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Development of clinical practice guidelines and primary care referral pathways for management of otorhinolaryngological conditions in Pakistan

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Abstract

Background Diseases of the ear, nose, and throat (ENT) account for a significant portion of a primary care physician's practice in Pakistan, a South Asian lower-middle income country. This increasing burden demands comprehensive clinical practice guidelines and primary care clinical referral algorithms to be devised so that general physicians can adequately provide standardized primary health care and prevent needless specialist ENT referrals.

Methods We selected eight guidelines regarding epistaxis, neck masses, hearing loss, Meniere's disease, dysphonia, allergic rhinitis, acute otitis externa, and rhinosinusitis from the American Academy of Otolaryngology–Head and Neck Surgery Foundation as the source guidelines and employed the GRADE-ADOLOPMENT approach to contextualize guidelines by adopting, adapting, or excluding recommendations from these guidelines. Clinical referral algorithms were created using recommendations from the created clinical practice guidelines, with additional recommendations being sought via a best evidence review process.

Results We successfully created local clinical practice guidelines for the eight ENT conditions using the GRADE-ADOLOPMENT process. While most recommendations were adopted in the local clinical practice guidelines, one recommendation for acute otitis externa, hearing loss, and epistaxis and two for allergic rhinitis were adopted with minor changes to provide supporting information. Six recommendations were excluded mostly due to the unavailability of services in Pakistan. Eight clinical referral algorithms were also created which incorporated 17 additional recommendations to fill gaps in clinical practice including four additional recommendations to the epistaxis algorithm, three for neck lumps/mass, rhinosinusitis, and allergic rhinitis, two for acute otitis externa, and one for Meniere's disease and dysphonia algorithms.

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Conclusion The newly created clinical practice guidelines will help in the provision of standardized, high-quality care at the primary care level. Concomitantly, the clinical referral pathways can assist the general physicians in the management of patients as well as guide appropriate timely referrals to ENT specialists.

Keywords ENT, Referrals, GRADE-ADOLOPMENT, Pakistan, Clinical practice guidelines

Introduction

Diseases of the ear, nose, and throat (ENT) account for a significant portion of a primary care physician's practice. ENT diseases affect populations of all ages and are a serious concern for public health universally [1]. The most common ENT disorders with which patients present to an out-patient setting include otitis media and externa, cerumen impaction, hearing loss, epistaxis, allergic rhinitis, sinusitis, and pharyngitis/tonsillitis [2, 3]. Several developing countries have a scarcity of ENT specialists and have inadequate facilities to support them, resulting in a heavy burden on the existing workforce [4]. In Pakistan, approximately 25% of a general physicians' (GPs') consultations in adults and 40% in children involve ENT-related complaints [5].

Improving the quality and performance of healthcare services is a priority for healthcare settings. Evidence-based clinical practice guidelines (CPGs) are the gold standard for diagnosing and managing diseases and lead to improved patient safety and outcomes [6]. A large number of CPGs for ENT disorders used on an international level have been developed by high-income countries such as the United States of America (USA) and the United Kingdom (UK) [7, 8], and are tailored to fit their healthcare systems. However, more often than not, LMICs are deficient in monetary resources and the necessary research infrastructure required to generate evidence-based CPGs on their own [9]. Pakistan, a developing country, faces a shortage of specialist doctors, which is expected to increase further by 2030 [10]. As a result, GPs oversee care provision for a vast burden of ENT conditions. A survey conducted in 2016 showed that most GPs in Pakistan received unsatisfactory ENT training during house job/foundation training [5]. Thus, there is a need for comprehensive CPGs to be devised for the local context in Pakistan, so that GPs can adequately provide standardized care, reduce the load of hospital care, prevent needless ENT referrals, and enhance primary health care [11].

Creating CPGs from scratch is an arduous process. It is often not possible due to inadequate resources, in the case of which the process should depend on a composition of adoption (integrating current recommendations as is), adaptation (revising specific recommendations according to local context), and de novo development of recommendations [9]. The term 'Adolopment' has been introduced to encompass components of adoption, adaptation, and de novo development. The GRADE

(Grading of Recommendations, Assessment, Development, and Evaluation)-ADOLOPMENT process makes use of evidence-to-decision (EtD) tables to dictate the process of adaptation [12–14]. EtD tables deliver general and context-specific evidence across fixed criteria against which experts make decisions regarding the validity of current recommendations and suggested modifications. The GRADE-ADOLOPMENT process has been used to create CPGs in many countries, such as Saudi Arabia [9], Tunisia [15], Mexico [16], the Eastern Mediterranean region [17], and Australia [18]. In Pakistan, this process has also been used previously to create local CPGs for the management of adult type-2 diabetes mellitus [19].

As the burden of ENT-related disease continues to rise in Pakistan, the existing GP workforce is becoming increasingly overwhelmed [20]. In order to achieve optimal standards of health care, it is essential to formulate CPGs by using a clear and standardized process that makes use of current evidence-based CPGs with relevant region-specific alterations. These local CPGs would improve ENT-related healthcare delivery in Pakistan and would have high reliability due to the transparent development processes. Primary care clinical pathways that guide primary care management and appropriate specialist referral can help streamline ENT-related primary care and reduce unnecessary specialist referrals. In this study, we describe our use of the GRADE-ADOLOPMENT process to develop local evidence-based CPGs and primary care clinical referral algorithms for the management of ENT conditions at the primary care level in Pakistan.

Methodology

Study setting

This study was conducted at the Centre for Clinical Best Practices (CCBP), a centre created in the Clinical and Translational Research Incubator (CITRIC) at the Aga Khan University (AKU), Karachi, Pakistan. AKU is one of Pakistan's leading healthcare and biomedical research facilities.

The CCBP is tasked with the development of CPGs and primary care management and referral pathways to standardize clinical practice across Pakistan. The CCBP collaborated with the Section of ENT at AKU and the USA GRADE working group to implement the GRADE-ADOLOPMENT process as described below to develop CPGs for eight common ENT-related complaints that commonly present to a primary care practitioner. The

primary intended audience for these CPGs includes the GPs of Pakistan.

Study team

The CCBP research team and experts from the AKU Section of ENT formed the study team. The CCBP team members have received extensive training in the GRADE-ADOLOPMENT process and the creation of CPGs.

Topic selection

The CCBP team approached the Section of ENT to identify the most common ENT disorders based on their clinical experience in Pakistan. The faculty selected eight topics, namely epistaxis, neck masses, sudden sensorineural hearing loss (SSNHL), Meniere disease, dysphonia, allergic rhinitis (AR), rhinosinusitis, and acute otitis externa (AOE).

Selection of source guideline

After the selection of topics, the process for the selection of source guidelines was initiated. The source guideline is the original standardized CPG that is chosen to undergo the GRADE-ADOLOPMENT process for the development of the local guideline. Two ENT specialists appraised several source CPGs after conducting an extensive literature search on Medline and Google Scholar from 2010 to September 2021. For each CPG, characteristics such as scope, local familiarity and application, rigor, and legitimacy of the establishing bodies were taken into account. As a result, the following source guidelines were selected for the creation of local CPGs via GRADE-ADOLOPMENT:

1. *Clinical practice guideline: acute otitis externa - American Academy of Otolaryngology-Head and Neck Surgery Foundation, 2014.* [21]
2. *Clinical practice guideline: Dysphonia - American Academy of Otolaryngology-Head and Neck Surgery Foundation, 2018.* [22]
3. *Clinical practice guideline: of Epistaxis - American Academy of Otolaryngology-Head, and Neck Surgery Foundation, 2020.* [23]
4. *Clinical practice guideline: Allergic rhinitis - American Academy of Otolaryngology-Head, and Neck Surgery Foundation, 2015.* [24]
5. *Clinical Practice Guideline: Evaluation of the Neck Mass in Adults – American Academy of Otolaryngology-Head, and Neck Surgery Foundation, 2017.* [25]
6. *Clinical Practice Guideline: Sudden Hearing Loss – American Academy of Otolaryngology-Head, and Neck Surgery Foundation, 2019.* [26]

7. *Clinical practice guideline (update): adult sinusitis - American Academy of Otolaryngology-Head, and Neck Surgery Foundation, 2015.* [27]

8. *Clinical Practice Guideline: Meniere's Disease - American Academy of Otolaryngology-Head, and Neck Surgery Foundation, 2020.* [28]

Review of source guideline

The CCBP team collaborated with the US GRADE working group to form an adaptation of the GRADE-ADOLOPMENT process. The steps of the adolopment process are outlined in Fig. 1. The modified GRADE-ADOLOPMENT process has been used previously by the CCBP team to create guidelines for type 2 diabetes mellitus [19]. A detailed description of the steps of our modified adolopment process can be found in Additional File 1.

Our modified adolopment process has one important difference from the original adolopment process: recommendations that required straightforward changes which did not modify the essence of the recommendation but only provided auxiliary information were not put through the complete adaptation process (entailing EtD tables and expert panel review). In our modified adolopment process, adaptation via EtD tables and expert panel reviews is only done if a content change is deemed necessary in a specific recommendation.

Focus group discussion to identify challenges and solutions

Two focus group discussions (FGDs) were carried out to identify potential solutions to problems that occurred throughout the process of creating the CPGs. The FGD was directed by a CCBP team member and participants included both CCBP employees and the Department of ENT. Prior to the FGD, participants were given the chance to individually communicate the challenges they faced and proposed solutions. Each obstacle was characterized as either a major or minor difficulty by agreement. The CCBP team then grouped the final list of individual challenges into broad themes with their suitable solutions.

Creation of referral pathways

The recommendations in our local CPG were used as core material for creation of primary care management and referral pathways. The ENT specialists at AKU worked with the CCBP staff to form the management algorithms for primary care physicians. They focused on early diagnosis, management at the level of primary care, and referral to specialists when needed.

If any gaps in care provision were found while drafting the clinical management and referral pathways, we sought additional recommendations through a best-evidence systematic review process. This preferably involved

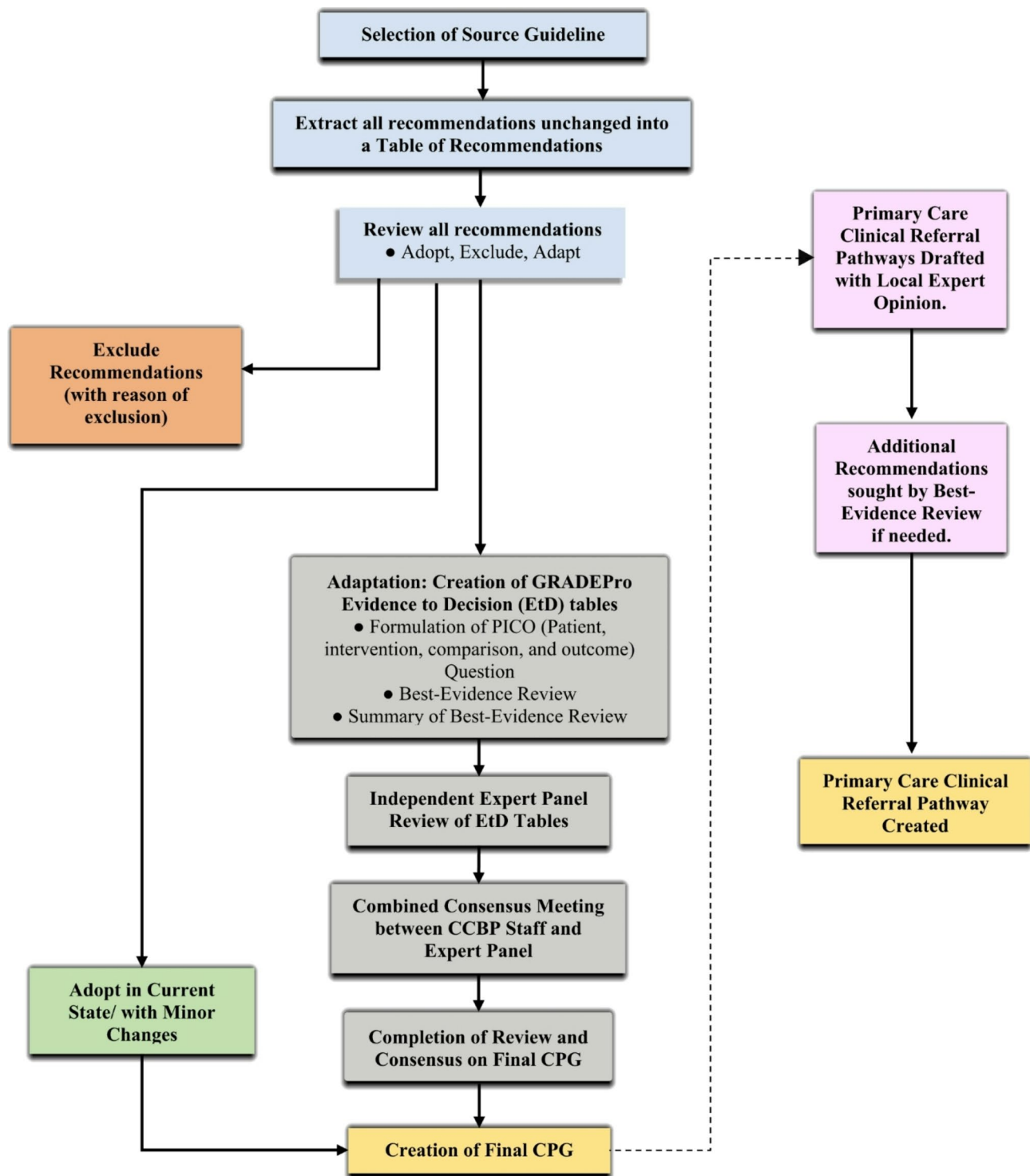


Fig. 1 Outline of the GRADE-ADOLOPMENT process

use of recommendations from already existing CPGs other than the selected source CPGs. The evidence collected to form the recommendation was then reviewed by the experts. If already existing recommendations in other CPGs were not found, recommendations were

drafted and included in the clinical management and referral pathways using peer-reviewed evidence from trustworthy information sources. If the best-evidence systematic review process resulted in no citable evidence, we made additions based on expert consensus.

Results

We created local CPGs for the eight most common ENT disorders seen in the primary care setting of Pakistan using the GRADE-ADOLOPMENT method. Across the 108 recommendations found in the source CPGs for the eight ENT disorders, five recommendations were adopted with minor changes into the local CPG (one recommendation for AOE, SSNHL, and epistaxis and two for AR) and six were excluded from the local CPGs (one recommendation from the epistaxis source CPG, two from SSNHL, and three from AR) (Tables 1 and 2). All other recommendations were adopted as is into our local CPGs. The finalized local CPGs can be found in Additional File 1.

We also created primary care clinical referral algorithms for these conditions based on the recommendations in the local CPGs (Additional File 2). We added four additional recommendations to the epistaxis algorithm, three for neck lumps/mass, rhinosinusitis, and AR, two for AOE, and one for Meniere's disease and dysphonia algorithms (Table 3).

The challenges faced while creating the CPGs were grouped into three main themes: stakeholder support and involvement, resources, and resistance to change (Additional File 1).

Discussion

The local CPGs we created can guide GPs regarding the eight most common ENT-related patient complaints in the primary care setting, including epistaxis, neck lumps, AOE, SSNHL, rhinosinusitis, AR, Meniere's disease, and dysphonia. These CPGs provide patient management details, starting with a thorough clinical evaluation, including history, examinations, and investigations, followed by step-by-step management encompassing pharmacological and non-pharmacological modalities. These local CPGs were organized into comprehensive yet simple primary care management and referral pathways for GPs. These referral pathways were created to make the recommendations in the CPGs more convenient for GPs to use and, where necessary, guide the decision for appropriate referrals to ENT specialists.

In the primary care setting, GPs function as gatekeepers to specialized ENT care. In fulfilling this role, GPs must be equipped with the knowledge of current evidence-based practices as applicable to their local setting and must be able to understand the extent of their role as care providers and determine when a patient warrants a referral to a specialist. This allows GPs to alleviate some of the burdens on the scarce specialist ENT resources while lowering healthcare costs, a consideration of

Table 1 Recommendations adopted with minor changes in the CPGs

| Recommendation | Change made |
|---|--|
| Acute otitis externa | |
| 1 "When a patient has a known or suspected perforation of the tympanic membrane, including a tympanostomy tube, prescribe a non-ototoxic topical preparation (e.g., ciprofloxacin ear drops). [Recommendation, Grade: D, level of confidence in evidence: Moderate]" | Description (e.g., Ciprofloxacin ear drops) added. Ciprofloxacin is available as non-ototoxic ear drops. |
| Epistaxis | |
| 1 "Nasal Packing: a) For patients in whom bleeding precludes identification of a bleeding site despite nasal compression, the clinician should treat ongoing active bleeding with nasal packing (with either merocel or cotton ribbon as available). Nasal Packing in Patients with suspected bleeding risk— b) The clinician should use resorbable packing (e.g., gel foam) for patients with a suspected bleeding disorder or for patients who are using anticoagulation or antiplatelet medications." [Recommendation, Grade: C]" | Description (with either merocel or cotton ribbon as available) added. Merocel and cotton ribbon are non-absorbable packing. Description (e.g., gel foam) added. Gel foam is a resorbable packing |
| Allergic Rhinitis | |
| 1 "Clinicians should recommend intranasal steroids (e.g., mometasone, fluticasone, beclomethasone) for patients with a clinical diagnosis of AR whose symptoms affect their quality of life. [Grade: A, High Level of confidence in evidence]" | Description (e.g., mometasone, fluticasone, beclomethasone) added. Mometasone, fluticasone and beclomethasone are widely available as intranasal preparations |
| 2 "Clinicians should recommend oral second-generation/ less sedating antihistamines (e.g., fexofenadine, cetirizine, loratadine) for patients with AR and primary complaints of sneezing and itching. [Grade: A, High Level of confidence in evidence]" | Description (e.g., fexofenadine, cetirizine, loratadine) added. Fexofenadine, cetirizine and loratadine are widely available oral second-generation/ less sedating antihistamines |
| Sudden Sensorineural Hearing loss | |
| 1 "In patients with SHL clinicians should obtain, or refer to a clinician who can obtain, audiometry (pure tone audiometry and speech discrimination score) as soon as possible (within 14 days of symptom onset) to confirm the diagnosis of SSNHL. [Recommendation, Grade: C]" | Description (pure tone audiometry and speech discrimination score) added. Both tests are required for an accurate assessment |

AR: Allergic Rhinitis, SHL: Sudden Hearing Loss, SSNHL: Sudden Sensorineural Hearing Loss

Table 2 Recommendation excluded from source guideline for management of ENT conditions in Pakistan

| Action | Recommendation | Reason for exclusion |
|--|---|------------------------------------|
| Epistaxis | | |
| Excluded | "Nosebleed Outcomes: Outcome of intervention within 30 days or transition of care in patients who had a nosebleed treated with non-resorbable packing, surgery, or arterial ligation/embolization should be documented." [23] | Due to cost effectiveness |
| Sudden Sensorineural Hearing loss | | |
| Excluded | "Initial Therapy with Hyperbaric Oxygen Therapy: HBOT combined with steroid therapy within 2 weeks of onset of SSNHL" [26] | Due to mass unavailability of HBOT |
| Excluded | "Salvage Therapy with Hyperbaric Oxygen Therapy: HBOT combined with steroid therapy as salvage within 1 month of onset of SSNHL." [26] | Due to mass unavailability of HBOT |
| Allergic Rhinitis | | |
| Excluded | "Inferior Turbinate Reduction: <i>Clinicians may offer, or refer to a surgeon who can offer, inferior turbinate reduction in patients with AR with nasal airway obstruction and enlarged inferior turbinate who have failed medical management."</i> [24] | Due to cost effectiveness |
| Excluded | "Acupuncture: Offer acupuncture, for patients with AR who are interested in nonpharmacologic therapy." [24] | Due to unavailability |
| Excluded | "Herbal Therapy: No recommendation regarding the use of herbal therapy for patients with AR." [24] | Redundant recommendation |

AR: Allergic Rhinitis, HBOT: Hyperbaric Oxygen Therapy, SSNHL: Sudden Sensorineural Hearing loss

particular importance in an LMIC setting [4, 45]. Our CPGs and referral algorithms enable GPs to provide better health care at the patient's initial point of contact while bridging the gap between primary and specialized secondary healthcare [46].

Referral rates from GPs to specialized ENT services in literature are generally variable, ranging from 4.3% up to 20% of all patients seen by GPs with ENT complaints [47–49]. This variability is attributable to differences in practices at the individual GP and the healthcare system level. However, this variability also highlights the burden of potentially inappropriate referrals to specialist ENT services, which in an LMIC like Pakistan, can further exacerbate shortages of specialist resources. Another form of inappropriate use of resources involves diagnostic tests. While baseline investigations are generally necessary for making the correct diagnoses, they can be overused, causing a needless financial burden on the patients without significantly improving their health status [50]. Our newly created local CPGs and clinical referral pathways can help in the standardization of ENT care provision at the primary care level and help minimize unnecessary specialist resource consumption.

In addition, the variability in certain management practices, such as the prescription of antibiotics for suspected infections, is also a matter of concern for antimicrobial stewardship efforts in the country [51]. Studies have shown that medical doctors in Pakistan generally have some misconceptions regarding appropriate antibiotic prescriptions [52, 53]. Additionally, GPs often feel pressured to administer antibiotics even if they are not convinced that they were indicated, with a major proportion doing so solely on the basis of patient's insistence. Thus, the element of patient education incorporated in

our clinical care pathways is of particular importance in the setting of Pakistan where lower literacy rates mean that patients are unaware of the far-reaching harmful consequences of inappropriate antibiotic prescription. Therefore, the use of these latest CPGs can help curb inappropriate prescription practices that lead to antimicrobial resistance and improve the standard of care for patients.

Strengths and weaknesses

Our study has some limitations. As the TOR review is done by individual experts, it is a subjective process that can introduce possible bias in the decision to adapt, adopt, or create recommendations. Another limitation of our study is that the experts who formed the guidelines were from the same tertiary hospital. A more diversified group of experts could reduce the likelihood of institutional bias. The guidelines have since been reviewed by Family Physicians within the hospital as well as external reviewers and the feedback received has been incorporated. Additionally, the feasibility of these recommendations remains a concern for rural implementation. The rural areas of Pakistan lack the infrastructure needed to provide specialist services, should patients require it. Hence, financial and geographical barriers are significant challenges to the implementation of the clinical referral pathways.

The strength of our CPG lies in the transparent and rigorous methodology used to create it. The transparency of the GRADE-ADOLOPMENT process will encourage GPs to confide in the recommendations provided and make informed decisions accordingly. The detailed step-by-step referral pathways will help streamline the entire process and assist with patient triage. Our process for

Table 3 Recommendations added to the clinical referral pathways

| Added Recommendation | | Source |
|--------------------------------|---|---------------------------|
| Epistaxis | | |
| 1 | Look for signs and symptoms – active nasal bleeding, spitting, or vomiting blood, dizziness, confusion, weakness, tachycardia, syncope, orthostatic hypotension, and amount of blood loss. | AAFP [29, 30] AFP [31] |
| 2 | Assess risk factors like nasal or facial trauma, prior nasal surgery, continuous positive airway pressure use, chronic kidney, or liver disease. | AAFP [30] |
| 3 | Educate the patient regarding risk factors which can cause epistaxis such as hot and dry environment, trauma, strenuous activity, digital trauma, excessive nose blowing and inappropriate drug use. | Medscape [32] |
| 4 | Investigations such as complete blood count, prothrombin time, and partial thromboplastin time may be conducted in patients with suspected bleeding disorder | AAFP [30] |
| Neck Masses/ Neck Lumps | | |
| 1 | Look for signs and symptoms – duration, change in size, hoarseness, dysphagia, sore throat, unexplained weight loss, dyspnea, and odynophagia | AJGP [33] |
| 2 | Assess risk factors, smoking, alcohol use, history of head and neck malignancy, inciting incident, family history, addictions, personal history of TB or exposure to TB patient, medication use and comorbid conditions | AJGP [33] |
| 3 | Suggest TB work-up if clinical suspicion of TB is present | AAFP [34] |
| Acute Otitis Externa | | |
| 1 | Look for signs and symptoms – severe otalgia, itching, aural fullness, tenderness of the tragus, hearing loss, jaw pain, and otorrhea | AAFP [35] |
| 2 | Educate the patient regarding risk factors which can cause AOE such as moisture, water contaminated with bacteria, insertion of foreign objects in ear and chronic dermatological conditions | AAFP [35] |
| Rhinosinusitis | | |
| 1 | Obtain comprehensive history and perform physical examination patients to evaluate nasal or postnasal discharge, nasal obstruction, facial pain, pressure/fullness, fever, and hyposmia/anosmia | AAFP [36] |
| 2 | Offer oral steroids with proton pump inhibitors for nasal polyps in a patient with chronic rhinosinusitis (ensure adjusted dose for diabetic patients) | AAAAI [37] JBDS [38] |
| 3 | Educate the patient regarding antibiotic use. | CDC [39] |
| Allergic Rhinitis | | |
| 1 | Clinicians should assess patients with a clinical diagnosis of AR for, and document in the medical record, the presence of associated conditions such as cystic fibrosis | CFF [40] |
| 2 | Recommend nasal saline irrigation for patients with allergic rhinitis | BSACI [41] |
| 3 | A complete blood count to see a raised eosinophil count for patients with a clinical diagnosis of allergic rhinitis may be considered | Medscape [42] |
| Meniere's Disease | | |
| 1 | Educate patients with Meniere's disease about dietary and lifestyle modifications that may reduce or prevent symptoms such as decreasing sodium and caffeine intake | Medscape [43] |
| Dysphonia | | |
| 1 | Advise voice rest | AFP [44] |

AAFP = American Academy of Family Physicians, AAAAI = American Academy of allergy, asthma & immunology, AFP = Australian Family Physician, AJGP = Australian Journal of General Practice, AOE: Acute Otitis Externa, AR: Allergic Rhinitis, BSACI = British Society of Allergy and Clinical Immunology, CDC = Centers for Disease Control and Prevention, JBDS = Joint British Diabetes Societies, TB = Tuberculosis

the creation of CPGs and referral pathways can potentially serve as a template for other resource-challenged countries, such as those in Africa, who are also experiencing the same challenges [4], and other countries with similar population demographics and disease burdens to form their own clinical guidelines and management algorithms.

Conclusion

We used the GRADE-ADOLOPMENT process to create eight local CPGs for common ENT disorders in Pakistan at the primary healthcare level. The recommendations provided by these CPGs will help in the provision of standardized, high-quality care by GPs across the

country. Concomitantly, eight referral pathways were also developed to guide stepwise evaluation, management, and specialist referral of patients presenting with ENT disorders. We believe that these newly created evidence practice guidelines and referral care pathways will enable the healthcare system in Pakistan to deliver the best possible standardized patient care for common ENT-related conditions in Pakistan.

Abbreviations

| | |
|--------|---|
| AKU | Aga Khan University |
| AR | Allergic Rhinitis |
| CCBP | Centre for Clinical Best Practices |
| CITRIC | Clinical and Translational Research Incubator |
| CPG | Clinical Practice Guidelines |
| EtD | Evidence to decision table |

| | |
|-------|-----------------------------------|
| ENT | Ear, nose, and throat |
| FGD | Focus Discussion Groups |
| GP | General Physician |
| LMIC | Lower-middle income country |
| SSNHL | Sudden sensorineural hearing loss |

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12875-025-02756-7>.

Supplementary Material 1

Supplementary Material 2

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Author contributions

S.A., H.M., M.K., S.K., N.A.R., M.A.M., A.A.R., S.N., and A.H.H. were all involved in conceptualizing and creating the guideline via the GRADE-ADOLOPMENT process. A.P., A.R.S., T.N., S.U.R., and R.S.M wrote the initial draft of the manuscript. The manuscript was critically reviewed and approved by all the authors.

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Availability of supporting data

All data generated or analysed during this study are included in this published article and its supplementary information files.

Declarations

Ethics approval

Given the lack of involvement of patients or other human participants, a waiver of ethics approval and informed consent was obtained from the Ethics Review Committee of the Aga Khan University. All methods were conducted in accordance with the highest ethical standards outlined in the 1964 Declaration of Helsinki and its future amendments.

Consent for publication

Not Applicable.

Competing interests

The authors declare no competing interests.

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