Introduction

We identified 4 sources of potential harm:

**Direct Harms**

1. “Subsequent diagnostic tests resulting from the screening”
2. “Early treatment of screen-detected asymptomatic disease”
3. “No studies assessed or addressed harms of screening”
4. “No studies of behavioral interventions reported harms... in terms of child, family, or system impact”

**Classification Errors**

1. “What is known about the number of false positives”
2. “Psychological harm from labeling”
3. “High level of parental stress associated with ASD diagnostic process... Both delays and demands associated with the ASD diagnostic process may place a burden on the families of children who falsely screen positive”
4. “Anxiety related to false positive screen (e.g., Chlamydia, Gonorrhea)”
5. “Invasive diagnostic workup secondary to a false positive screen”
6. “Concern about false negatives”

**Opportunity Costs**

1. “The time and effort required by both patients and the health care system to implement the preventive care service”
2. “Some families access diagnostic and treatment services quickly, while other families report significant time (e.g., waitlists) and financial barriers in accessing evaluation resources”

**Overdiagnosis**

1. “The unintended consequence of creating ‘disease’ that often leads to unnecessary and ineffective treatment”
2. “It is unknown whether [children who received ASD diagnosis but no longer qualified when re-evaluated] represent diagnostic errors; correct diagnoses in children whose developmental pattern encompasses significant improvements in ASD-related impairments, or are the results of accurate early diagnosis and treatment”
3. “Overdiagnosis and overtreatment [of disease] that would never have harmed the patient in the absence of screening (e.g., skin cancer, corrective lenses for children whose visual acuity is not causing harm)”

**Discussion**

USPSTF “I” statements often prioritize Classification Error and Overdiagnosis, over Opportunity Costs and Direct Harms.

**Classification Error, or Diagnostic Error** in the example of ASD, relates to concern about the possibility that ASD screening can lead to both false positive and false negative errors.

- False positive errors could expose families to stigma and unnecessary, timely, and costly services.
- False negative errors could delay other needed services through inappropriate reassurance.

**Overdiagnosis** of correct ASD diagnoses that will not provide benefit.

**Contributing Factors:**

- Dissemination of ASD screening to asymptomatic populations
- Growing awareness and an accompanying reduction in stigma
- Improvement of diagnostic procedures and changes in diagnostic criteria
- Potential for biased clinical judgement

**Conclusion**

- The heterogeneity in ASD could be associated with varied response to treatment, making it difficult to determine population-wide benefit.

**Future Directions**

- High quality studies on: 1) the intermediate and long-term health outcomes of children without obvious signs and symptoms and whether earlier identification is associated with clinically important improvements; 2) patients who receive no benefit from accurate ASD diagnosis; and 3) the potential harms of ASD screening.

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