the sponsor (LEO Pharma) to update the Precautions and Adverse Effects sections of the PI for ingenol mebutate with appropriate information.

Picato gel is indicated in actinic keratosis. Its mechanism of action is to induce local lesion cell death and to promote an inflammatory response by production of proinflammatory cytokines and chemokines to infiltrate the immunocompetent cells. This mechanism in itself causes application site pain, pruritus, irritation, infection and oedema.

The CMI for ingenol mebutate instructs patients to ‘follow carefully all directions given to you by your doctor or pharmacist’. With this in mind, advice to health professionals is to provide patients with clear instructions regarding application of this medicine and consider providing them with a copy of the CMI.

Read the full alert [here](#).

**An update from the Global Burden of Disease Study 2013**

This study highlighted the degree of disability due to skin disease and compared it with other diseases. In 2013, skin conditions contributed 1.79% to the global burden of disease measured in disability-adjusted life years (DALYs) from 306 diseases and injuries. Although overall skin disorders were the eighteenth leading cause of disability, when mortality was excluded, they were the fourth leading cause of disability. Most skin diseases are chronic, so there may be lifelong disability, whereas other disorders may be cured or lead to patient death. The burden from skin diseases was 41.0 million DALYs, which was only just below the burden from tuberculosis, which was 49.8 million DALYs. The leading cause of global DALYs over the past decade has been ischaemic heart disease, responsible for 150.2 million DALYs. When mortality was excluded, the years lived with disability from skin diseases (36.4 million) were larger than those caused by diabetes mellitus (29.5 million) and migraines (28.9 million). These data can be used to prioritise funding for research and treatments of skin diseases, and show governments that skin diseases are as needful as other disorders.

*JAMA Dermatol 2017;153(5):406–12*

**Improving patient care with teledermatology**

Australian dermatologists are using teledermatology to help patients in rural and remote areas to access specialist health care services. There are two models of telehealth currently being used by dermatologists – videoconferencing and store-and-forward. Store-and-forward is when a dermatologist provides a diagnosis using digital images taken by a patient’s GP or another doctor. As technology advances, these new models of care will provide much needed dermatology services to patients with skin conditions or skin cancers in rural areas, or for those who can’t easily get to their doctor.

According to Professor H Peter Soyer, Director of the Dermatology Research Centre at The University of Queensland, teledermatology can rapidly reduce waiting times and the burden on patients and the health care system, particularly in rural and remote regions of Australia. Research shows that diagnosis of skin conditions with teledermatology is accurate and reliable. The Dermatology Research Centre conducted a study of patients presenting with dermatology conditions in the Emergency Department of the Princess Alexandra Hospital in Brisbane. The results found that 93% of cases received a dermatologist’s opinion within two hours using teledermatology and there was 98% agreement between tele-diagnosis and the final diagnosis. While currently not funded by Medicare, store-and-forward telehealth may provide significant improvements in the quality of care for dermatology emergencies and for long term patient management.

Read more [here](#).
News in brief

Need to know more about multi-item billing?
The Department of Human Services has released an education guide to help work out when to multi-item bill under the Medicare Benefits Schedule (MBS). The guide has useful information and practical scenarios so you know when to use multi-item billing. It also explains MBS item descriptors and when benefits are payable. The scenarios include paying benefits if you attend to a patient multiple times on the same day, and attendances with another service.
Click here to read the multi-item billing education guide.

Reminder: New Medicare Benefits Schedule listings have commenced for Mohs surgery item number 31340
As of 1 May 2017, practitioners have been able to claim the items for Mohs surgery (31000-31002) with item 31340 for the excision of muscle, bone or cartilage. For details of the changes please refer to Health Insurance Legislation Amendment (2017 Measures No. 1) Regulations 2017 (click on the ‘Explanatory Statement’ tab) or visit MBS Online.

TGA announces new SAS Category C for unapproved goods
From 3 July 2017, certain unapproved therapeutic goods can be supplied immediately to patients without first requiring approval by the TGA, under the new Special Access Scheme (SAS) Category C pathway. This will include certain allergens for confirmation of suspected allergic reactions. Through these changes, practitioners will be able to provide needed treatments that are deemed to have an established history of use to their patients in a timelier manner.
Read more here.

New ACD abstracts website
The new Australasian College of Dermatologists website for Annual Scientific Meeting abstracts has now gone live. The website contains all abstracts from the 2012 to 2017 meetings and will be utilised as an ongoing resource in the future.
Please click here to go to the meeting abstracts website.
Product Listing and Reimbursement

Etanercept biosimilar Brenzys PBS listed
From April 1, etanercept biosimilar Brenzys was listed on the PBS for the treatment of patients with severe active RA, severe psoriatic arthritis, severe chronic plaque psoriasis, and ankylosing spondylitis.
Read more here.

PBS listing of adalimumab for hidradenitis suppurativa
Adalimumab (Humira) is now listed on the PBS for treatment of patients with moderate to severe hidradenitis suppurativa. Clinical criteria include Hurley stage II or III grading with an abscess and inflammatory nodule count greater than or equal to three and failure, adverse reaction or contraindication to antibiotics (two courses of different antibiotics each for three months). Patients must be treated by a dermatologist.
Read more here.

PBAC recommendations
The PBAC recommended the General Schedule Authority Required (Streamlined) PBS listing of methotrexate pre-filled syringe (with embedded needle) for subcutaneous administration for the treatment of RA or psoriasis when methotrexate oral tablets are unsuitable, on a cost minimisation basis with methotrexate 50 mg vial, taking into account the offsets associated with reduced administration costs.
Read more here.
The PBAC recommended the listing of vemurafenib monotherapy for the treatment of patients with BRAF V600 mutation positive unresectable malignant melanoma as an authority required listing in the General Schedule on a cost-minimisation basis with dabrafenib. The PBAC recommended that the restriction should be the same as the restriction for dabrafenib monotherapy for unresectable Stage III or IV malignant melanoma.
Read more here.

Conferences, Workshops, and CPD

Please click on the links below for upcoming local and international dermatology meetings, workshops and CPD.
The Australasian College of Dermatologists - Events
DermNet New Zealand - Conferences
Australian Dermatology Nurses’ Association - Events
TheConferenceWebsite - Dermatology Conferences
Conferenceseries.com - Dermatology Conferences

Research Review publications

Dermatology Research Review
with Dr Warren Weightman
http://tinyurl.com/qgez49g

Psoriasis Research Review
with Clinical Professor Kurt Gebauer
http://tinyurl.com/zcg897n

Melanoma Research Review
with Assoc Prof Pascale Guitera, Assoc Prof Schaider and Dr Megan Lyle
http://tinyurl.com/zcb7sw7

Skin Cancer Research Review
with Dr Peter Soyer
http://tinyurl.com/vby4htzj

ASCO 2017 Conference Review - focus on melanoma
http://tinyurl.com/ya8hs7n2

ACD 2017 Conference Review
http://tinyurl.com/v85gqtap

AAD 2017 Conference Review
http://tinyurl.com/vbze77d

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