Evidence Gaps Research Taxonomy Table
Research to Address Evidence Gaps in Preventive Services for the USPSTF
Topic: Research Gaps for Screening for Speech and Language Delay and Disorders in Children

To fulfill its mission to improve health by making evidence-based recommendations for preventive services, the USPSTF routinely highlights the most critical evidence gaps for making actionable preventive services recommendations. As summarized in the research needs and gaps table (Table 2) in the recommendation statement, the USPSTF often needs additional evidence to create the strongest recommendations for everyone and especially for persons with the greatest burden of disease.

In this table, the USPSTF summarizes key bodies of evidence needed to make recommendations for Screening for Speech and Language Delay and Disorders in Children. For each of the evidence gaps listed below, the USPSTF provides guidance to researchers and funders on the types of studies needed to expand the evidence in screening for speech and language delay and disorders in children and enable the USPSTF to make evidence-based recommendations for screening in primary care settings and be inclusive of populations disproportionately affected by speech and language delay and disorders.

The research taxonomy is intended to provide general guidance to investigators. Investigators are encouraged to develop research designs that are responsive to the research taxonomy outlined in the table, in collaboration with their research teams and areas of expertise and experience. The research developed will be reviewed according to standard USPSTF criteria for inclusion in its evidence report; inclusion criteria are summarized in the final Research Plan (https://uspreventiveservicestaskforce.org/uspstf/document/final-research-plan/speech-language-delay-disorders-children-age-5-years-younger-screening) and Procedure Manual (https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/procedure-manual).

Research Gap	Key Questions* or Contextual Questions	Direct/ Indirect Pathway†	Type of Gap‡	Study Characteristics	Population	Intervention/ Comparison	Outcomes/ Timing	Setting
Research is needed to assess the benefits and harms of preventive interventions in the primary care setting. • Studies of screen-detected populations that follow children over short and longer (>1 year) durations to detect improvement in outcomes such as academic performance, social and emotional health, or child and family well-being. • These studies should focus on enrolling children from groups with the greatest burden of speech and language delay and disorders (Black, Hispanic/Latino, and children from households with low incomes). These types of studies would help to understand if changes in speech and language outcomes translate into changes in the broader health and well-being of children and their families,	KQ4 KQ5 KQ6	Indirect (KQs 4, 5, 6)	Grade assignment/ health equity	RCTs, controlled trials, and observational studies. Studies should be well designed§ with low risk for bias using contemporaneous comparison groups.	Screen-detected and asymptomatic populations. Studies should prioritize enrolling participants from low SES households and racial and ethnic groups (Black and Hispanic/Latino) disproportionately affected by speech and language delay and disorders.	Interventions vs. no intervention or waitlist controls¶ in screen-detected populations.	<u>Outcomes</u> KQs 4–6: Speech and language outcomes, including speech domains (e.g., stuttering, fluency, and articulation) and language domains (e.g., expressive language, receptive language, phonology, vocabulary, syntax, and pragmatics), academic performance, social and emotional health, or child and family well-being.	KQs 4–6: Clinical and referable from primary care (i.e., educational and home settings).

Research Gap	Key Questions* or Contextual Questions	Direct/ Indirect Pathway†	Type of Gap‡	Study Characteristics	Population	Intervention/ Comparison	Outcomes/ Timing	Setting
including how children function in school and at home.							Timing KQs 4–6: Both short and longer (>1 year) duration.	
There was significant heterogeneity in reporting on speech and language outcomes. Standardization of outcome measurement across studies would greatly strengthen the evidence base and improve the ability to pool data.	KQ4 KQ5 KQ6	Indirect	Grade assignment	RCTs			KQ4: Selected speech and language outcomes relevant to intervention focus. Ideally, a core set of outcomes would be used consistently across studies of the same/similar intervention types. KQ5: Measures of academic skills or achievement (e.g., early literacy skills), parental/caregiver stress, and socioemotional functioning).	
Studies on the potential harms of screening and treatment such as labeling, parent anxiety, or burden of time for intervention.	KQ3 KQ6	Indirect	Grade assignment	Controlled cohort studies, RCTs, and nonrandomized controlled trials	KQ3: Asymptomatic children age 5 years or younger.** Studies should be representative of the U.S. population and inclusive of groups disproportionately affected by speech and language delay and disorders. KQ6: Children who were diagnosed with a speech and language delay or disorder at age 6 years or younger.	KQ3: Screening vs. no screening. KQ6: Interventions vs. no intervention, preferably in screen-detected and asymptomatic populations.	KQ3: Potential harms of screening, including labeling and parent/caregiver anxiety. KQ6: Potential harms of interventions, including burden on parent/caregiver.	KQ3: Settings applicable to U.S. primary care. KQ6: Clinical, educational, and home settings.

* Key questions are an integral part of the approach to conducting systematic reviews that the USPSTF uses in its recommendation process. Along with the analytic framework, these questions specify the logic and scope of the topic and are critical to guiding the literature searches, data abstraction, and analysis processes (https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/procedure-manual).
† The direct pathway is typically derived from RCTs of the targeted screening or preventive intervention that adequately measure the desired health outcomes in the population(s) of interest. If certainty for net benefit cannot be derived from the direct pathway, then the USPSTF determines if the evidence is sufficient across the key questions and linkages in the indirect pathway to determine overall certainty.
‡ Types of gaps may include: grade assignment (moving from an I statement to a letter grade), change in letter grade (e.g., from a C to B or C to D), health equity (e.g., populations with a disproportionate burden of the condition), combined (e.g., grade assignment and health equity), or general gap (e.g., uptake of a clinical preventive service).
§ Well-designed studies should include, but are not limited to, nonbiased selection of screening participants, addressing confounders (e.g., use of well-matched comparison groups at recruitment on baseline clinical and demographic characteristics), and avoidance of use of historical controls. For additional information on guidelines used by the USPSTF to evaluate evidence please see: Harris RP, Helfand M, Woolf SH, et al. Current methods of the U.S. Preventive Services Task Force: a review of the process. *Am J Prev Med*. 2001;20(3):21-35.
¶ If possible, studies should report the characteristics of wait-listed participants.
** Children whose caregivers or clinicians do not have specific concerns about their speech, language, hearing, or development.

Abbreviations: KQ=key question; RCT=randomized, controlled trial; SES=socioeconomic status; USPSTF=U.S. Preventive Services Task Force.