South African National Essential Medicine List
Primary Health Care Medication Review Process
Component: Skin conditions

MEDICINE REVIEW:

1. **Executive Summary**

Date: 20 March 2018
Medicine (INN): Corticosteroids, topical
Medicine (ATC): D07A
Indication (ICD10 code): Chronic paronychia (B37.2)
Patient population: Adults
Prevalence of condition: Unknown
Level of Care: Primary level
Prescriber Level: Nurse prescriber
Current standard of Care: Clotrimazole 2%, topical cream.
Efficacy estimates: (preferably NNT)
- *Improvement at 9 weeks:* Itraconazole, oral: 29/64 (45.3%) vs terbinafine, oral: 30/57 (52.7%) vs methylprednisolone aceponate, topical 38/48 (79.1%).
- *Cure rate at 9 weeks:* Itraconazole, oral: 0/64 vs terbinafine, oral: 0/57 vs methylprednisolone aceponate, topical: 3/48 (6.2%) with a NNT of 16.
Motivator/reviewer name(s): Ms TD Leong
PTC affiliation: n/a

2. **Name of author(s)/motivator(s):** Ms TD Leong

3. **Author affiliation and conflict of interest details:** National Department of Health, Essential Drugs Programme, Secretariat to the Primary Health Care Expert Review Committee of NEMLC; no conflicts of interest.

4. **Introduction/ Background**
   During the review of the Primary Health Care (PHC) Standard Treatment Guidelines (STGs) and Essential Medicine List (EML), a dermatologist submitted a comment that chronic paronychia is not infective and is an irritant form of dermatitis. Clotrimazole 1% cream was probably inappropriate and management involves keeping the hands clean and dry as far as possible, during day and application of topical steroids to nail folds at night. A review of the evidence ensued to determine the appropriate treatment of chronic paronychia.

5. **Purpose/Objective i.e. PICO question**
   -P *(patient/population):* Adults
   -I *(intervention):* Topical corticosteroids
   -C *(comparator):* Topical antifungals
   -O *(outcome):* Symptom control

6. **Methods:**
   a. **Data sources:**
      i. **Pubmed**
      ii. **Tripdatabase**
   b. **Search strategy**
      i. **Pubmed:** ((chronic[All Fields] AND ("paronychia"[MeSH Terms] OR "paronychia"[All Fields]) AND ("antifungal agents"[Pharmacological Action] OR "antifungal agents"[MeSH Terms] OR ("antifungal"[All Fields] AND "agents"[All Fields]) OR "antifungal agents"[All Fields] OR "antifungal"[All Fields]) AND ("steroids"[MeSH Terms] OR "steroids"[All Fields] OR "steroid"[All Fields])) AND Randomized Controlled Trial[ptyp] AND "humans"[MeSH Terms]) AND (Randomized Controlled Trial[ptyp] AND "humans"[MeSH Terms])
      ii. **Tripdatabase**: "chronic paronychia" and "steroids" and "antifungal", restricted to controlled trials.

   c. **Excluded studies:** No RCTs were sourced from the published literature, that was relevant to the PICO question. The searches were restricted to English publications. However, one RCT was found that compared topical steroids to oral antifungals.

   d. **Evidence synthesis**

Author, date	***Type of study***	**n**	**Population**	**Comparators**	**Primary outcome**	**Effect sizes**	**Comments**
Tosti et al, 2002[i]	Double blind, double dummy, RCT over 3 weeks	45	Adult patients with chronic paronychia	Methylprednisolone aceponate (MPA), topical or terbinafine, oral or itraconazole, oral or placebo.	Not stated. Assumed to be: Improvement or cure at 9 weeks.	<u>At 9 weeks:</u> i) *Improved* - Itraconazole: 29/64 (45.3%) - Terbinafine: 30/57 (52.7%) - MPA: 38/48 (79.1%) ii) *Cured* - Itraconazole: 0/64 - Terbinafine: 0/57 - MPA: 3/48 (6.2%) Statistical analysis showed that MPA was more effective vs itraconazole or terbinafine.	Selection and concealment bias risk minimal as study was a double blinded, double dummy study. However, RCT was underpowered. Possible underestimation of effect, as topical steroid was compared to systemic antifungal agents. Details of statistical analysis not described. The authors state that the results of this study confirm the opinion that chronic paronychia is not a mycotic infection, but rather an inflammatory disorder of the proximal nailfold caused by environmental noxae.

   e. **Evidence quality:** Limited evidence of low methodological quality from only one RCT could be sourced, suggesting that topical corticosteroids are effective in treating chronic paronychia.

7. **Alternative agents:**
   Other potent topical steroids (group III):
   Betamethasone, beclomethasone, diflucortolone, fluocinolone, fluticasone, hydrocortisone butyrate, mometasone.

EVIDENCE TO DECISION FRAMEWORK

<table>
<tr><th></th><th>JUDGEMENT</th><th>SUPPORTING EVIDENCE & ADDITIONAL CONSIDERATIONS</th></tr>
<tr><td>QUALITY OF EVIDENCE</td><td>What is the overall confidence in the evidence of effectiveness?

Confident [ ] Not confident [ ] Uncertain [x]</td><td>See details and quality comments of evidence above.</td></tr>
<tr><td>BENEFITS & HARMS</td><td>Do the desirable effects outweigh the undesirable effects?

Benefits outweigh harms [ ] Harms outweigh benefits [ ] Benefits = harms or Uncertain [x]</td><td>Harms was not studied in the RCT described in the table, above.</td></tr>
<tr><td>THERAPEUTIC INTERCHANGE</td><td>Therapeutic alternatives available:

Yes [x] No [ ]

List the members of the group.
Betamethasone, beclomethasone, diflucortolone, fluocinolone, fluticasone, hydrocortisone butyrate, mometasone.

List specific exclusion from the group: n/a</td><td>Rationale for therapeutic alternatives included:
Methylprednisolone aceponate is a potent topical steroid (group III). Other agents included in this group include:
- betamethasone, beclomethasone, diflucortolone, fluocinolone, fluticasone, hydrocortisone butyrate, mometasone.

References:
WHO ATC DDD database

Rationale for exclusion from the group: n/a
References: n/a</td></tr>
<tr><td>VALUES & PREFERENCES / ACCEPTABILITY</td><td>Is there important uncertainty or variability about how much people value the options?
Minor [ ] Major [ ] Uncertain [x]

Is the option acceptable to key stakeholders?
Yes [x] No [ ] Uncertain [ ]</td><td></td></tr>
<tr><td>RESOURCE USE</td><td>How large are the resource requirements?

More intensive [ ] Less intensive [ ] Uncertain [ ]</td><td>Cost of medicines/ month:
<table>
<tr><th>Medicine</th><th>Cost (ZAR)</th></tr>
<tr><td>Beclomethasone 0.1%, 15 g**</td><td>18.93</td></tr>
<tr><td>Betamethasone dipropionate 0.05%, 20 g**</td><td>253.86</td></tr>
<tr><td>Betamethasone valerate, 15 g 0.1%*</td><td>3.73</td></tr>
<tr><td>Diflucortolone 0.1%, 20 g**</td><td>109.23</td></tr>
<tr><td>Fluocinolone 0.025%*</td><td>13.08</td></tr>
<tr><td>Fluticasone 0.05%**</td><td>76.45</td></tr>
<tr><td>Hydrocortisone butyrate 0.1%**</td><td>97.86</td></tr>
<tr><td>Methylprednisolone aceponate 0.1%, 20 g**</td><td>130.57</td></tr>
<tr><td>Mometasone 0.1%, 20 g**</td><td>132.21</td></tr>
</table>
* Contract circular HP08-2017SSP
** SEP database 16 March 2018
Additional resources: n/a</td></tr>
</table>

EQUITY	**Would there be an impact on health inequity?** Yes ☐ No ☒ Uncertain ☐	
FEASIBILITY	**Is the implementation of this recommendation feasible?** Yes ☒ No ☐ Uncertain ☐	

Type of recommendation	We recommend against the option and for the alternative	We suggest not to use the option or to use the alternative	We suggest using either the option or the alternative	We suggest using the option	We recommend the option
	☐	☐	☐	☒	☐

Recommendation: Based on this evidence review, the Primary Health Care Committee reccommends potent topical corticosteroids (group III) for the management of chronic paronychia as opposed to topical antifungal agents.

Rationale: Evidence of efficacy for potent topical corticosteroids for management of chronic paronychia.

Level of Evidence: III Disease-oriented RCT of low methodological quality

Review indicator:

Evidence of efficacy	Evidence of harm	Price reduction
x	x	

VEN status:

Vital	Essential	Necessary
	x	

Monitoring and evaluation considerations

Research priorities

References:

[i] Tosti A, Piraccini BM, Ghetti E, Colombo MD. Topical steroids versus systemic antifungals in the treatment of chronic paronychia: an open, randomized double-blind and double dummy study. J Am Acad Dermatol. 2002 Jul;47(1):73-6. https://www.ncbi.nlm.nih.gov/pubmed/12077585