AAO-HNSF
Clinical Practice Guideline:
Allergic Rhinitis
(Publication February 2015)

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Learner Objectives

- Describe the process in development of the allergic rhinitis practice guidelines
- Discuss implications of key action statements (KAS) and recommendations to your nursing practice
- Identify nursing areas for inquiry based on the guidelines

Disclosures

Dr. Krouse has no conflicts of interest and nothing to disclose

CPG Leadership

- Michael D. Seidman, MD (Chair)
- Richard K. Gurgel, MD (Assistant Chair)
- Sandra Y. Lin, MD (Assistant Chair)
- Seth R. Schwartz, MD, MPH (Methodologist)

Purpose

To provide evidence-based recommendations for clinicians managing patients with allergic rhinitis, optimize patient care, promote effective diagnosis and therapy, and reduce harmful or unnecessary variations in care.
EMPOWERING PHYSICIANS TO DELIVER THE BEST PATIENT CARE

Burden

- Allergic rhinitis (AR) is one of the most common diseases affecting adults. It is the most common chronic disease in children in the United States today; and is the fifth most common chronic disease in the U.S. overall.
- AR is estimated to affect nearly one in every six Americans and generates $2 to $5 billion dollars in direct health expenditures annually.
- It can impair quality of life and through, loss of work and school, is responsible for as much as $2 to $4 billion dollars in lost productivity annually.

Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Allergic rhinitis (AR)</td>
<td>Allergic rhinitis is an inflammatory disease of the nasal mucose membrane after exposure to allergens. Symptoms include sneezing, itching, tearing, nasal congestion, nasal itching, and sneezing.</td>
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<tr>
<td>Seasonal allergic rhinitis (SAR)</td>
<td>Occurs during the pollen season. Symptoms are usually seasonal and extent of seasonal exposure to these allergens is dependent on geographic location and climate.</td>
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<td>Perennial allergic rhinitis (PAR)</td>
<td>Caused by an IgE-mediated reaction and is characterized by the presence of potential allergens (i.e. dandelion, ragweed).</td>
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<td>Interim allergic rhinitis</td>
<td>Caused by a high concentration of allergens and not necessarily associated with pollen.</td>
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<tr>
<td>Persistent allergic rhinitis</td>
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<tr>
<td>Pediatric allergic rhinitis</td>
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Target Population

- Pediatric (over two years of age) and adult patients with Allergic Rhinitis.

External Peer Review

- 43 reviewers from the 21 organizations/committees (listed below) submitted 682 comments. Resulted in 333 edits/changes to the draft CPG.

- AAO-HNSF Board of Governors
- AAO-HNSF Imaging Committee
- AAO-HNSF Board of Directors
- AAFP Section on Allergy (SAM)
- American Academy of Family Physicians
- AAO-HNSF Complementary and Integrative Medicine Committee
- AAO-HNSF Extracranial/Intracraniopharyngioma Head-Neck Nurses
- American Rhinologic Society (ARS)
- American College of Physicians (ACP)
- American Academy of Otolaryngic Allergy (AAOA)
- American Society of Pediatric Otolaryngology (ASPO)
- AAO-HNSF 3P Workgroup
- American Academy of Otolaryngic Allergy (AAOA)
- Canadian Otolaryngology Society
- AAO-HNSF Rhinology & Allergy Education Committee
- AAO-HNSF Board of Governors
- AAO-HNSF Rhinology and Paranasal Sinus Committee (RPS)
- Society for Ear, Nose and Throat Advances in Children (SENAT)

CPG Development

- Developed using an explicit and transparent a priori protocol
- Three systematic literature searches by information specialist (guidelines, SRs, RCTs, lower level evidence as needed). The 31 CPGs, 360 SRs, and 1,605 RCTs were broken down into the 14 key action statement categories. This material was supplemented, as needed, with targeted searches to address specific needs identified in writing the guideline through February, 2014. After assessing quality and relevance, we retained 7 of the CPGs, 74 of the SRs, and 186 of the RCTs.
- Creation of actionable quality improvement statements based upon the supporting evidence and weighted by the balance of benefit and harm
- Extensive peer review (43 reviewers and 682 comments)

KAS 1: Patient History & Physical Examination

STATEMENT 1. PATIENT HISTORY AND PHYSICAL EXAMINATION: Clinicians should make the clinical diagnosis of allergic rhinitis when patients present with a history and physical exam consistent with an allergic cause and one or more of the following symptoms: nasal congestion, runny nose, itchy nose, or sneezing. Findings of AR consistent with an allergic cause include, but are not limited to, clear rhinorrhea, nasal congestion, pale discoloration of the nasal mucosa, red and watery eyes. Recommendation based on observational studies with a paucity of studies in affected patients.

Benefits: Avoid unnecessary treatment or testing, early referral, institute a specific therapy, improve QOL and productivity, improve accurate diagnosis

Risks, harms, costs: Inappropriate treatment, potential misdiagnosis from using history and physical alone
KAS 1: Patient History & Physical Examination

Action Statement Profile

- Quality improvement opportunity: To promote a consistent and systematic approach to initial evaluation of the patient with allergic rhinitis
- Aggregate evidence quality: Grade C
- Level of confidence in evidence: High
- Benefit-harm assessment: Preponderance of benefit over harm
- Role of patient preferences: Limited - Patient may request additional testing be conducted before deciding on initiation of treatment

KAS 2: Allergy Testing

Action Statement Profile

- Quality improvement opportunity: Improve accurate diagnosis and avoid unnecessary testing
- Aggregate evidence quality: Grade B
- Level of confidence in evidence: High
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgment: Patients may benefit from identification of specific allergic cause
- Role of patient preferences: Moderate - Shared decision-making in discussion of harms and benefits of testing; clinicians and patients should discuss potential costs, benefits, adverse effects of additional testing, and type of testing, either skin or blood, if neither is contraindicated

KAS 3: Imaging

Statement 2. Allergy Testing: Clinicians should perform and interpret, or refer to a clinician who can perform and interpret, specific IgE (skin or blood) allergy testing for patients with a clinical diagnosis of allergic rhinitis who do not respond to empirical treatment, or when the diagnosis is uncertain, or when knowledge of the specific causative allergen is needed to target therapy. Recommendation (against) based on randomized controlled trials and systematic reviews with a preponderance of benefit over harm.

Benefits: Confirming diagnosis, directing pharmacologic therapy, directing immunotherapy, avoidance strategies, avoidance of ineffective therapy, reduce cost of unnecessary testing

Risks, harms, costs: Cost of testing, adverse events from testing, misrepresentation of results, inaccurate test results (false positives and negatives)

KAS 4: Environmental Factors

Statement 4. Immunotherapy: Clinicians may advise avoidance of known allergens or may advise environmental controls (i.e. removal of pets, the use of air filtration systems, bed covers, and acaricides [chemical agents that kill dust mites]) in allergic rhinitis patients who have identified allergens that correlate with clinical symptoms. Recommendation (against) based on randomized controlled trials with minor limitations and observational studies with equivocation of benefit and harm.

Benefits: Decreased allergen levels and possible reduction in symptoms

Risks, harms, costs: Cost of environmental controls, emotional effect (i.e. recommending animal avoidance in pet lovers), cost of ineffective recommendation
KAS 4: Environmental Factors

**Action Statement Profile**
Quality improvement opportunity: Reduce expenditures on environmental measures that do not improve symptoms
Aggregate evidence quality: Grade III
Level of confidence in evidence: Moderate: With the exception of studies on house dust mites, the majority of the studies were small
Benefit-harm assessment: Equilibrium
Value Judgments: Many studies have demonstrated a reduction in allergen levels with environmental controls, however benefits in alleviating symptoms is limited. Use of multiple avoidance techniques may be more effective than individual measures
Role of patient preferences: Large: Shared decision-making in discussion of evidence for effectiveness of possible controls and the need to weigh the costs and benefits

**Primary Prevention: Exclusively Breastfeeding**
Meta-analysis of 6 prospective studies
- Combined sample of 3303 participants
- No significant association between exclusively breastfeeding infants and prevention of childhood allergic rhinitis
Evidence reveals no clear risk reduction in development of AR in breastfed infants
Area is controversial since literature continues to support this recommendation


**Primary Prevention: House Dust Mite Sensitization**
Large randomized-controlled European birth cohort study
- Effects of mite-impermeable mattress covers on development of HDM sensitization in infants
- No difference in development of HDM sensitization between two groups of infants


**In depth look at the evidence**

**KAS 4: Environmental Factors**

Primary Prevention
Goal: Prevent the onset of sensitization to specific allergens so that exaggerated immune response is not produced in their presence
Development of atopic disease early in life
- Exclusively breastfeeding infants against development of allergic disease, particularly allergic rhinitis
- Role of pet ownership and early exposure
- Development of house dust mite (HDM) sensitization

**Primary Prevention: Early Pet Exposure**
Focus on role of early exposure to pets in either contributing to sensitization or reducing the risk of developing pet allergies
Results from large birth cohort studies, randomized trials, meta-analyses, and literature reviews
- Lacked consistency in findings
- Outcomes influenced by type of pets, time and length of exposures and genetics

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KAS 4: Environmental Factors

Secondary Prevention: House Dust Mite (HDM Control)

Cochrane Review (2010)
Reviewed 9 RCTs investigated effectiveness of measures to decrease exposure to HDM
- Use of impermeable covers
- Air filtration (HEPA filters)
- Acaricides
- Combination treatments

Acaricides found to be most effective single therapy

Combination of environmental measures best to reduce HDM exposure and improve AR symptoms


KAS 4: Environmental Factors

Secondary Prevention: Animal Dander Control

Hodson and colleagues (1999) examined effectiveness of washing dogs to reduce Can f 1 allergen levels
- Can f 1 allergen levels significantly reduced after washing with shampoo for five minutes then blow dry
- However, pre-washed levels returned by days 3-4
- Conclusion: In order to be effective dog needs to be washed at least twice a week

Similar studies on washing cats revealed reduction in Fel d1 levels initially but not maintained at one week

Benefits in reducing symptoms have not been shown

Hodson T et al. Washing the dog reduces allergen levels but the dog need to be washed twice a week. J Allergy Clin Immunol. 1999;103:581-585.

KAS 4: Environmental Factors

Secondary Prevention: Mechanical Laundering

EVALUATED MECHANICAL LAUNDERING

Compared 4 washing modes with detergent
- 30°C (86°F)
- 40°C (104°F)
- 60°C (140°F)
- Steam water (SW)

Results
- D. Farinae – HDM
  - After 30°C & 40°C washing modes; 5.5%-9.8% dead
  - After 60°C & SW washing modes; all D. Farinae were dead
- Dog Allergens
  - Significantly lower levels after 60°C & SW washing modes

Pet and HDM allergens can be effectively removed using water hotter than 55°C (130°F)


KAS 5: Chronic Conditions and Comorbidities

Action Statement Profile

Quality improvement opportunity: Identification of significant comorbid conditions or complications. Potential for treatment optimization
Aggregate evidence quality: Grade B
Level of confidence in evidence: High
Benefit-harm assessment: Preponderance of benefit over harm
Role of patient preferences: None
KAS 6: Topical Steroids

**Action Statement Profile**

**Quality improvement opportunity:** Optimizing the use of proven effective therapy.

**Aggregate evidence quality:** Grade A

**Level of confidence in evidence:** High

**Benefit-harm assessment:** Preponderance of benefit over harm

**Role of patient preferences:** Large- There are multiple classes of effective therapy with differing risks, adverse effects, costs and benefits. The clinician should use his or her expertise in assisting patients to evaluate the best treatment and to ensure patient compliance.

**STATEMENT 6. TOPOCAL STEROIDS:** Clinicians should recommend intranasal steroids for patients with a clinical diagnosis of allergic rhinitis whose symptoms impact their quality of life (QOL). Strong Recommendation based on randomized controlled trials with minor limitations and a preponderance of benefit over harm.

**Benefits:** Improved symptom control, improved QOL, better sleep, potential cost savings with monotherapy, targeted local effect

**Risks, harms, costs:** Topical side effects, epistaxis, drug side effects, potential growth concerns in children, septal perforation and the cost of medication.

KAS 7: Oral Antihistamines

**Action Statement Profile**

**Quality improvement opportunity:** Avoidance of sedating antihistamine use and promotion of use of effective symptom directed therapy

**Aggregate evidence quality:** Grade A

**Level of confidence in evidence:** High

**Benefit-harm assessment:** Preponderance of benefit over harm

**Role of patient preferences:** Large- Shared decision-making in considering the benefits, harms, costs and evaluation of the best treatment options. Clinicians should offer a comparison of evidence for the effectiveness of oral versus nasal administration of antihistamines and nasal steroids that will provide good patient adherence and treatment efficacy.

**STATEMENT 7. ORAL ANTIHISTAMINES:** Clinicians should recommend oral second generation/less sedating antihistamines for patients with allergic rhinitis and primary complaints of sneezing and itching. Strong Recommendation based on randomized controlled trials with minor limitations and a preponderance of benefit over harm.

**Benefits:** Rapid onset of action, oral administration, relief of symptoms, counter irritability, potentially cost-saving (generic brand), relief of eye symptoms

**Risks, harms, costs:** Systemic side effects (sedation), dry eyes, urinary retention

KAS 8: Intranasal Antihistamines

**Action Statement Profile**

**Quality improvement opportunity:** Improve awareness of this class of medications as another effective treatment for allergic rhinitis that may be an alternative to other medication classes

**Aggregate evidence quality:** Grade A

**Level of confidence in evidence:** High, but most of the trials were of short duration

**Benefit-harm assessment:** Equilibrium

**Role of patient preferences:** Large- There is equilibrium of benefits to risks when using intranasal antihistamine. Shared decision making may help ensure that the patient understands the potential benefits versus harms of undergoing this treatment, while also promoting patient compliance with medication

**Exclusions:** Not approved for children below the age of 5

**STATEMENT 8. INTRANASAL ANTIHISTAMINES:** Clinicians may offer intranasal antihistamines for patients with seasonal, perennial, or episodic allergic rhinitis. Option based on randomized controlled trials with minor limitations and observational studies with equilibrium of benefit and harm.

**Benefits:** Rapid onset, increased effectiveness over oral antihistamines for nasal congestion

**Risks, harms, costs:** Increased cost relative to oral antihistamines, poor taste, sedation, more frequent dosing, epistaxis, local side effects
KAS 9: Oral Leukotriene Receptor Antagonists (LTRAs)

**Action Statement Profile**
- **Quality improvement opportunity:** Reduced use of a less effective agent for initial therapy
- **Aggregate evidence quality:** Grade A
- **Level of confidence in evidence:** High
- **Benefit-harm assessment:** Preponderance of benefit over harm
- **Value judgment:** The panel was concerned with the cost of this medication in combination with the evidence that it is less effective than first line medications
- **Role of patient preferences:** Low - rare patients with intolerance of intranasal therapy and concerns regarding somnolence may benefit from consideration of use of this class of medicine
- **Exclusions:** Patient with concurrent diagnosis of asthma. These patients may benefit from oral leukotriene receptor antagonists as a first line therapy

**STATEMENT 9. ORAL LEUKOTRIENE RECEPTOR ANTAGONISTS (LTRAs):** Clinicians should not offer oral leukotriene receptor antagonists as primary therapy for patients with allergic rhinitis. Recommendation (against) based on randomized controlled trials and systematic reviews with a preponderance of benefit over harm.

**Benefits:** Avoid ineffective or less effective therapy, cost saving, decreased variations in care

**Risks, harms, costs:** There may be a subset of patients who would benefit from this medication (i.e. Patient with both AR and asthma)

KAS 10: Combination Therapy

**Action Statement Profile**
- **Quality improvement opportunity:** Reduce variations in care. Improve symptom control.
- **Aggregate evidence quality:** Grade A
- **Level of confidence in evidence:** High
- **Benefit-harm assessment:** Equilibrium
- **Role of patient preferences:** Moderate - Shared decision making in consideration of evidence for benefits, harms and cost of combinations, effective dosing and potential medication interactions to assist the patient in more effective treatment compliance
- **Exclusions:** Decongestants that are part of some combined products are not approved for children under the age of 4

**STATEMENT 10. COMBINATION THERAPY:** Clinicians may offer combination pharmacologic therapy in patients with allergic rhinitis who have inadequate response to pharmacologic monotherapy. Option based on randomized controlled trials with minor limitations and observational studies with equilibrium of benefit and harm.

**Benefits:** Improved effectiveness and symptom control of combined therapy

**Risks, harms, costs:** Increased cost, overdose of medication, use of ineffective combinations, multiple medication side effects, drug interactions

KAS 11: Immunotherapy

**Action Statement Profile**
- **Quality improvement opportunity:** Increased appropriate use of immunotherapy and reduce variation in care; Increased awareness of immunotherapy
- **Aggregate evidence quality:** Grade A
- **Level of confidence in evidence:** High
- **Benefit-harm assessment:** Preponderance of benefit over harm

**STATEMENT 11. IMMUNOTHERAPY:** Clinicians should offer or refer to a clinician who can offer immunotherapy (sublingual or subcutaneous) for patients with allergic rhinitis who have inadequate response to symptoms with pharmacologic therapy with or without environmental controls. Recommendation based on randomized controlled trials and systematic reviews with a preponderance of benefit over harm.

**Benefits:** Altered natural history, improved symptom control, decreased need for medical therapy, long term cost effectiveness, may improve or prevent asthma or other comorbidities, and may prevent new sensitizations

**Risks, harms, costs:** Local reactions, and systemic reactions including anaphylaxis, increased initial cost, frequency of treatment (logistics), pain of injection, delayed onset of symptom control (months)
KAS 12: Inferior Turbinate Reduction

STATEMENT 12. INFERIOR TURBINATE REDUCTION: Clinicians may offer, or refer to a surgeon who can offer, inferior turbinate reduction in patients with allergic rhinitis with nasal airway obstruction and enlarged inferior turbinates who have failed medical management. Option based on observational studies with a preponderance of benefit over harm.

**Benefits**: Improved symptoms, improved QOL, improved medication delivery, reduced medication use, better sleep

**Risks, harms, costs**: Unnecessary surgery, cost of surgery, risks of surgery, atrophic rhinitis

KAS 13: Acupuncture

STATEMENT 13. ACUPUNCTURE: Clinicians may offer acupuncture, or refer to a clinician who can offer acupuncture, for patients with allergic rhinitis who are interested in non-pharmacologic therapy. Option based on randomized controlled trials with limitations, observational studies with consistent effects, and a preponderance of benefit over harm.

**Benefits**: Effective alternative to medical therapies, reduction of symptoms, may more closely align with patient values, improved quality of life, avoidance of medication use and potential side effects

**Risks, harms, costs**: logistics of multiple treatments, need for multiple needle sticks, cost of treatment, rare infections

KAS 14: Herbal Therapy

STATEMENT 14. HERBAL THERAPY: No recommendation regarding the use of herbal therapy for patients with allergic rhinitis. No recommendation based on limited knowledge of herbal medicines, concern about the quality of standardization and safety.

**Benefits**: Improved awareness of alternative treatments, improved education of side effects of herbal therapy

**Risks, harms, costs**: Not applicable
**Summary of Guideline Key Action Statements**

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<th>Statement Strength</th>
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<td>Recommendation</td>
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<td>Topical Steroids (Statement 6)</td>
<td>Strong recommendation</td>
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<td>Oral Antihistamines (Statement 7)</td>
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<td>Inferior Turbinate Reduction (Statement 12)</td>
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<td>Acupuncture (Statement 13)</td>
<td>Option</td>
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<tr>
<td>Herbal Therapy (Statement 14)</td>
<td>No Recommendation</td>
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**Research Needs**

The GDG identified 15 research needs as a result of writing this guideline.

1. Determine the effect of environmental control strategies on AR. The aggregate evidence profile for environmental controls was grade B. Controlled trials to identify the efficacy of environmental controls on measurable AR endpoints are needed.

2. Evaluate the safety and efficacy of SLIT specifically. SLIT has been few U.S.-based studies evaluating SLIT which have been offered in the United States in an office setting, non-FDA approved formulations. With FDA approval of ORAKLAR, a nasal allergen extract consisting of the following antigens (Grass, Mold, Orchid, Pollen, Peanut, Rye, Timothy, and Kentucky Blue Grass), Genentech (treatment for Timothy grass pollen) and Regeneron (treatment for short ragweed pollen) in 2014, prospective, randomized, controlled studies are needed to properly evaluate the effect of the office-based physician-directed, non-standardized products and other SLIT preparations.

3. Cost-effectiveness research (including direct and indirect costs) of SCIT compared to SLIT is needed. There also needs to be better comparisons of SLIT vs. SCIT which are very few and far between or that which are in place in the United States.

4. Determine the molecular effects of first-line therapies for AR target and/or immune responses (i.e. topical steroids and antihistamines for nasal symptoms). Basic research in the fields of allergy and immunology, addressing the underlying triggers for specific patients is needed, as well as other immune-modulating treatments that alter the pathophysiology of AR and its control.

5. Determine the safety and efficacy of acupuncture for AR. There is a relative paucity of data in the English literature regarding the use of complementary and integrative medicine for AR. As such, specific recommendations for or against these treatments could not be made. Higher levels of evidence regarding these therapies need to be obtained through well-designed clinical trials and/or systematic reviews of existing data.

6. The studies on herbal therapies involve use of preparations that combine herbal extracts in varying amounts, thus research needs to be conducted on specific herbal extracts along with standardization of dosing to determine efficacy for AR.

7. Controlled trials comparing surgical versus medical management of inferior turbinate hypertrophy with nasal congestion in patients with AR. In addition, there is a need for further research regarding the role of aspirin in the treatment of AR.

8. Determine the relationship between AR and comorbid conditions such as asthma and rhinitis. In addition, research is needed to determine the effect of AR treatment on comorbid conditions and the effect of treatment for comorbid conditions on AR.

9. Impact of patient adherence to different treatments, and treatment outcomes, which often is neglected in establishing the evidence base for AR or other treatments in trials. There is a need for increased diversity in trial subjects and the examination of other factors influencing treatment outcomes such as ease or utility of treatment administrations, as well as the impact of patient education aids, etc. on patient adherence and consequent outcomes.

10. More research, including basic and/or translational trials, evaluating novel forms of immunotherapy such as peptide vaccines, DNA conjugated vaccines, intradermal specimens, or intranasal injections. There are all strategies that are hypothesized to reduce the allergenicity of extracts while maintaining or enhancing the beneficial effects of the immune system.

11. Analyze the impact of immunosuppressive agents for the treatment of allergies on allergic rhinitis.

12. Determine the relationship between AR and comorbid conditions such as asthma and rhinitis. In addition, research is needed to determine the effect of AR on comorbid conditions.

13. Determine whether different forms of allergy testing can provide clinically meaningful information. It is still unclear whether one form of testing is superior to the other in identifying clinically relevant allergies.

14. Studies to determine the effect of combined allergen formulations for AR that are standardized, tolerable and effectively dosed.

15. Outcome measures needed using SRS-20 or other tools to measure and compare efficacy of medical and surgical treatments for nasal congestion/AR in both children and adults.

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**Thank you for your attention!**

**QUESTIONS?**