Effective Health Care

Testing for Celiac Disease
Nomination Summary Document

Results of Topic Selection Process & Next Steps

- *Testing for Celiac Disease* will go forward for refinement as an update to or expansion of an existing comparative effectiveness or effectiveness review. The scope of this topic, including populations, interventions, comparators, and outcomes, will be further developed in the refinement stage.

- When key questions have been drafted, they will be posted on the AHRQ Web site for public comment. To sign up for notification when this and other EPC Program topics are posted, please go to https://subscriptions.ahrq.gov/service/multi_subscribe.html?code=USAHRQ.

Topic Description

Nominator(s): ***Individual***

Nomination Summary: The nominator is a celiac disease (CD) patient interested in finding out about "easier ways" to test for CD. This topic brief focuses on approaches to establish the primary diagnosis of CD. The current strategy for diagnosing CD involves serial serologic and histopathologic testing. After initial evaluation and testing for iron, folate and vitamin B12 deficiencies and ruling out other potential conditions that can either mask as CD or accompany CD, a dietary evaluation is performed followed by serologic testing. Patients with positive serology tests are then referred for biopsy to confirm CD.

Staff-Generated PICO
Population(s): Patients with suspected CD with a positive serology test
Intervention(s): Alternative confirmatory test strategies including additional serologic testing, HLA typing and alternative approaches to endoscopy
Comparator(s): Endoscopic small bowel biopsy
Outcome(s): Diagnostic performance of alternative strategies (e.g. sensitivity, specificity) and avoidance of the potential harms associated with biopsy

Key Questions from Nominator: Is there an "easier way" to test for celiac disease?

Considerations

- The topic meets all of the EHC Program selection criteria. (For more information, see http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/.)

- Diagnosing CD can be difficult because symptoms of the disease are common to many other gastrointestinal diseases, and confirmation currently requires serial testing. The current strategy uses serial serologic and histopathologic tests to establish the diagnosis. For serology testing, a blood sample is drawn from the patient, while biopsy is performed by enteroscopy. Enteroscopy can be associated with patient discomfort and small risk of bowel perforation. The nominator poses a clinically important question about "easier ways" to diagnose CD.

- This topic was found to be best suited to move forward as an update to or expansion of the existing archived AHRQ evidence report entitled *Celiac Disease*, which was published in 2004. The nominated topic overlaps with some of the key questions examined in this report, which are listed below. Specifically, this nomination relates to an update of Objectives 1 and 4.

1. **Objective 1 - Sensitivity and specificity of tests for CD (Celiac 1)**
    a. **What is the sensitivity and specificity of the following tests for CD:**
        i. **AGA;**
        ii. **EMA;**
        iii. **human tTG IgA antibodies;**
        iv. **HLA (DQ2/DQ8);**
        v. **duodenal/jejunal biopsy (see section below on celiac definition)**
    b. **Do sensitivity and specificity vary in different target populations (e.g., symptomatic vs. asymptomatic; geographic populations)?**
2. Objective 2 - Prevalence and incidence of CD (Celiac 2)
    a. What is the prevalence and incidence of symptomatic and "clinically silent" CD in:
        i. the general population;
        ii. high-risk populations:
            1. family member of patient with CD;
            2. type 1 diabetes mellitus;
            3. iron deficiency anemia (IDA);
            4. osteoporosis?
    b. How does prevalence and incidence in the general population vary in different geographic and racial/ethnic populations?
3. Objective 3 - Celiac associated lymphoma (Celiac 3)
    a. What is the association between CD and GI lymphoma?
        i. What is the cumulative risk of developing GI lymphoma in patients with CD?
        ii. Does the cumulative risk vary with clinical presentation?
4. **Objective 4 - Expected consequences of testing for CD (Celiac 4)**
    a. **What are the expected consequences of testing for CD in the following populations:**
        i. **patients with symptoms suggestive of CD;**
        ii. **asymptomatic, at-risk populations (affected family members, patients with type 1 diabetes);**
        iii. **the general population?**
    b. **"Consequences" include:**
        i. **false-positive results;**

ii. **follow-up testing;**
iii. **invasive procedures (biopsies);**
iv. **cases diagnosed;**
v. **patients complying with treatment; and**
vi. **response to treatment.**

5. Objective 5 - Promoting or monitoring adherence to a GFD (Celiac 5)
    a. What interventions are effective for promoting or monitoring adherence to a GFD?

- Since the AHRQ evidence report was published, new evidence concerning testing for CD has emerged, including evidence demonstrating the high accuracy of serologic tests in diagnosing CD, An update to 2004AHRQ report may help to inform the diagnosis of CD that could include serologic testing, HLA typing and biopsy. The current topic overlaps with only part of the archived AHRQ report entitled *Celiac Disease*. The topic may need to be re-scoped to include the other aspects that were addressed in the original report and to ensure a link between diagnostic tests and patient outcomes is maintained.