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This summer edition of *NPS News* explores the place of topical therapies in managing the diverse conditions of solar keratoses, basal cell carcinoma (BCC) and superficial fungal infections.

Treating BCC and solar keratoses

There are a wide range of treatment options for managing solar keratoses and basal cell carcinoma (BCC) with varying effectiveness and side effects. Few comparative trials have evaluated the long-term efficacy of different treatment options.

Involving the patient in treatment decisions is essential. Choice of treatment depends on the site, size, number and thickness of lesions and, for BCC, the overall risk of recurrence (see Box 1).^{1,3} Other considerations include age, general health, patient preference, access to primary or secondary health care, and cost (some treatments are not subsidised under the Pharmaceutical Benefits Scheme [PBS]).^{1,3}

BCC is the most common type of cancer in Caucasians and Australia has the highest rate in the world.¹ Advise everyone about sun avoidance and regular surveillance to detect skin cancers early.^{1,2,4,5} Visit www.cancer.org.au/cancersmartlifestyle/SunSmart.htm for more information and resources to help people reduce their risk of skin cancer.

Surgery still the gold standard for BCC

Surgery remains the mainstay of treatment for most BCCs.^{1,4} Surgical excision has a high success rate and allows histological evaluation of the tumour and its margins. Long-term recurrence rates are reported to be less than 2% at 5 years for primary BCC following histologically confirmed complete excision.⁶ Other treatments may be useful if surgical excision is

contraindicated or poses an unacceptable risk (e.g. bleeding, scarring, keloid formation); confirm the histological tumour type before other surgical or non-surgical approaches.⁴

Risk of recurrence guides treatment choice

Wide-margin surgical excision, radiotherapy and Mohs micrographic surgery are suitable options for high-risk BCC. Other treatments are generally only suitable for low-risk lesions.²

Ensure patients understand the expected benefits and risks of treatment options including, if possible, the anticipated rate of recurrence and need for further treatment.¹

Box 1: Risk factors for recurrence of basal cell carcinoma (BCC)^{1,2}

Tumour location (head and neck, central face, especially near eyes, lips, nose and ears)
Tumour size (large tumour [> 2 cm])
Morphology (poorly defined borders)
Histological subtype (morphoeic, infiltrating and micronodular BCC more likely to recur)
Recurrent lesions (following treatment)
Immunosuppression

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Topical therapies limited role in BCC

Reserve topical therapies for superficial BCC with a low risk of recurrence² because they have lower cure rates than surgery. Photodynamic therapy is an option for low-risk superficial and nodular BCC.^{2,4} Compared with surgery, better cosmetic outcomes have been reported with photodynamic therapy using topical methyl aminolevulinate for nodular BCC (87% rated 'good' or 'excellent' by the investigators vs 54% with surgery) but the estimated rate of sustained complete response at 5 years was lower (76% vs 96% with surgery).⁷

In short-term trials, topical imiquimod* achieved histological clearance rates of 82% at 12 weeks for superficial tumours. However, its success relies on adherence to a 6-week treatment course.⁹ Long-term data on recurrence after treatment is limited; one report estimates a recurrence rate of 21% at two years after initial complete clearance (clinically evaluated) of superficial BCC.¹⁰

Imiquimod sachets are not designed for multiple use. The manufacturers recommend opening a new sachet before each treatment and discarding any residual cream after each treatment¹¹; there are no data on the sterility or stability of the cream in opened sachets. Local skin reactions with imiquimod are common (> 50% of people in trials) and can be severe.¹¹ For more information see *NPS RADAR: Imiquimod cream (Aldara) for superficial basal cell carcinoma* (available at www.nps.org.au/radar_imiquimod_2006).

There are few data on the efficacy of 5-fluorouracil in BCC and it is not approved for this indication.

When to refer for specialist management

Consider referring patients who have high-risk primary BCC or recurrent disease, or when there is uncertainty about diagnosis or appropriate management.¹

Topical therapies for solar keratoses

Solar (actinic) keratoses are markers for skin cancer. Examine patients fully for skin cancers anywhere on their body.¹² Histological diagnosis is recommended if malignancy is suspected.^{3,12}

Solar keratoses have a high rate of spontaneous regression (up to 25% over 12 months).¹³ Regular use of emollients can improve mild lesions as seen in the placebo (vehicle) arm of diclofenac trials.^{14,15} Salicylic acid's keratolytic and emollient effects may also be beneficial.^{3,12} Broad-spectrum sunscreens used regularly and other rigorous sun protection measures may delay development, or even lead to remission, of some solar keratoses.^{16,17}

Topical therapies (such as 5-fluorouracil, imiquimod, photodynamic therapy and diclofenac [see Table 1]) may be useful for field treatment of multiple lesions. There are limited data on the comparative efficacy of treatment options, and studies have not assessed whether they prevent invasive skin cancer. None of these topical therapies are listed on the PBS for solar keratoses, although 5-fluorouracil is listed on the Repatriation PBS.

Cryotherapy and photodynamic therapy using topical methyl aminolevulinate both demonstrated high complete response/cure rates (70% to 90%) in short-term clinical trials (3 to 6 months follow up), although relative efficacy varied between trials.¹⁸⁻²⁰

For solar keratoses around the mouth or eyes, cryotherapy, curettage or photodynamic therapy may be more suitable than 5-fluorouracil, diclofenac and imiquimod.³

* Imiquimod is PBS listed for the treatment of biopsy-confirmed primary superficial BCC in immunocompetent patients for whom surgical excision, cryotherapy or curettage with diathermy are inappropriate and topical drug therapy is required.⁸

Table 1: Topical therapies for solar keratoses

Topical therapy	Reported efficacy	Possible side effects
5-fluorouracil 5% (Efudix)	84% to 98% complete clearance in comparative trials (30 days after end of treatment and 6-month follow up). ^{21,22}	Temporary pain, burning, redness, blistering and cracking of the skin in the treated area; these usually resolve after treatment is discontinued. ²³
Imiquimod 5% (Aldara)	45% to 84% complete clearance of lesions on the face and scalp (2–8 weeks after the end of treatment). ^{24–27}	Local skin reactions (itching, burning, pain, erythema, flaking, scaling, dryness, scabbing, crusting, erosion and ulceration) are common and can be severe. ²⁵ In trials, 5% of imiquimod treated patients withdrew because of local skin reactions, 41% of patients required at least one rest period but most resumed treatment thereafter. ¹¹ Systemic flu-like symptoms may occur (e.g. malaise, fever, nausea, myalgia). ¹¹
Photodynamic therapy using methyl aminolevulinate (Metvix)	78% to 91% complete response in short-term comparative trials (after 3 to 6 months of follow-up). ^{18–20,28} Cryotherapy may be more suitable for thicker lesions ^{19,28} and those in less cosmetically sensitive areas. ^{3,18,20}	Temporary pain, burning, erythema, itching, oedema and crusting. Pain is sometimes severe and may require analgesia and/or local anaesthesia, or rarely, treatment cessation. ²⁹
Diclofenac (Solaraze 3% gel)	50% complete clearance vs 20% with placebo (30 days follow-up after the end of treatment). ¹⁵	Contact dermatitis, erythema, rash, inflammation, irritation, pain, itching, tingling or blistering in the treated area. ³⁰ Probably better tolerated than 5-fluorouracil ²² ; mild to moderate local reactions were reported in about 30% of people in trials. ^{14,15}

Treating common superficial fungal infections

Most superficial fungal skin infections can be treated with topical agents, many of which are available over the counter and are PBS subsidised for Aboriginal and Torres Strait Islander peoples (see Insert).

Treat mild uncomplicated fungal skin infections empirically

Topical antifungal agents are the preferred choice for mild localised skin infections. Treatment can start without sampling for microscopy and culture.³¹ Samples should always be taken when the clinical diagnosis is uncertain, the infection is severe or widespread, and when considering oral therapy.^{12,32}

Consider topical azoles (e.g. clotrimazole, bifonazole, miconazole) or terbinafine as initial therapy for superficial tinea infections of the skin, groin and feet.^{33–36} Individual azoles provide similar cure rates.³³ Topical terbinafine once daily for 7 days is as effective as topical azoles for 4 weeks, and more effective when terbinafine treatment is longer (4–6 weeks).³³ A short course of topical terbinafine may be more suitable than other agents if compliance is likely to be poor.²⁹

A short course of an antifungal with a corticosteroid is only indicated when there is severe inflammation.³¹ Stop the combination preparation once inflammation subsides. Continue topical antifungal therapy (except for terbinafine) for up to two weeks after signs and symptoms of infection resolve and cultures, if taken, are negative.^{12,29,31}

Discuss with the patient factors that may contribute to fungal infections and strategies for preventing recurrence of infection (see Table 2).

When to refer patients to a GP

Pharmacists and nurses should refer patients with superficial fungal infections to a GP when there is:

- uncertainty about the diagnosis
- severe or extensive fungal infection
- no sign of clinical improvement within 2–4 weeks of topical treatment
- an indication for systemic treatment (e.g. tinea capitis, onychomycosis).³¹

Table 2: Strategies to prevent common superficial fungal infections^{12,29,31,32,37-39}

Tinea (superficial skin infections including athlete's foot) and toenail onychomycosis	
<ul style="list-style-type: none">• keep affected areas clean, cool and dry (e.g. dry skin thoroughly, wear clean 100% cotton socks and non-occlusive/breathable footwear, change underwear daily)• wear well-fitting shoes that reduce pressure or trauma to the foot (choose shoes with a wide toe box, avoid narrow-toed shoes and high heels)	<ul style="list-style-type: none">• protect feet by wearing thongs/flip flops around swimming pools and other communal bathing areas• keep toenails short and use a second clipper to cut the infected nail(s)• recognise and treat tinea pedis (athlete's foot) early to avoid spreading to the toenail
Fingernail onychomycosis	
<ul style="list-style-type: none">• keep hands and fingernails dry and clean• avoid biting or picking fingernails	<ul style="list-style-type: none">• wear cotton-lined rubber gloves if immersing hands in water frequently or for prolonged periods• avoid artificial nails or nail varnish on affected nail
Tinea capitis	
<ul style="list-style-type: none">• avoid sharing towels, hairbrushes, combs and hats• treat affected contacts and animals	<ul style="list-style-type: none">• disinfect bedding and hair care items

When to start oral antifungals

Reserve oral antifungals (e.g. terbinafine, azoles and griseofulvin) for:

- widespread or chronic, mycologically confirmed superficial fungal infection that fails to respond to repeated topical therapy
- tinea in hair-bearing areas (groin and scalp ringworm) or on the palms of the hands or soles of the feet
- tinea previously treated with corticosteroids.^{12,31,32,40}

A Cochrane review found that oral terbinafine was more effective than griseofulvin in curing athlete's foot (tinea pedis). Small trials found no significant differences in efficacy between the different azoles, or terbinafine and itraconazole, or ketoconazole and griseofulvin.⁴¹

Oral terbinafine is PBS listed (streamlined authority) for the treatment of dermatophyte infection in an Aboriginal or a Torres Strait Islander person where topical treatment has failed.⁸

Oral antifungals for tinea capitis

Tinea capitis (scalp ringworm) is highly contagious and most commonly infects children.³⁹ Start oral antifungals after cultures have been taken but without waiting for culture results if clinical suspicion is high.^{12,42} There is insufficient evidence that topical treatments alone (for example ketoconazole and selenium sulfide shampoos) are effective for curing tinea capitis; they may be used as an adjunct to oral antifungals to help limit the spread of infection.^{31,32,42}

Safety, tolerability and ease of use are important considerations when choosing an oral antifungal agent for children.^{32,42} Oral terbinafine, itraconazole and fluconazole are likely to be as effective as griseofulvin.⁴³ However, griseofulvin is the only oral antifungal drug approved for treating children with tinea capitis.

Rare but life-threatening adverse effects reported with terbinafine

Reports of hepatic failure, Stevens–Johnson syndrome and blood dyscrasias prompted the TGA to recommend prescribing oral terbinafine, only after topical treatment has failed, for the shortest possible time and with regular monitoring.⁴⁴

Onychomycosis (nail infections) — who needs treatment?

Oral antifungal agents have potentially serious adverse effects and important drug interactions. Specific treatment is generally recommended for people with diabetes and peripheral vascular disorders who are at higher risk of serious complications, including secondary bacterial infections.^{38,45}

Discuss reasonable expectations of antifungal treatment with patients (i.e. likelihood of cure and duration of treatment) to help them decide about starting therapy. Affected nails may look abnormal for 12 months or longer.⁴⁶

Oral terbinafine for dermatophyte nail infections

In clinical trials, oral terbinafine consistently improved mycological and clinical cure rates and lowered relapse rates for dermatophyte nail infections compared with other antifungal agents.^{47,48} A meta-analysis of 36 studies found higher cure rates with terbinafine (76%) than for pulsed itraconazole (63%), continuous itraconazole (59%), griseofulvin (60%) or fluconazole (48%).⁴⁸

Oral terbinafine is PBS listed (authority required) for proximal or extensive onychomycosis (> 80% nail involvement) caused by dermatophyte infection (proven by microscopy or culture) when topical treatment has failed.⁸

Treat fingernail infections with oral terbinafine for 6 weeks and toenail infections for at least 12 weeks.²⁹

Azoles are best for candidal infections

Consider itraconazole for people unable to tolerate oral terbinafine and also for people with candidal nail infections.³⁸ One small non-blinded trial of pulse therapy with itraconazole found mycological cure rates of 90% for toenail infections (3 courses) and 100% for fingernail infections (2 courses).⁴⁹

Limited role for topical antifungals in onychomycosis

Topical antifungal agents are only suitable in mild superficial onychomycosis (early infection in the distal part of the nail), and for people unable or unwilling to take oral antifungals.^{12,38,45} Used alone they have a low cure rate and often require prolonged treatment (12 months or longer). There is no strong evidence to support the routine combination of systemic and topical antifungal therapies for onychomycosis.

Determine response to treatment as the nail grows

Infection that progresses despite initial treatment may respond to an alternative drug, a combination of systemic and topical therapies or nail avulsion.^{12,38,50} Encourage patients and carers to adhere with antifungal regimens to eradicate infection.

Seek dermatologist advice if the diagnosis is uncertain, skin infections are severe or unresponsive to oral antifungal therapy, or if patients are immunocompromised.³¹

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The information contained in this material is derived from a critical analysis of a wide range of authoritative evidence. Any treatment decisions based on this information should be made in the context of the clinical circumstances of each patient.



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Topical antifungal agents^{1,2}

Agent (examples of brand names)	Indications	PBS restriction	Formulation	Usual treatment regimens for localised fungal infection*
amorolfine 5% (Loceryl)	Onychomycosis	RPBS (restricted benefit): Onychomycosis.	Liquid	Apply once or twice-weekly until the nail re-grows (generally 6 months for fingernails and 12 months or longer for toenails).
bifonazole 1% (Mycospor, Canesten)	Tinea Cutaneous candidiasis Pityriasis versicolor	RPBS (unrestricted benefit). PBS authority required (streamlined): Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.	Cream	Apply once daily for 2–3 weeks (2–4 weeks for cutaneous candidiasis).
ciclopirox 1.5% (Stieprox Liquid)	Seborrhoeic dermatitis (including dandruff)	RPBS (restricted benefit): Severe seborrhoeic dermatitis.	Shampoo	Apply 2–3 times weekly. Leave in hair for 3–5 minutes, repeat.
clotrimazole 1% (Canesten, Clonea, Topizol)	Tinea Cutaneous candidiasis Paronychia Pityriasis versicolor	Cream and lotion, RPBS (unrestricted benefit). Lotion, PBS authority required (streamlined): Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.	Cream, lotion 1% Combination cream: clotrimazole 1%, hydrocortisone 1% (Hydrozole)	Apply 2–3 times daily for 2–4 weeks, continue for 2 weeks after signs of infection disappear (except combination).
econazole 1% (Pevaryl)	Tinea Cutaneous candidiasis Paronychia Pityriasis versicolor	Not listed	Cream, liquid	Cream: apply 2–3 times daily for 2–4 weeks, continue for 1–2 weeks after signs of infection disappear. Liquid: apply to wet skin on 3 consecutive nights, allow to dry on skin.
ketoconazole 2% cream, 1% and 2% shampoo (Nizoral, DaktaGOLD)	Tinea Cutaneous candidiasis Pityriasis versicolor Seborrhoeic dermatitis	Cream, shampoo, PBS authority required (streamlined): Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person. Shampoo, RPBS (restricted benefit): Severe seborrhoeic dermatitis.	Cream, shampoo	Cream: apply once daily for 2–3 weeks for candidal infections, longer for dermatophyte infections, continue for a few days after signs of infection disappear. Shampoo: apply twice weekly for up to 4 weeks. Allow at least a 4 week interval between treatment courses.

* Refer to prescribing information for individual products.



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Topical antifungal agents^{1,2} (*continued*)

Agent (examples of brand names)	Indications	PBS restriction	Formulation	Usual treatment regimens for localised fungal infection*
miconazole 2% (Daktarin)	Tinea Cutaneous candidiasis (including paronychia) Pityriasis versicolor Seborrhoeic dermatitis	Cream, liquid, lotion, powder, PBS authority required (streamlined): Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person. Cream, liquid, RPBS (unrestricted benefit).	Cream, liquid, lotion, spray, powder, ointment, shampoo Combination creams: miconazole 2% and hydrocortisone 1% (Resolve Plus), miconazole 2% and bufexamac (Resolve Balm) Combination ointment: miconazole 0.25% and zinc oxide 15% (Daktozin)	Cream: apply twice daily for 2 weeks (cutaneous candidiasis), 4 weeks for dermatophyte infections. Continue for 2 weeks after signs of infection disappear. Liquid: (nail infections) apply twice daily up to 6 months for fingernail infections (12 months or longer for toe nail infections).
nystatin 100,000 units per g (Mycostatin)	Cutaneous candidiasis	PBS authority required (streamlined): Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person. RPBS (unrestricted benefit).	Cream	Apply twice daily, continue for 2 weeks after signs of infection disappear.
terbinafine 1% (Lamisil)	Tinea Cutaneous candidiasis Pityriasis versicolor	Cream, PBS authority required (streamlined): Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person. Gel, cream, RPBS (restricted benefit): Tinea pedis.	Cream, gel, liquid	Apply once daily for 7 days (tinea pedis), 1–2 weeks for cutaneous candidiasis. Treatment should not exceed 4 weeks.
tolnaftate (Tinaderm, mycil healthy feet, ringworm ointment)	Tinea Pityriasis versicolor	Spray, RPBS (unrestricted benefit).	Cream, liquid, ointment, spray, powder	Apply twice daily, continue for 1–2 weeks after signs of infection disappear.

* Refer to prescribing information for individual products.

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