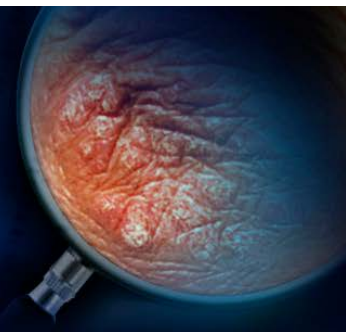
Dermatology Practice Review™



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Welcome to the second 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.

In this issue we report updated US guidelines for the prevention of peanut allergy which recommend that infants with severe eczema, egg allergy, or both should be introduced to peanuts in their diet as early as 4 to 6 months of age. Staying in the United States, the *NEJM* has reported an unusual rash in a pregnant woman with locally-acquired Zika virus infection; the first non-travel-associated case of Zika virus infection in the United States. On the local front, an interesting new report says there is no evidence that tick-borne Lyme disease exists in Australia. And finally 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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Medical Research Advisor

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Clinical Practice

US consensus clinical treatment plans for juvenile dermatomyositis with persistent skin rash

Juvenile dermatomyositis (JDM) is the most common form of idiopathic inflammatory myopathy in children. Persistence of skin rash is a common problem, despite complete resolution of muscle involvement. This study, by The Childhood Arthritis and Rheumatology Research Alliance, a North American consortium of paediatric rheumatologists and other healthcare providers, described the development of clinical treatment plans for children with JDM characterised by persistent skin rash.

A combination of Delphi surveys and nominal group consensus meetings was used to develop clinical treatment plans that reflected consensus on typical treatments for patients with JDM with persistent skin rash.

Consensus was reached on patient characteristics and outcome assessment. Patients should have previously received corticosteroids and methotrexate (MTX). Three consensus treatment plans were developed. Plan A added intravenous immunoglobulin (IVIG) if it was not already being used. Plan B added mycophenolate mofetil, while Plan C added cyclosporine. Continuation of previous treatments, including corticosteroids, MTX, and IVIG, was permitted in plans B and C.

The authors state that these clinical treatment plans reflect typical treatment approaches and are not to be considered treatment recommendations or standard of care. Using prospective data collection and statistical methods to account for nonrandom treatment assignment, it is expected that these clinical treatment plans will be used to allow treatment comparisons, and ultimately determine the best treatment for these patients.

J Rheumatol. 2017 Jan;44(1):110-116

Updated US guidelines for prevention of peanut allergy

The US National Institute of Allergy and Infectious Diseases (NIAID) has released updated guidelines for peanut allergy prevention, with specific strategies for infants at various levels of risk.

The guidelines focus, in particular, on early introduction of peanut-containing foods into the diets of infants. The recommendations will allow healthcare providers to guide parents on how to proceed with introduction based on an individual child's risk of developing a peanut allergy.

Topics addressed include the definition of risk categories, appropriate use of testing (specific [immunoglobulin E (IgE)] measurement, skin prick tests, and oral food challenges), and the timing and approaches for introduction of peanut-containing foods in the health care provider's office or at home.

Infants with severe eczema, egg allergy, or both

Infants with severe eczema, egg allergy, or both are at high risk of developing peanut allergy. To reduce the risk, the guidelines recommend that peanut-containing foods should be introduced into their diets as early as 4 to 6 months of age.

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Clinical Practice

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However, before introducing these foods, clinicians should first perform allergy testing in these children. If the peanut sIgE level is less than 0.35 kU_A/L, peanut should be introduced into the infant's diet soon after, providing a cumulative dose of approximately 2 g peanut protein.

However, if the peanut sIgE level is 0.35 kU_A/L or greater, the provider should refer the infant to a specialist for assessment and additional tests, such as a skin prick test with peanut extract. After skin prick test, for infants who develop a wheal with a diameter of 2 mm or less above saline control, peanut should be introduced into the diet soon after, providing a cumulative dose of approximately 2 g peanut protein.

In contrast, infants who develop a wheal 3 to 7 mm in diameter should undergo supervised peanut feeding first at a specialist's office. However, those who develop a wheal 8 mm or greater in diameter have a high chance of a preexisting peanut allergy.

In this case, specialists may consider not introducing peanut to the infant's diet, and instead might advise the child avoid peanuts completely.

Infants with mild or moderate eczema

For infants with mild or moderate eczema, the guidelines recommend that parents introduce peanut-containing foods into the children's diets at about 6 months of age, either at home or in the provider's office.

Infants with no eczema or egg allergy

Infants with no eczema or egg allergy are considered at low risk of developing peanut allergy. Peanut-containing foods can be freely introduced into their diet with other solid foods, according to the family's preference, also at around 6 months of age.

Download the article here.

Cutaneous eruption in a US woman with locally-acquired Zika virus infection

The *NEJM* has reported a non-travel-associated case of Zika virus infection in the United States. The pregnant woman, locally infected in the United States with the Zika virus, presented with an unusual rash last year.

The 23-year-old woman who was 23 weeks and 3 days pregnant and had not yet sought prenatal care, presented with a 3-day fever, widespread itchy rash, and sore throat. Two days later, myalgias and joint pain developed. The woman had reddish follicular macules and papules spread across her abdomen, back, and arms, scattered tender pink papules on the palms, and a few petechiae on the hard palate.

Screenings showed no signs of dengue, measles, chickenpox, rubella, syphilis, Epstein–Barr virus, influenza, hepatitis B or C, or mumps. Liver and kidney function were normal.

Zika RNA was detected in both urine and blood and continued to be detected for 2 weeks in urine samples and for 6 weeks in blood samples.

The woman's fever and rash subsided after 3 days of care. The baby was delivered at full term at 6.6 pounds. Head size and intracranial anatomy were normal and there were no calcifications.

No signs of Zika were found in the placental tissue or in neonatal laboratory testing.

As of December 28, 2016, travel-associated cases of Zika in the US numbered more than 4500. But in this case, neither the patient nor her partner had travelled outside the US in 2 years. As of January 18, 2017, 217 locally acquired mosquito-borne cases had been reported.

N Engl J Med. 2017 Jan 11

Biosimilar survey finds knowledge gaps among US specialists

A recently published biosimilar survey administered to specialists in the United States found five knowledge gaps.

The gaps included the following: not being able to define biologics, biosimilars or biosimilarity; not understanding how the FDA uses a "totality of evidence" to approve biosimilars; not understanding that the biosimilar is as safe as the originator; an inability to understand the rationale for extrapolation of indications; and an inability to define interchangeability or pharmacy-level substitution rules.

Between November 2015 and January 2016, researchers from the Biosimilars Forum designed a 19-question survey that was administered to 1201 specialists who prescribed biologics. The group included dermatologists, gastroenterologists, haematologists, oncologists, medical oncologists, nephrologists and rheumatologists.

The survey was intended to provide a baseline level of knowledge about biosimilars and will be repeated in 2–3 years in order to monitor trends over time.

Adv Ther. 2017;33(12),:2160-72

Clinical Practice

Practice patterns of US dermatologists versus guidelines for primary cutaneous melanoma

This online survey conducted in the USA aimed to evaluate to what extent dermatologists follow clinical guidelines. The study surveyed dermatologists (540 respondents) to assess preferred biopsy methods for lesions suspicious for melanoma, margins used for excision, and recommended follow-up intervals.

Only 31% of dermatologists used narrow excisional biopsy (<5mm margins) as a preferred excision method for suspicious cutaneous melanoma, while in most of the guidelines (American Academy of Dermatology and National Comprehensive Cancer Network) this is the recommended method. Shave biopsy and saucerisation/scoop shave accounted for about half of the methods used (45%). According to Dr Helena Collgros and Associate Professor Pascale Guitera from the Sydney Melanoma Diagnostic Centre, this may reflect a low suspicion of melanoma, or biopsies for lentigo maligna, in which shave is appropriate, however this seems unlikely given the extent of usage. It is most likely due to time constraints, which should not be more important than patient care. The use of punch biopsy may be justified to confirm the diagnosis of a melanocytic lesion versus non-melanocytic, knowing that the complete excision will be performed if it is melanocytic; in facial or acral lesions without a clear clinical diagnosis of melanoma, or in large lesions such as congenital nevi, targeting the area of concern. There is less controversy in melanoma excision margins, however strikingly 14% of respondents used <1cm margins for excising melanomas >1 mm thick.

The most commonly recommended follow-up interval was 6 months for the first 5 years (49%), extending to yearly reviews afterwards (64%). This is consistent with the recommendation of the guidelines that state every 3 to 12 months. The authors highlight that the deviation noted from the guidelines may indicate that there is a need for continuous education of dermatologists, but also that clinical guidelines should be reassessed and updated frequently. To ensure a homogeneous quality of care, guidelines should be followed.

J Am Acad Dermatol 2016 Dec;75(6):1193-1197

Is there a Lyme-like disease in Australia? Summary of the findings to date

Lyme Borreliosis is a common tick-borne disease of the northern hemisphere caused by the spirochaetes of the *Borrelia burgdorferi* sensu lato (*B. burgdorferi* s. l.) complex. It results in multi-organ disease with arthritic, cardiac, neurological and dermatological manifestations.

Suggestions that a Lyme-like disease may exist in Australia remain controversial and no study to date has identified the presence of a *Borrelia* species infecting people that have a locally acquired Lyme-like syndrome. It is unclear whether the cause of this syndrome is a *B. burgdorferi* s. l. related organism, another pathogen altogether or of non-infectious aetiology.

Over 500 Lyme-like cases in Australian patients have been published but upon investigation, these diagnoses were highly questionable due to significant flaws in the diagnostic process or presentation of results. Only in one case has a Lyme Borreliosis-causing *Borrelia* species been cultured from an Australian patient. This patient had a history of travel to a Lyme endemic area of the northern hemisphere so overseas acquisition cannot be ruled out. Serology has a low positive predictive value in non-endemic areas and cannot be relied upon for diagnosis. The reported culture of possible *Borrelia* spirochaetes from 109 Australian ticks was not reproduced in over 10,000 ticks. *B. burgdorferi* s. l. has never been cultured from an Australian patient that could not have acquired the infection overseas and therefore there is currently no proof that *B. burgdorferi* s. l. or any other kinds of *Borrelia* species are infecting people in Australia.

If there is a Lyme-like disease that exists in Australia it may well be of a different aetiology. The authors of this review recommend that in the non-endemic context such as Australia, in addition to following the RCPA protocol for the diagnostic laboratory testing of Borreliosis, a minimum of live *Borrelia* culture combined with a positive, sequenced *B. burgdorferi* s. l. specific PCR and independent verification of the identity of that organism by an experienced reference laboratory is required to confirm any future diagnosis of Australian acquired Lyme Borreliosis.

One Health. 2016;2:42-54

News in brief

Australian best practice guidelines for melanoma care goes digital

Health professionals treating melanoma patients have access to the first in a series of new, wiki-based clinical recommendations with the launch of electronic clinical practice guidelines for the diagnosis and management of melanoma. The first in a comprehensive series of updated melanoma guidelines, it provides evidence-based recommendations on the recognition of melanomas, biopsy of suspicious lesions, when to perform sentinel node biopsy and margins for radical excision of primary melanomas. The new set of guidelines are available at: wiki.cancer.org.au/australia/Guidelines:Melanoma

Sunscreen use and individual reactions: a message from Cancer Council Australia

Cancer Council Australia says that reactions to its SPF 50+ Kids sunscreen are being investigated and that Cancer Council's sunscreen range remains safe and effective for the vast majority of users. Anyone with concerns is urged to phone the sunscreen info line on 1300 364 515. Cancer Council is working with two individuals who reported concerns to determine the specific cause of their reactions.

Cancer Council Australia, January 5, 2017.

TGA review on the safety of titanium dioxide and zinc oxide in sunscreens

The TGA has recently conducted a literature review on the safety of zinc oxide (ZnO) and titanium dioxide (TiO) nanoparticles (NPs) present in sunscreens. The majority of in vitro studies (using both animal and human skin) and in vivo studies have shown that both ZnO and TiO NPs either do not penetrate or minimally penetrate the stratum corneum and underlying layers of skin. This suggests that systemic absorption, hence toxicity, is highly unlikely. They conclude that, based on current evidence, neither TiO nor ZnO NPs are likely to cause harm when used as ingredients in sunscreens and when sunscreens are used as directed.

Read more here.

Product listing and reimbursement

TGA approvals

Ixekizumab has been registered for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Talimogene laherparepvec, a modified herpes simplex virus type 1 (HSV-1) encoding GMCSF, has been approved for the treatment of melanoma that is regionally or distantly metastatic.

Sonidegib diphosphate, a potent, selective, and orally bioavailable smoothened antagonist, has been approved for the treatment of adult patients with:

- Locally advanced basal cell carcinoma who are not amenable to curative surgery or radiation therapy.
- Metastatic basal cell carcinoma.

Read more here and here.

PBS listings

Secukinumab is now available on the PBS for patients with severe psoriatic arthritis, severe chronic plaque psoriasis and ankylosing spondylitis.

Certolizumab pegol is now available on the PBS for patients with active ankylosing spondylitis and severe psoriatic arthritis.

Read more here.

PBAC recommendations

The PBAC recommended the Restricted Benefit listing of **calcipotriol with betamethasone** foam spray for the treatment of chronic stable plaque psoriasis vulgaris subject to a cap on PBS expenditure. The PBAC noted the PBS cost was sensitive to the assumed number of packs per service and further recommended that the usage of calcipotriol with betamethasone foam spray be reviewed following listing.

The PBAC recommended the listing of an **infliximab biosimilar** (Renflexis) of infliximab (Remicade) on a cost minimisation basis with infliximab (Remicade) for all indications – rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, chronic plaque psoriasis, Crohn's disease, fistulating Crohn's disease and ulcerative colitis. The PBAC considered that the evidence presented in the submission supported the claims of comparative safety and effectiveness of Renflexis and Remicade.

Read more here.

Conferences

The Dermatology Nurses' Association 35th Annual Convention
1-4 March, 2017, Orlando, FL, USA
Details: http://www.dnanurse.org/

American Academy of Dermatology Annual Meeting
3-7 March, 2017, Orlando, FL, USA
Details: https://www.aad.org/meetings/annual-meeting

12th International Congress on Systemic Lupus Erythematosus & the 7th Asian Congress on Autoimmunity
26-29 March 2017, Melbourne, VIC
Details: http://lupus2017.org/

Australasian College of Dermatologists Annual Scientific Meeting
6-9 May, 2017, Sydney, NSW
Details: http://www.acdasm2017.com/

16th European Dermatology Congress
7-8 June, 2017, Milan, Italy
Details: http://dermatology.conferenceseries.com/europe/

Workshops, Webinars and CPD

Vitiligo Master Class
5 May, 2017, Sydney, NSW
Further information available here.

Patch Testing Training Day
5 May, 2017, Sydney, NSW
Further information available here.

Research Review publications

Dermatology Research Review
with Dr Warren Weightman
http://tinyurl.com/gqez49g

Psoriasis Research Review
with Clinical Professor Kurt Gebauer
http://tinyurl.com/zcq897n

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

