Adolopment of atopic dermatitis management guidelines for Pakistan

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Abstract

Background: Pakistan lacks national evidence-based clinical practice guidelines for dermatology, and there are challenges in using the international guidelines.

Aim: To develop context-specific guidelines for clinical management of atopic dermatitis in Pakistan.

Method: We conducted on PubMed, Google Scholar and Cochrane Library a critical review and appraisal of clinical guidelines for the management of atopic dermatitis published between January 2019 and March 2024. Using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, we selected and reviewed the 2023 Grading of Recommendations Assessment, Development and Evaluation (GRADE) and the Institute of Medicine-based recommendations of the American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters. We selected, prioritized, modified, and adopted those recommendations applicable to Pakistan.

Results: Of the 25 recommendations in the source guidelines, 12 were adopted and used to develop 27 recommendations for Pakistan.

Conclusion: GRADE adolopment of clinical practice guidelines is a feasible method that countries with limited resources can use to adapt international guidelines to local context.

Keywords: adolopment, practice guidelines, atopic dermatitis, dermatology, lower-middle-income country, Pakistan

Citation: Malik SS, Akhtar A, Khan BM, Anwar A, Bashir U, Malik S, Iftikhar R. Adolopment of atopic dermatitis management guidelines for Pakistan. East Mediterr Health J. 2025;31(9&10):552–559. https://doi.org/10.26719/2025.31.10.552.

Received: 22/09/2024; Accepted: 25/03/2025

Background

Among all skin diseases, atopic dermatitis has the highest global burden of disease in terms of disability-adjusted life-years and it is among the top 15 non-fatal diseases (1). Atopic dermatitis leads to substantial social and financial expenditure, thus placing a heavy burden on health systems. It affects 204.05 million (2.6%) people globally, occurring in 101.27 million (2.0%) adults and 102.78 million (4.0%) children (2). More females (2.8%) than males (2.4%) are affected (2). A study of prevalence across Asian countries reported 5–20% incidence among children (3).

There are no studies reporting atopic dermatitis prevalence in Pakistan, however, a study from North India reported 8.92% incidence, with a majority of patients (80.1%) less than 6 years old and a male to female ratio of 1.3:1 (4).

There are 315 610 registered medical practitioners in Pakistan for a population of 259.1 million, of whom only 840 dermatologists are registered with the Pakistan Association of Dermatology (5). It is impossible for the few dermatologists in the country to provide dermatological services to all those in need of services. However, if there are good local evidence-based guidelines for the management of major skin diseases like atopic dermatitis, psoriasis, pemphigus vulgaris and vitiligo, general practitioners and other medical specialists will be able to manage these conditions if diagnosed accurately.

Evidence-based clinical practice guidelines are used worldwide. They provide recommendations for optimizing patient care throughout the care cycle and are based on a systematic review of evidence and an assessment of the pros and cons of alternative treatment options (6). These guidelines help improve the quality of health care services, maintain care consistency, empower patients, influence public policymaking, guide the development of evaluation criteria for disease performance, and guide the design of high-value interventions (7). Adolopment of updated international clinical practice guidelines using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology makes them applicable to local context in resource-constrained settings.

GRADE methodology for guideline development

The GRADE method is the internationally accepted guidance model for rating the quality of evidence and grading the strength of recommendations in health care practice (14). It is the backbone of evidence profiling of published literature for systematic reviews, clinical practice guidelines and health policy assignments. It is a systematic and transparent framework for questions formulation, consensus on the valuable outcomes, summarizing evidence related to these, and progressing

from evidence to recommendation formulation. The GRADE methodology for the development of clinical guidelines has been adopted and endorsed by many (more than 80) influential medical organizations globally, marking its significance in evidence-based clinical practice guidelines formulation (*8*).

Resource constraints such as shortage of finance, lack of trained personnel and time, as well as credibility issues, are common barriers to the development of new local guidelines. Using the GRADE methodology helps remove such barriers because it allows quick and cost-effective adoption and adaptation of recommendations for local use from internationally published guidelines.

The Clinical and Translational Research Incubator (CITRIC) Center for Clinical Best Practices (CCBP) at Aga Khan University (AKU), Pakistan, has use the GRADE adolopment methodology for developing guidelines for many diseases, including psychiatric and chronic respiratory conditions (*9*,*10*). We document how we applied this methodology also for dermatology (11).

Methods

Setting and context

Dermatologists at the National University of Medical Sciences (NUMS), Pakistan, conducted this study, in collaboration with the Center for Evidence-based Health Care Practices (CEBHP) at NUMS and AKU CITRIC CCBP. AKU CITRIC CCBP deals with the adolopment and development of EBCPGs and care channels to standardize and improve healthcare in Pakistan and other LMICs. CEBHP strives to collaborate with "Cochrane", an international network of health care researchers maintaining quality evidence, to make published medical literature available for research purposes. CEBHP aims to standardize and improve health care practices in all hospitals in Pakistan under the umbrella of NUMS. AKU's CITRIC team has trained a CEBHP multidisciplinary team in systematic review and meta-analysis and GRADE development of guidelines. Our team worked in collaboration with the GRADE working group using GRADE pro GDT. As patients were not directly involved in the process, this study was exempted from clearance by the ethics review board.

Our study team consisted of 20 dermatologists from NUMS, who were mostly professors of dermatology and acted as panellists and researchers.

Source guideline selection

Selecting the source guideline was the first most important step in the adolopment process. The source guideline is the single best, original EBCPG that undergoes the GRADE-adolopment process in the development of a local EBCPG. Two dermatologists conducted a critical appraisal of clinical guidelines for the management of atopic dermatitis after a thorough literature search on PubMed, Google Scholar and Cochrane Library for January 2019 to March 2024. The inclusion criteria were scope, credibility of the formulating bodies, most recent work, applicability of guidelines to all age groups and clinical contexts, and use of GRADE in the development of the guidelines. Guidelines that were more than 5 years old and those in languages other than English were excluded. Two guidelines were shortlisted and after consensus by the panel, one of them was selected, i.e. the 2023 GRADE- and Institute of Medicine-based recommendations of the "American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters (*12*). This guideline was selected because it covers the management of atopic dermatitis across all age groups in a single document and was developed using GRADE. Permission was obtained from the corresponding author of the guideline before using it for the adolopment process.

Guideline content review and GRADE adolopment

We used the method explained by GRADEpro GDT for adolopment (14). Two of the dermatologists in the panel converted all the 25 recommendations into questions and uploaded them on the GRADEpro GDT. Seven of the questions were excluded during the question formulation stage. Two of these 7 were excluded because they did not have the dupilumab and tralokinumab treatment options. Most of the panellists were of the opinion that even if we arranged for dupilumab from abroad, it would be too expensive for our patients. One question relating to the use of low dose Baricitinib (1 mg) was excluded because 4 mg was considered the recommended dosage. Two questions relating to the use of bleach baths and allergen immunotherapy in mild atopic dermatitis were merged with questions relating to moderate to severe cases of atopic dermatitis. The question relating to the use of adding topical antimicrobial in uncontrolled atopic dermatitis with no serious bacterial skin infection was excluded because most of the panellists thought it was unnecessary to keep this recommendation. The question about one recommendation was excluded, i.e. "against the usage of methotrexate in patients with moderate-severe atopic dermatitis refractory to topical treatment and systemic treatment inclusive of a biologic recommended, which was a conditional recommendation with low-certainty of evidence". Most of the panellists had good experience with its use and it is a cost-effective alternative for children and adults with atopic dermatitis in our setting. Nine new patient/population, intervention, comparison, outcome (PICO) questions pertaining to 9 new recommendations were also added to GRADEpro GDT based on the recommendations and suggestions of the panellists.

The outcome for each recommendation was finalized after consensus among the panellists and further prioritization was done by voting and comments. "Rapid" systematic reviews were conducted to gather evidence for the decision on each recommendation. One question comparing methotrexate with ciclosporin in moderate to

severe atopic dermatitis was supported by the systematic review and meta-analysis using preferred reporting items for systematic reviews and meta-analyses (PRISMA) and Cochrane methodology and it was published as a separate article (*13*).

Then the adolopment module for GRADEpro GDT was activated after informing the GRADE working group. Three recommendations were adapted with minor changes either after revision of the evidence for decision or based on recommendations by the panel of experts. Fifteen recommendations were adopted following consensus by the panellists.

GRADEpro GDT works like a modified Delphi technique starting with the disclosure of conflict of interest by the panellists and researchers (*14*). It starts with PICO question generation, followed by summarising evidence and judging the quality and certainty of evidence, the development of recommendations and determination of their strengths, consensus on wording of recommendations, reporting and peer review, and then dissemination. GRADEpro GDT is the official GRADE working group software for producing summary of findings and evidence for decision. Conflicts in the comments of the reviewers were resolved through WhatsApp poll and small focus group discussions. These additional strategies were used for timely and smooth execution of the process (Table 1).

Results

The new document contains 27 recommendations (Table 1), after excluding 7 recommendations from the initial 25 in the source guideline, adding 9 new recommendations relating to the management of atopic dermatitis during pregnancy and lactation, adapting 3 recommendations with minor changes, and adopting 15 recommendations.

Discussion

This paper describes the process for adolopment of atopic dermatitis guidelines for Pakistan using the GRADE methodology. This is a first step towards dissemination of the guidelines and we welcome constructive criticism that could help improve the process for the future.

We have not included the recommendation for dupilumab as first line treatment option because this biologic is unavailable in our setting and if we import it, the cost per patient would be around US$ 32–3300 per month, which is very expensive. However, it is the first line biological treatment option based on evidence and

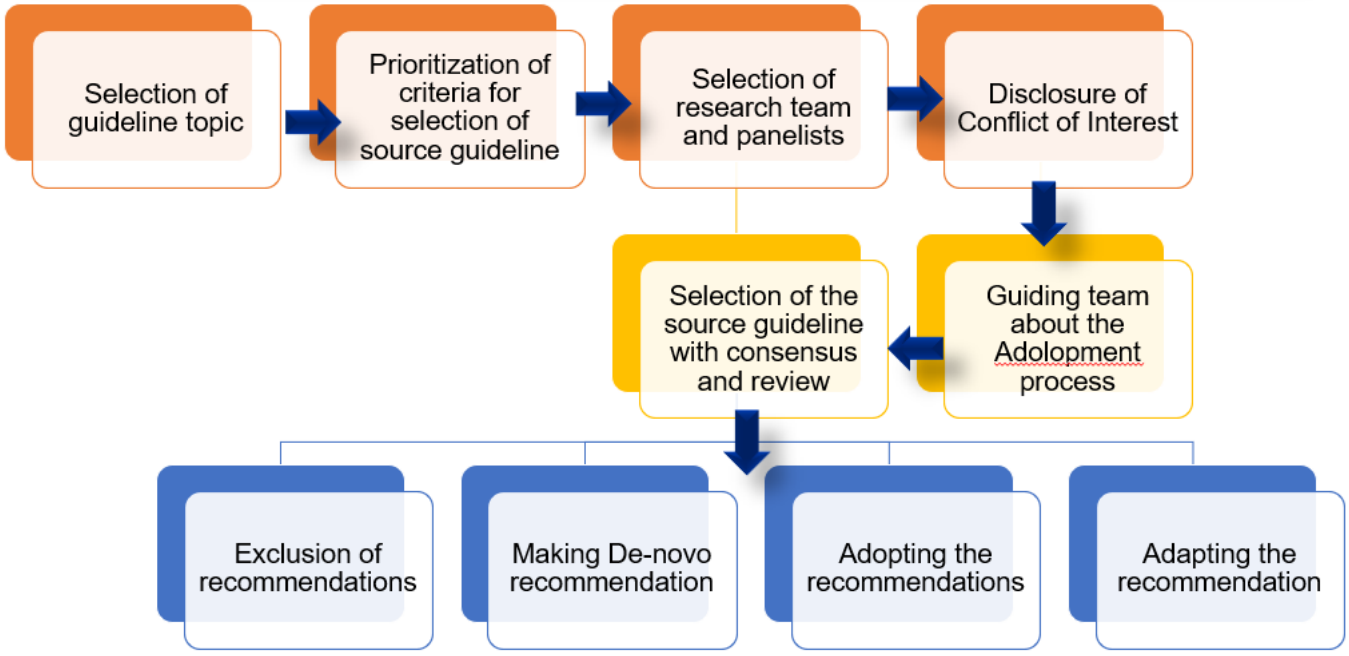

Figure 1 GRADE adolopment of guidelines methodology used

Table 1. Final recommendations after GRADE adolopment

Recommendations adopted from the source guideline	
1.	Clinicians managing atopic dermatitis cases should ensure the following good practice before any further treatment (*12*): a. Ensure diagnosis and check any complication b. Educate the patient about the disease c. Emphasize avoidance of triggers d. Emphasize adherence to treatment plan e. Encourage symptomatic use of bland emollients as much as required **(strong recommendation, high certainty evidence)**
2.	In atopic dermatitis patients, use of a standard, fragrance-free and contact allergens-free moisturizer/emollient (white soft paraffin/ aqueous cream) over a branded one is recommended (*12*). **(conditional recommendation, low certainty of evidence)**
3.	In uncontrolled atopic dermatitis unresponsive to moisturizer usage alone, the addition of a topical corticosteroid ointment (TCS) is recommended (10). **(strong recommendation, high-certainty evidence)**
4.	In uncontrolled atopic dermatitis unresponsive to moisturization alone at age ≥3 months, the addition of a topical calcineurin inhibitor (TCI) tacrolimus/pimecrolimus is recommended (*12*). **(strong recommendation, high certainty evidence)**
5.	In localised uncontrolled atopic dermatitis unresponsive to mid- to high-potency topical regime, the adoption of a "time and body area limited" application (ranging from 4–7 days a week; from minimum 1 hour to maximum overnight, once a day) trial of occlusive low- to mid-potency TCS; with or without wet dressings is recommended (*12*). **(conditional recommendation, very low certainty evidence)**
6.	In uncontrolled atopic dermatitis being managed with mid- to high-potency topical regimes, the once-a-day application, twice a day regime is preferrable and recommended (12). **(conditional recommendation, moderate certainty evidence)**
7.	In atopic dermatitis having frequent relapses, the use of proactive therapy, i.e. routine intermittent use of 2–3 times topical application a week to frequently flaring areas with a TCI or mid-potency TCS is recommended (*12*). **(strong recommendation, moderate-certainty evidence)**
8.	In moderate to severe atopic dermatitis, along with topical therapy, dilute bleach baths with complete written instructions to the patient based on their feasibility and tolerance due to fissuring in the eczematous skin are recommended (*12*). **(conditional recommendation, low-certainty evidence)**
9.	In moderate to severe atopic dermatitis not responding to mid-potency topical regimes, the addition of allergen immunotherapy (based on availability) to standard topical protocol is recommended (*12,15*)Click or tap here to enter text.. **(conditional recommendation, moderate-certainty evidence)**
10.	In moderate to severe atopic dermatitis unresponsive to mid- to high-potency topical regime and systemic management options, the suggestion is against the use of oral azathioprine (*12*). **(conditional recommendation, low-certainty evidence)**
11.	In moderate to severe atopic dermatitis unresponsive to mid- to high-potency topical regime and systemic management options, adding oral cyclosporine (CsA) along with continued topical standard care is recommended (*12*). **(conditional recommendation, low-certainty evidence)**
12.	In moderate to severe atopic dermatitis unresponsive to mid- to high-potency topical regime and systemic management options, the panel suggests adding in-hospital narrow band ultraviolet B-light phototherapy in the outpatient department of the dermatology clinic (*12*). **(conditional recommendation, low-certainty evidence)**
13.	In adults with atopic dermatitis unresponsive to standard topical regimes and systemic treatment, replacing the systemic treatment with one of the oral JAK inhibitors, generally (abrocitinib, baricitinib, upadacitinib) is suggested. **(conditional recommendation, low-certainty evidence)**
14.	In mild to moderate atopic dermatitis refractory to moisturization alone, the panel suggests adding topical crisaborole 2% ointment over usual care alone. **(conditional recommendation, low-certainty evidence)**
15.	In adults with mild to moderate atopic dermatitis refractory to moisturization alone, the JTF panel suggests against adding topical ruxolitinib. **(conditional recommendation, low-certainty evidence)**

Recommendations adapted from the source guideline	
16.	Original recommendation: In moderate to severe atopic dermatitis unresponsive to mid- to high-potency topical regime and systemic management options, the panel suggests against using mycophenolate mofetil (MMF). Adapted version: Panel conditionally recommends MMF in place of CsA as a systemic treatment option for moderate to severe atopic dermatitis in patients who cannot tolerate or receive CsA due to medical reasons, but not in women who can or want to become pregnant (*16*). **(conditional recommendation, low-certainty evidence)** Based on revised evidence for decision
17.	Original recommendation: In atopic dermatitis, the use of elimination diets versus unrestricted diet is not recommended. Adapted version: In atopic dermatitis, our panel suggests the use of elimination diets versus unrestricted diet based on specific IgE to food allergens test report and positive history. **(conditional recommendation, low-certainty evidence)** Based on the recommendation of panellists after reviewing evidence for decision
18.	Original recommendation: In atopic dermatitis unresponsive to topical regimes and other systemic treatment options, including NB-UVB, the use of systemic corticosteroids is not recommended. Adapted version: In atopic dermatitis, the panel suggests using systemic corticosteroids reserved exclusively for acute, severe disease flares and as a short-term bridge option (less than 30 days) between other systemic, corticosteroid-sparing drugs. **(conditional recommendation, low-certainty evidence)** Based on the recommendations of panellists
New recommendations	
19.	In pregnant females with atopic dermatitis, the panel recommends the use of TCS of lowest effective potency, i.e. preferably of classes 6 & 7, with precautions in body areas prone to striae formation, e.g. breasts, abdomen and thighs. Classes 1 & 2 TCS should be avoided during pregnancy due to the risk of systemic absorption and side-effects, but can be used in localised chronic and lichenified lesions and as occasional rescue management option (*17,18*)Click or tap here to enter text.. **(strong recommendation, moderate-certainty evidence)**
20.	In pregnant and lactating females with atopic dermatitis the panel recommends conditional off-label use of TCI. Tacrolimus use is recommended as the preferred TCI during pregnancy due to the large available existing data in published literature. It is only conditionally recommended for use in areas prone to striae formation due to topical steroids like face, flexures, thighs, abdomen and breast or for localized resistant disease not responding to moisturizers alone (*18*). **(conditional recommendation, low-certainty evidence)**
21.	In pregnant and lactating females with atopic dermatitis the panel recommends conditional use of phototherapy especially NB-UVB as second line treatment option in settings where this facility is available. Folate supplementation should be done. Face should be covered with mask during NB-UVB to avoid melasma (*18*). **(conditional recommendation, low-certainty evidence)**
22.	In pregnant and lactating females with atopic dermatitis not responding to topical treatment and phototherapy, the use of AZA vs CsA is not recommended. CsA is regarded as the default but off-label immunosuppressive therapeutic option in atopic dermatitis during pregnancy when continuous treatment is required, abiding by all the precautions for non-pregnant cases. AZA may be used as off-label treatment alternative for continuation therapy in atopic dermatitis cases already on AZA at the time of conception (*18*). **(strong recommendation, moderate-certainty evidence)**
23.	The panel recommends that systemic corticosteroids use for atopic dermatitis be limited to moderate to severe cases not responding to topical treatment and phototherapy after 1st trimester. Prednisolone, but not dexamethasone, must be used if required in atopic dermatitis patients with pregnancy, and only for shorter periods of time, generally less than 2–3 weeks and 0.5 mg/kg/day. Children born to mothers receiving > 35 mg/day prednisolone at the time of delivery should be observed for a 48-hour period in NICU. Treatment with systemic TCS during lactation is safe, since <0.1% of maternal dosage is secreted in breast milk (*18*). *(conditional recommendation, low-certainty evidence)*
24.	In patients with atopic dermatitis, the panel suggests multidisciplinary treatment approach involving educational training for patients and families of patients, including input from paediatricians, dermatologists, pulmonologists, allergists and psychologists. (The Pakistan Association of Dermatology will develop a standardized educational programme for atopic dermatitis patients and conduct training for atopic dermatitis patients and families monthly at teaching hospitals without additional payments). **(strong recommendation, moderate-certainty evidence)**
25.	Panel suggests the use of probiotics as alternative treatment for moderate to severe atopic dermatitis in children and adults either alone or in combination with prebiotics but not in infants (*19,20*). **(conditional recommendation, low-certainty evidence)**
26.	In patients with moderate to severe atopic dermatitis requiring systemic immunosuppressant, our panel recommends ciclosporin for short-term quicker disease control and methotrexate in the long-term for maintaining remission (*21*). Both CsA and MTX are effective, well-tolerated treatment options for moderate to severe atopic dermatitis in children and adults not responding to topicals and phototherapy. MTX must be avoided in pregnant women and should be stopped 6 months before conception in men and women. **(conditional recommendation, moderate-certainty evidence)**
27.	In moderate to severe atopic dermatitis requiring systemic therapy not responding to, or unable to receive, systemic corticosteroids, CsA, MTX or MMF can be given as a trial of biologic i.e. omalizumab in special instances for disease control, as dupilumab is not available locally (*22*). **(conditional recommendation, low-certainty evidence)**

we intend to make amendments to the guidelines in the future if this drug becomes available in Pakistan (*12*,*23*).

Dupilumab is a humanized monoclonal antibody targeting interleukin-4 (IL-4) receptor alpha subunit, leading to inhibition of interleukin-4 and interleukin-13 (IL-13), signalling to reduce cytokine-induced responses involving the secretion of proinflammatory cytokines, chemokines and immunoglobulin E. IL-4 and IL-13 are the cytokines deriving type 2 inflammation in atopic dermatitis. A network meta-analysis involving 28 686 atopic dermatitis patients revealed that by adding dupilumab to standard atopic dermatitis care led to better patient outcomes, including for severe atopic dermatitis, itching, sleep disturbance, and quality-of-life. There are no remarkable adverse effects with 52 weeks or more of treatment besides conjunctivitis (6% with dupilumab vs 2% with placebo) (*24*).

We have not mentioned antihistamines in our guidelines because the latest research does not support their role in reducing itching or eczema in atopic dermatitis patients. The American Academy of Dermatology also does not support routine use of antihistamines in atopic dermatitis. Only sedative antihistamines have some role in treating sleeplessness and associated allergies in atopic dermatitis patients (*23*).

National collaborations, for example, with the Pakistan Association of Dermatology can be very useful as a platform for facilitating the development and use of guidelines. Creating awareness among young dermatologists about evidence-based clinical guidelines is essential because ignorance of the concept can be a barrier to the implementation of guidelines. We therefore strongly recommend awareness programmes among young doctors about EBCPGs.

These guidelines will be updated every 2 years using the GRADE adolopment protocol. They can be adopted by any LMIC because they generally recommend cost-effective and feasible treatment options for atopic dermatitis without undue financial burden on the health system.

Limitations of the study

We did not consider the primary health care referral pathways in our processes, which can reduce the burden on dermatology as a specialty in the fight against atopic dermatitis and eczema. Atopic dermatitis is a complex disorder, influenced by genetic, epigenetic and environmental factors especially skin microbiome involved in its pathophysiology. Its management involves paediatricians, allergists, microbiologists, and clinical pharmacologists besides dermatologists. We did not included the patients' perspectives and did not adopt the multidisciplinary approach in selecting panellists for the adolopment of these guidelines, and we consider this a limitation. This was mainly because of the comprehensive nature of the parent guidelines and the involvement of the different departments in the initial processes. We contextually modified the parent guidelines, and paediatricians and clinical pharmacologists conducted an external review of the guidelines after the panel had decided on the recommendations.

Acknowledgements

We thank Prof. Sohail Sabir (Director CEBHP) for providing us the platform, Prof. Naeem Raza (President PAD) for bringing the dermatologists together for this project and Dr Nashia Rizvi and the team of CITRIC AKU for teaching us the GRADE methodology. We thank our panellists whose contribution helped us in the GRADE adolopment process i.e. Prof. Zafar Iqbal Sheikh, Prof. Naeem Raza (President Pakistan Association of Dermatologists), Prof Ashar Ahmed Mashhood, Prof Arfan ul Bari, Prof. Nadia Iftikhar, Prof. Aamir Habib, Prof. Qamaruddin Khan, Prof. Attiya Rehman, Prof. Moizza Tahir, Prof. Najia Ahmad, Dr Irfan Anwar, Dr Tehseen Naveed, and Dr Ghazala Yasmeen, all of them dermatologists from Pakistan. We acknowledge the efforts of our paediatricians, Dr Arshad Khushdil and Dr Kanwal Jehanzeb, and Assistant Professor of Pharmacology, Dr Wasiullah Khan, in reviewing the guidelines. Dr Raheel Iftikhar (clinical haematologist and bone marrow transplant specialist) and Dr Sakina Sadiq Malik were the chief methodologists and researchers. Other authors were researchers and were all dermatologists.

Funding: None.

Conflict of Interest: None declared.

Lignes directrices pour la prise en charge de la dermatite atopique au Pakistan : adoption, adaptation ou élaboration *de novo*

Résumé

Contexte : Le Pakistan ne dispose pas de lignes directrices nationales fondées sur des données probantes pour la pratique clinique en dermatologie, et l'utilisation des lignes directrices internationales soulève plusieurs défis.

Objectif : Élaborer des lignes directrices adaptées au contexte pour la prise en charge clinique de la dermatite atopique au Pakistan.

Méthodes : Nous avons réalisé un examen critique et une évaluation des lignes directrices cliniques pour la prise en charge de la dermatite atopique publiées entre janvier 2019 et mars 2024, en utilisant PubMed, Google Scholar et la Cochrane Library. À l'aide de la méthodologie GRADE (Grading of Recommendations Assessment, Development

and Evaluation), nous avons sélectionné et examiné les recommandations de 2023 issues du système GRADE ainsi que celles basées sur les principes de l'Institute of Medicine, élaborées par le Groupe de travail conjoint sur les référentiels de pratique de l'American Academy of Allergy, Asthma and Immunology/l'American College of Allergy, Asthma and Immunology. Nous avons sélectionné, hiérarchisé, modifié et adopté les recommandations applicables au contexte pakistanais.

Résultats : Sur les 25 recommandations des lignes directrices sources, 12 ont été adoptées et utilisées pour élaborer 27 recommandations adaptées au Pakistan.

Conclusion : L'adoption, l'adaptation ou l'élaboration de *novo* de lignes directrices de pratique clinique selon la méthodologie GRADE est une approche réalisable que les pays disposant de ressources limitées peuvent utiliser pour adapter les lignes directrices internationales à leur contexte local.

تكييف المبادئ التوجيهية ل لعلاج التهاب الجلد التأتُّبي بما يناسب السياق في باكستان

سكينة صادق ملك، عائشة أختر، بشرى مظفر خان، عائشة أنور، عظمى بشير، سادية ملك، رحيل افتخار

الخلاصة

الخلفية: تفتقر باكستان إلى مبادئ توجيهية وطنية للممارسات السريرية مسندة بالدلائل في مجال طب الأمراض الجلدية، وهناك تحديات فيما يتعلق باستخدام المبادئ التوجيهية الدولية.

الأهداف: هدفت هذه الدراسة الى وضع مبادئ توجيهية محددة السياق للعلاج السريري لالتهاب الجلد التأتُّبي في باكستان.

طرق البحث: أجرينا استعراضًا نقديًّا وتقييماً للمبادئ التوجيهية السريرية لعلاج التهاب الجلد التأتُّبي المنشورة في الفترة ما بين يناير/ كانون الثاني 2019 ومارس/ آذار 2024 في قاعدتي البيانات PubMed وGoogle Scholar ومكتبة كوكرين. وباستخدام منهجية تصنيف التوصيات وتقديرها ووضعها وتقييمها، اخترنا التوصيات المستندة إلى المنهجية المذكورة وتوصيات معهد الطب لعام 2023 التي صدرت عن فرقة العمل المشتركة بين الأكاديمية الأمريكية للحساسية والربو وعلم المناعة والكلية الأمريكية للحساسية والربو وعلم المناعة والمعنية بمعايير الممارسة، واستعرضنا تلك التوصيات. وقد اخترنا التوصيات المنطبقة على باكستان وأعطيناها الأولوية وأجرينا تعديلات عليها واعتمدناها.

النتائج: من بين التوصيات البالغ عددها 25 توصية الواردة في المبادئ التوجيهية المصدر، اعتُمدت 12 توصية واستُخدمت لوضع 27 توصية لباكستان.

الاستنتاجات: إن تكييف المبادئ التوجيهية للممارسات السريرية باستخدام منهجية تصنيف التوصيات وتقديرها ووضعها وتقييمها طريقة مُجدية يمكن للبلدان ذات الموارد المحدودة استخدامها لتكييف المبادئ التوجيهية الدولية بما يناسب السياق المحلي.

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