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Screening for Speech and Language Delays and Disorders in Children Age 5 Years or Younger: A Systematic Review for the U.S. Preventive Services Task Force

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Structured Abstract

Purpose: To evaluate the evidence on screening and treating children for speech and language delays or disorders for the U.S. Preventive Services Task Force (USPSTF).

Data Sources: PubMed/MEDLINE®, the Cochrane Library, PsycInfo®, ClinicalTrials.gov, HSRProj, the World Health Organization International Clinical Trials Registry Platform, and reference lists of published literature (through July 2014).

Study Selection: Two investigators independently selected studies reporting on benefits and harms of screening; accuracy of screening tools compared with diagnostic evaluations; and benefits or harms of treatment of speech and language delays or disorders compared with placebo, watchful waiting, or wait-list interventions. To provide context for evaluating our Key Questions, we also included studies describing screening instruments and risk factors for speech and language delays or disorder.

Data Extraction: One reviewer extracted data and a second checked accuracy. Two independent reviewers assigned quality ratings using predefined criteria.

Data Synthesis: No included studies examined the effects of screening on speech and language or other functional outcomes. We included 23 studies evaluating the accuracy of speech and language screening in primary care settings to identify children for diagnostic evaluations and interventions. Among instruments in 13 studies in which parents rated their children's skills, sensitivity ranged from 50 to 94 percent and specificity ranged from 45 to 96 percent. Of the three instruments widely used in the United States, the MacArthur Bates Communication Development Inventory (CDI) and the Language Development Survey (LDS) outperformed the Ages and Stages Questionnaire (ASQ) Communication Domain, especially in terms of their specificity, correctly identifying, on average, 82 percent (CDI) and 91 percent (LDS) compared with 58 percent (ASQ) of children without a language disorder. The ASQ and CDI have versions for infants, toddlers, and preschool-age children, with the CDI being more robust across age groups. The accuracy of professionally or paraprofessionally administered instruments was more variable across studies, and many did not perform as well as parent-rated instruments. Because few studies examined the same instrument in different populations or in different ages, it is unclear how professionally or paraprofessionally administered instruments for multiple ages fare more broadly or whether there is an optimal age for screening. We found no studies addressing adverse effects of screening, such as deleterious consequences of false conclusions from screening. We also found no studies concerning the role of enhanced surveillance by a primary care provider.

We included 13 studies examining treatment for speech and language delays or disorders. Although the treatment approaches sometimes overlap, we organized our findings by outcome: language (including expressive and receptive language and more specific aspects of language, such as vocabulary, syntax/morphology, and narratives), speech sounds (including articulation, phonology, and speech intelligibility), and fluency (stuttering). Although results were mixed, the majority of studies found treatment to be effective. Characteristics of effective studies include higher intensity, treating children with more severe delays, and individualizing treatment to the

child. We found little evidence concerning other functional outcomes or adverse effects of treatment.

Risk factors that were generally associated with speech and language delays or disorders in multivariate analyses of cohort populations included being male, a family history of speech and language concerns, and lower levels of parental educational achievement.

Limitations: As in the earlier review, we did not find any well-conducted trials that could address our overarching question of whether screening leads to improved outcomes. Many screening studies do not include unselected samples from the population but rather participants with and without language delays. Intervention studies did not consistently control for additional community services that children may have been receiving and varied greatly in treatment approach and outcome measurement. Also, because young children with disabilities are entitled to treatment, it may not be possible for future studies in the United States to examine treatment versus no treatment.

Conclusion: Our review yields evidence that two parent-rated screening instruments, the CDI and LDS, can accurately identify children for diagnostic evaluations and interventions and likely can be interpreted with little difficulty in the primary care setting. Some treatments for young children identified with speech and language delays and disorders may be effective.

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Chapter 1. Introduction

Overview and Objective

This systematic review provides evidence to be used to update U.S. Preventive Services Task Force (USPSTF) recommendations released in 2006 concerning screening preschool children (i.e., children age 5 years or younger) for language delays and disorders in primary care settings. The 2006 USPSTF recommendation and conclusions, which are described below, provide the context and rationale for the current update. The rest of the Introduction includes a description of speech and language delays and disorders in children age 5 years or younger; an overview of the epidemiology of the condition; a description of screening, intervention, and current clinical practice; and a discussion and justification of the changes in scope of the current review. The Methods section describes the Key Questions (KQs), contextual questions, and analytic framework that guided this update review, as well as the search strategy, study selection, data abstraction, quality rating, and data analyses. The Results section presents findings organized by KQ. The Discussion section summarizes the findings and presents information on the applicability and context of the findings; any limitations, gaps, and future research needs; and conclusions.

Previous USPSTF Recommendation and Conclusions

In 2006, the USPSTF concluded that the evidence was insufficient to recommend for or against routine use of brief, formal screening instruments in primary care to detect speech and language delays in children age 5 years or younger (I recommendation).

Importance

The USPSTF noted that speech and language delays affect up to 8 percent of preschool-age children and, if untreated, often persist into the school years. Such delays may be associated with diminished school achievement and behavioral problems.

Detection

The USPSTF concluded that there was insufficient evidence that brief instruments suitable for use in primary care can accurately identify speech and language delays in preschool-age children. Although there is extensive literature evaluating the reliability and validity of many instruments, the optimal method of screening for speech and language delays or disorders has not been identified.

Benefits of Detection and Early Intervention

Although the USPSTF did not find evidence that screening for speech and language delays is

beneficial for identifying children who would profit from further assessment and intervention, it found fair evidence that speech and language interventions can improve outcomes in the short term. However, the USPSTF noted that no studies evaluated whether brief screening yields any benefits beyond those that are found by addressing clinical or parent concerns.

Harms of Detection and Early Treatment

The USPSTF indicated that no studies addressed the harms of either screening or intervention for speech and language delays. Thus, it was unable to determine the benefit-harm ratio of using brief, formal screening instruments to screen for these delays in the primary care setting.

Risk Factors and Prevalence Rates

The USPSTF was unable to develop a list of specific risk factors to guide primary care providers in selective screening. The most consistently reported risk factors included a family history of speech and language delays, male sex, and perinatal factors, such as prematurity and low birth weight. In studies that evaluated speech and language delays in preschool children ages 2 to 4.5 years, the prevalence of speech and language delays ranged from 5 to 8 percent, while studies of only language delays reported rates of 2.3 to 19 percent.

Condition Definition

A speech or language delay implies that the child is developing speech or language in the correct sequence but at a slower rate than expected, while a speech or language disorder suggests that the child's speech or language ability is qualitatively different from typical development.

The distinction between the two is complicated because screening instruments are unable to distinguish between a child who has a delay (i.e., a child with late-emerging language during the first 2 years of life) that subsequently resolves and one who will go on to display a speech and language disorder (i.e., a child who will later receive a formal diagnosis of specific language impairment). Some researchers report that many children with language delays, particularly in expressive language, score in the normal range by age 4 or 5 years, but that their performance is often weaker than that of children without delays.[1-4] Because children with delays often test in the normal range by school age, the ability of screening instruments to make long-term predictions based solely on preschool screening findings is limited.[1]

Other terms used to describe speech and language delays or disorders are speech and language "disabilities" and "impairment." In the remainder of the report, we use the terms "speech and language delay," "speech and language disorder," "speech and language impairment," and "speech and language disability" interchangeably.

The Individuals with Disabilities Education Act (IDEA) defines a speech and language disability as "a communication disorder, such as stuttering, impaired articulation, a language impairment, or a voice impairment, that adversely affects a child's educational performance."[5] Children with

speech and language disorders function well below the norm for their age in one or more aspects of speech or language.

A defining feature of these disorders is whether the impairment is considered primary or secondary. In some cases, children have other developmental, sensory, or physical problems that "explain" their speech and language difficulties, such as intellectual disabilities, autism spectrum disorders, hearing loss, structural abnormalities (such as cleft lip or palate), an impairment of motor function (such as cerebral palsy), or some combination of these factors; such children are categorized as having a secondary speech and language disorder. In other cases, no specific explanation for the speech and language delay or disorder is ever identified; these children are diagnosed as having a primary language disorder. Another term for primary language disorder is specific language impairment (SLI).

Although it is likely to be useful to distinguish between primary and secondary language disorders in determining appropriate treatment, in the context of screening, it may not be possible. Early screening may flag symptoms of speech and language disorders later determined to be associated with another developmental disorder in which speech and language delays are prominent. At the time of the screening, the primary care provider will be blind to the eventual diagnostic outcome. For example, the most common early concern reported by parents prior to their children's eventual diagnosis of autism spectrum disorder is related to speech and language development.[6,7]

Another way of thinking about speech and language disorders is to consider their etiology. Speech and language disorders may be acquired or developmental. In acquired cases, the language disorder is the result of an injury that occurred sometime after birth (e.g., focal lesion; acquired aphasia secondary to a seizure disorder; brain damage after tumors, infections, or radiation; and traumatic brain injury). Developmental language disorders become apparent as development unfolds but are thought to be present at birth, and often for no apparent reason. When no other condition exists that explains the language difficulty, it is labeled a primary speech or language disorder.

The focus of this review is on primary speech or language disorders whose etiology is developmental and is limited to children who have not been previously identified with another disorder or disability, not those with acquired, focal causes of speech and language delay, and with the understanding that some of the children identified will receive a primary diagnosis for a disorder such as autism or mental retardation subsequent to the screening. This may be considered an additional outcome of screening.

Other classifications of speech and language disorders consider symptoms. For example, the International Classification of Diseases (ICD), 10th edition, lists specific speech and language developmental disorders, including specific speech expressive disorder, expressive language disorder (difficulty getting a message across to others), and receptive language disorder (difficulty in understanding messages from others). The use of the modifier "specific" in the ICD-10 indicates that the disorder is not a symptom of another disorder, such as intellectual disability, hearing loss, or autism spectrum disorder. The American Speech-Language-Hearing Association (ASHA) guidelines[8] describe a speech disorder as an impairment of the articulation

of speech sounds, fluency, or voice, and a language disorder as impaired comprehension or use of spoken, written, or other symbol systems. ASHA further states that the disorder may involve the form of language (phonology, morphology, syntax), the content of language (semantics), and the function of language in communication (pragmatics) in any combination. Prelinguistic communication behaviors (e.g., gestures, babbling, joint attention) are important precursors of language ability; they have been found to predict language development in typically developing children[9] as well as subsequent language delays.[10-12] For these reasons, this review considers screening for both verbal and preverbal communication skills.

Prevalence

Speech and language delays and disorders are common problems in pediatric populations. A systematic review conducted by Law et al[13] estimated the prevalence of speech and/or language delays in children ages 2 to 5 years to be between 5 and 12 percent, with a median of 6 percent.[13] This estimate was based on data from six studies on either speech or language delays among children in the United Kingdom. More specifically, the prevalence of primary language delays (not including speech) has been estimated to be between 3 and 16 percent, with a median prevalence of 7 percent. This estimate was based on eight studies of preschoolers in the United Kingdom, Canada, New Zealand, the United States, and Hong Kong.

Other studies of single populations provide similar prevalence estimates. In a population-based study in Utah of children age 8 years, the prevalence of communication disorders (speech or language), based on special education or ICD-9 classifications, was 63.4 cases per 1,000 children.[14] Removing all cases identified with communication disorders that also met diagnostic criteria for autism spectrum disorder or intellectual disability, the prevalence dropped to 59.1 cases per 1,000 children. This was the only prevalence study conducted in the United States; no U.S. prevalence studies of preschool children have been conducted.

A population study in a large town in Finland reported a prevalence of 10 cases per 1,000 children for SLI (not a component of another primary diagnosis) in children age 6 years or younger.[15] In a nationally representative sample of children ages 4 and 5 years in Australia, 13 percent of parents reported being "a little concerned" and 12 percent reported being "concerned" about some aspect of how their child talked and made speech sounds, and 5 percent were "a little concerned" and 4 percent were "concerned" about how their child understood language.[16]

Approximately 2.6 percent of children ages 3 to 5 years (298,274 children) were served under IDEA in 2007 for speech and language disabilities in the United States.[17]

The usefulness of language screening in the primary care setting is best measured by how well it identifies children who are not already flagged as having potential speech or language delays. Therefore, specific groups of children who would have been identified as at higher than average risk, such as children diagnosed with hearing deficits, intellectual disability, or craniofacial abnormalities, would not be considered in determining the value of screening.

Burden

ASHA[18] estimates that speech sound disorders affect 10 percent of children, the prevalence of language difficulty in preschool children is between 2 and 19 percent, and specific language impairment affects 7 percent of children. As adults, children who had speech and language disorders, especially when language is affected, may hold lower-skilled jobs and are more likely to be unemployed than unaffected children.[19] According to one study detailing the economic impact of communication disorders,[20] the rate of unemployment among individuals with communication impairments is 43 percent. Further, these researchers found that 44 percent of individuals whose speech makes it difficult for them to be understood are in the lowest income strata compared with 17 percent of those free of disabilities. Finally, they estimated that in 1999 dollars, the total economic impact of communication disorders, including costs of unemployment, underemployment, rehabilitation, and special education services, was approximately $154 billion, about 2.5 percent of total gross domestic product.

Course, Comorbidity, and Sequelae

Etiology and Natural History

In contrast to acquired speech and language disorders, developmental speech and language disorders, which are not secondary to another condition, are often of unknown origin. Still, many speech and language disorders originating in childhood are known to cluster in families.[21-23] Recent studies of twins have shown a strong concordance for language impairment in monozygotic twins.[24-27] The Twins Early Development Study[26,27] found that concordance increases at the more extreme ends of the language impairment distribution, with genetic influences being similar for males and females. Moreover, genetic linkage studies have identified a number of candidate genes associated with stuttering, speech sound disorders, and other SLIs.[22,23,28,29] Although only a small proportion of childhood speech and language disorders can be explained by genetic findings to date, the increasing sophistication of genetic approaches is likely to yield a better understanding of the role of genetics in these disorders in the near future.[22,23,28,29]

Sequelae

Childhood speech and language disorders include a broad set of disorders with heterogeneous outcomes. Evidence from studies of children identified with these disorders who are followed into early school years, adolescence, and adulthood is accumulating to provide outcomes for this population. Although few of these studies account for participants' treatment histories, it is unlikely that most individuals were completely untreated for their speech and language disorders. Thus, a true picture of the natural history of language delays and disorders is limited. Followup studies report that when young children have speech and language delays, they are at increased risk for learning disabilities once they reach school age,[30] and children with both speech sound disorders and language impairment are at greatest risk for language-based learning disabilities.[31,32] These children may have difficulty reading in elementary school[33-36] and may

have difficulty with written language.[37] These issues may lead to overall academic underachievement[38] and, in some cases, lower IQ scores[39] that may persist into adulthood.[40] Estimates of the increased risk for poor reading outcomes in second and fourth grades, according to the findings of one research group, are 7 to 8 times greater for children with nonspecific language impairment (i.e., language impairment accompanied by low IQ) and about 5 times greater for children with a SLI.[33,41,42] These estimates are in line with the findings from a study of children referred as preschoolers for speech and language assessments who were subsequently prioritized for an intervention based on the assessment results; they were significantly more likely to exhibit language and literacy impairments in elementary school than children never referred for speech and language assessments.[43]

The risk for poor outcomes is greater for children whose disorders persist past the early childhood years and for those who have both lower IQ scores and language impairments rather than only speech impairments.[44] Estimates of the proportion of children with early speech and language delays whose disorders persist into the school years vary and may depend to some extent on the inclusion criteria for children based on their early characteristics. In one large study using a database of children who received preschool services in Florida under IDEA part B, Delgado[45] found that 54 percent of 2,045 children classified as having a speech or language delay for preschool service eligibility were classified as having an educational disability when they were in the fourth grade.[45] A study in England[43] followed up with 196 of 350 children ages 7 to 9 years who were initially referred to community clinics for speech and language concerns prior to age 3.5 years. The researchers found that 36 percent of the group of children prioritized for intervention after their early assessment showed significant language and literacy impairments (at least 2 standard deviations below the mean on one or more assessments) at followup compared with 16 percent of the referred nonprioritized group and 8 percent of the control group. In addition to persisting speech- and language-related underachievement (verbal, reading, spelling), language-delayed children have also shown more behavior problems and impaired psychosocial adjustment, and the psychosocial problems can persist into adulthood.[46-48]

Current Clinical Practice in the United States

Identification of Speech and Language Delays and Disorders in Primary Care Settings

Screening for speech and language disorders has been defined as using standardized tools to detect the risk of a delay, which can be corroborated by a full-scale diagnostic evaluation. Screening for speech and language disorders in clinical practice most often occurs in pediatric outpatient clinics in the context of routine developmental surveillance and screening. By surveillance we mean the informal checks about developmental progress that occur during routine well-child visits; surveillance is also known as monitoring.

In 2006, the American Academy of Pediatrics published clinical guidelines for developmental screening and surveillance in the primary care setting.[49] These guidelines recommend that pediatric health care providers perform surveillance at every well-child visit for children younger than age 36 months, and if any concerns arise, to screen using standardized developmental tools.

Irrespective of concerns, the guidelines identify 9, 18, and 30 (or 24) months as the specific ages when developmental screening should be done. The American Academy of Pediatrics also developed the Bright Futures Guidelines for Health Supervision of Infants, Children, and Adolescents,[50] which offer primary care providers a set of processes and tools for surveillance; documentation of findings; and talking with parents about health, global development, and concerns. Bright Futures Guidelines recommend screening for developmental concerns, including speech and language, at regular intervals as part of well-child visits. Irrespective of the procedures used, when a child screens positive, the primary care provider should make a referral for further evaluation and treatment.

A variety of tools have been used to screen for speech and language delays; many are part of a broader screening for developmental delays. Some screening tools are designed to be administered to the child; others are checklists that are designed to be completed by a parent or teacher. Often primary care providers use broad-band instruments that screen for a variety of developmental issues. One such instrument is the Parents' Evaluation of Developmental Status questionnaire;[51] it asks parents about concerns they may have about their child's development using one question on each of several different developmental domains, including expressive and receptive language. The results indicate the need for further screening or referral. Alternatively, other broad-band instruments such as the Denver II[52] and the Ages and Stages Questionnaire (ASQ)[53] have separate scales that probe for more detailed information about the different developmental domains (e.g., language, motor, adaptive, social-emotional skills). While the Denver II directly assesses the child, the ASQ asks parents about their child's development. In contrast to broad-band instruments, narrow-band instruments are designed to screen only for speech and language skills. Some narrow-band screening instruments for speech and language include the Language Development Survey (LDS)[54] and the MacArthur-Bates Communicative Development Inventory (CDI);[55] parents complete these screening instruments, but they can be scored by a primary care provider.

The rationale for identifying speech and language problems during the years prior to formal schooling is that early intervention services may be initiated before these problems interfere with school learning. However, individual clinicians lack specific pediatric organizational or governmental policy recommendations concerning the effectiveness of speech and language screening outside of more global developmental screening recommendations. Additionally, because a variety of screening instruments are available, practitioners may be confused about which tools are best at which times. Screening may be considered a low priority because administering the instruments is time consuming and the reimbursement level may be considered low. Further complicating the motivation for speech and language screening is the lack of a universal system for referral and management once abnormalities are detected through screening.

Interventions/Treatment

Once a child is diagnosed with a speech-language disorder, he or she is typically referred for therapy. Therapies and treatment plans for childhood speech and language disorders are highly variable and are commonly individualized to the patterns of symptoms exhibited by a particular child.[56] Treatments are designed to adapt to the child's interests, personality, and learning style, and to address the priorities of the child, parents, or teachers based on the functional impact of

the child's disorder in different settings.

The content of therapy sessions depends on the child's identified needs. For example, for a child with an articulation disorder, the speech-language pathologist may model the production of problematic sounds, cue the child on placement of the articulators, and provide multiple opportunities for practice. When speech sound disorders are determined to follow rule-based error patterns (phonological disorders), the therapy addresses the disorder using systematic presentation of speech sound stimuli to help the child learn the phonological rules of the language.[57,58] Similarly, for children with language disorders, therapy is designed to address the symptoms, guided by knowledge of what is developmentally appropriate and by assessment information identifying the child's specific weaknesses in expressive or receptive language related to vocabulary, syntax, pragmatics, or some combination of these. Strategies include environmental adaptations and a rich exposure of the child to vocabulary, language structures, and varied language interactions or a more focused program of modeling, prompting, and practicing specific language targets that are appropriate next steps based on the child's current developmental level.[59-61]

For children who have severe communication impairments that include limited or no ability to speak intelligibly, an augmentative and alternative communication system might be designed in conjunction with the speech-language therapy. These systems are sometimes built around "high tech" speech-generating devices; in other cases, the systems are "low tech" and involve the use of picture communication boards or books, sometimes combined with gestures. Many assistive technology options are now available to support individuals with speech and language disorders in their daily functioning.[62,63]

Therapy may take place in various settings, such as speech and language specialty clinics, home, schools, or classrooms. Therapy may be administered to an individual or group. Therapists may be speech-language pathologists, parents, or teachers. Therapy may be child-centered or include peer and family components. The duration and intensity of the intervention varies depending on the severity of the speech or language disorder and the child's progress in meeting therapy goals.

Rationale for Changes to Scope Since 2006 Review

The USPSTF used this report to update its 2006 recommendations on brief, formal screening for speech and language delays and disorders in children age 5 years or younger in primary care settings.

This review summarizes the evidence to date for the benefits and harms of screening and the accuracy of screening tests in children age 5 years or younger, and the benefits and harms of treating speech and language delays and disorders using accepted techniques among children who were identified by age 6 years.

The updated review generally adheres to the scope of the previous review, with rigorous attention to including only studies of children who were not previously identified with hearing impairments; developmental disorders such as Down syndrome, fragile X syndrome, or autism;

craniofacial anomalies; or neurological/neurogenetic impairments. Studies including these populations of children, some of which were included in the previous review, are not useful because they include children who have already been diagnosed with conditions that are marked by deficits in speech and language. The updated review also does not include studies of screening in children older than age 5 years if separate data are not available for preschool-age children; some of these studies were included in the previous review. Although the previous review included some studies in which screening occurred in school settings, the current review does not address questions concerning the effectiveness of screening in settings such as preschools or kindergartens and the role of primary care providers vis-à-vis these other screening programs. We have included this as a contextual question.

Chapter 2. Methods

Key Questions and Analytic Framework

The Evidence-based Practice Center (EPC) investigators, USPSTF members, and Agency for Healthcare Research and Quality (AHRQ) Medical Officers developed the scope, KQs, and analytic framework (**Figure 1**) that guided the literature search and review. The KQs are listed below.

Key Questions

1. Does screening for speech and language delays or disorders lead to improved speech and language outcomes as well as improved outcomes in domains other than speech and language?
2. Do screening evaluations in the primary care setting accurately identify children for diagnostic evaluations and interventions?
    a. What is the accuracy of these screening techniques, and does it vary by age, cultural/linguistic background, whether the screening is conducted in a child's native language, or how the screening is administered (i.e., parent report, parent interview, or direct assessment of child by professional)?
    b. What are the optimal ages and frequency for screening?
    c. Is selective screening based on risk factors more effective than unselected, general-population screening?
    d. Does the accuracy of selective screening vary based on risk factors? Is the accuracy of screening different for children with an inherent language disorder compared with children whose language delay is due to environmental factors?
3. What are the adverse effects of screening for speech and language delays or disorders?
4. Does surveillance (active monitoring) by primary care clinicians play a role in accurately identifying children for diagnostic evaluations and interventions?
5. Do interventions for speech and language delays or disorders improve speech and language outcomes?
6. Do interventions for speech and language delays or disorders improve other outcomes, such as academic achievement, behavioral competence, socioemotional development, or health outcomes, such as quality of life?
7. What are the adverse effects of interventions for speech and language delays or disorders (e.g., time, stress, and stigma)?

Contextual Questions

We included three contextual questions to help inform the report. We do not show these questions in the analytic framework because they were not analyzed using the same rigorous systematic review methodology as the studies that met the report's inclusion criteria. At the title and abstract and full-text article review stages, reviewers categorized studies not included to answer KQs that related to the specific contextual questions.

We addressed techniques of screening, risk factors for speech and language delays or disorders, and the role of primary care providers if screening is conducted in other venues via the following contextual questions:

1. What are the techniques for screening for speech and language delays or disorders, and do they differ by the child's age or cultural background?
2. What risk factors are associated with speech and language delays or disorders?
3. What is the role of primary care providers in screening children age 5 years or younger that is performed in other venues (such as Head Start or preschool)?

Search Strategies

We searched PubMed/MEDLINE®, the Cochrane Library, PsycInfo®, and CINAHL for English-language articles published from January 1, 2004 through July 20, 2014. We used Medical Subject Headings as search terms when available and keywords when appropriate, focusing on terms to describe relevant populations, screening tests, interventions, outcomes, and study designs. **Appendix A** describes the complete search strategies. We conducted targeted searches for unpublished literature by searching ClinicalTrials.gov. To supplement electronic searches, we reviewed the reference lists of pertinent review articles and studies meeting our inclusion criteria and added all previously unidentified relevant articles.

Study Selection

We selected studies on the basis of inclusion and exclusion criteria developed for each KQ based on the PICOTS approach for identifying populations, interventions, comparators, outcomes, timing, settings, and study designs (**Appendix A**). **Appendix B** lists the excluded studies. We imported all citations identified through searches and other sources into EndNote X7. Two investigators independently reviewed titles and abstracts. We dually and independently reviewed the full text of abstracts marked for potential inclusion by either reviewer. Two experienced team members then resolved disagreements.

Population

We included studies that focused on screening in children age 5 years or younger. Also, all children who scored positive on a screening had to receive diagnostic assessments for speech or language delays or disorders by age 6 years. Treatment studies had to focus on the treatment of children who were screened or diagnosed according to our age criteria. If studies included a mix of ages and only some children met our age requirements, the studies were included only if evidence was available for subgroups of children who met our inclusion criteria.

Interventions

For KQs 1 through 3, we searched for studies that examined screening instruments specific to speech and language conditions, as well as more general developmental screening tools with

speech and language modules, that clinicians could use to identify speech and language delays and disorders. All tools needed to be feasible for primary care settings (i.e., could be administered or interpreted by primary care providers). For KQ 4, we searched for studies that examined processes of monitoring speech and language rather than use of formal screening instruments. For KQs 5 through 7, we searched for studies that examined treatment interventions for children diagnosed with specific speech and language delays or disorders. We searched for interventions designed to improve speech or language in children, as long as diagnosis occurred at age 6 years or younger.

Comparators

For KQs 1 and 3, we included studies that compared screened with unscreened groups. For KQ 2, we included studies that compared screening outcomes with those of a reference standard. For subparts of KQ 2, we included studies that compared screening accuracy in different subpopulations, and for KQ 4, we included studies examining surveillance versus other approaches to referral for diagnosis. For KQs 5 through 7, we included studies that compared an intervention with no intervention, delayed treatment, or watchful waiting.

Outcomes and Timing

We searched for studies on improvements in all aspects of speech and language functioning as well as improvements in other types of functioning, such as emergent academic skills, academic achievement (e.g., reading, writing, spelling, arithmetic), behavior competence, socioemotional functioning, quality of life, and parental satisfaction. Additionally, we excluded any screening study that did not provide test accuracy because it would prevent us from calculating sensitivity and specificity of the screening instruments.

Settings

Screening studies had to be conducted within a primary care setting or screening instruments had to be interpretable in a primary care setting (KQs 1 through 4). Treatment studies were not limited by location and could be conducted in speech and language clinics, schools, or homes (KQs 5 through 7). For all KQs, we limited our search to studies conducted in the United States or in countries with a high Human Development Index.

Study Designs

For KQs 1 through 4, we included randomized, controlled trials (RCTs); cohort studies; and systematic reviews. For KQs 5 through 7, we included RCTs and systematic reviews of RCTs. We systematically searched for studies for all KQs from 2004 forward, and we hand-searched the references from included systematic reviews. Studies identified from the hand search could have been published at any time.

Studies in the 2006 Review

We applied the inclusion and exclusion criteria dually and independently to all studies included in the 2006 review.[64] We resolved disagreements by discussion and consensus; if necessary, we sought adjudication of conflicts from other experienced team members. We also conducted a check of the quality rating to ensure that studies met our current quality rating criteria. If the reviewer did not agree with this earlier assessment, we re-rated the quality of the study through dual review. Among included studies from the 2006 report, one reviewer checked for errors in previously generated abstraction tables and updated them as needed.

Newly Identified Studies

We abstracted pertinent information from each newly included study; details include methods and patient characteristics. A second investigator checked all data abstractions for completeness and accuracy. Using predefined criteria developed by the USPSTF and others, two investigators independently assessed the quality of each study as good, fair, or poor. **Appendix C** describes the quality rating criteria.[65] Disagreements were resolved by discussion and consensus. Studies with fatal flaws were rated as poor quality. For KQ 2, fatal flaws that could result in poor-quality ratings included use of an inappropriate reference standard (i.e., a reference standard not typically used by speech-language pathologists for diagnosis of speech and language disorders), improper administration of the screening test, biased ascertainment of the reference standard, very small sample size, or a very narrowly selected spectrum of patients. For KQs 5 and 6, fatal flaws that could result in poor-quality ratings included assembly of groups that were not initially comparable or maintained throughout the study, use of unreliable or invalid measurement instruments or instruments that were not applied equally across groups (including not masking outcome assessment), lack of intention-to-treat analysis, a very high rate of loss to followup, or important differential loss to followup.

Data Synthesis and Analysis

In the Results, we first summarize the newly identified studies that met inclusion criteria. We then describe the previously identified studies that continue to meet current inclusion and quality criteria. Finally, we present a qualitative synthesis of previous and current findings. The Discussion summarizes conclusions from the previous review, the 2006 USPSTF recommendation statement, and the implications of the new synthesis for previous conclusions. In addition, we assess the overall summary of the body of evidence for each KQ, using methods developed by the USPSTF, based on the number, quality, and size of studies; consistency of results among studies (similar magnitude and direction of effect); and applicability of the results to the population of interest.

Expert Review and Public Comment

A draft report was reviewed by outside content experts, USPSTF members, and AHRQ Medical Officers and was posted for public comment on the USPSTF Web site from November 18 to

December 15, 2014. In response to public comments, the EPC authors added three additional comments to the Discussion section of the report. The first is a reminder to the reader that the findings apply to children without developmental disabilities and that the review does not address speech and language screening in children with intellectual disabilities, sensory or motor impairments, or structural abnormalities of the head or neck. The second concerns factors that may be associated with the effectiveness of treatment. We note that we are unable to comment on the minimum amount of intensity required for a treatment to likely be effective, and that intensity alone cannot account for either positive or null findings among treatment trials. Third, we specifically acknowledge the need for studies of children who are non-English speakers. Lastly, while we agree that consideration of risk factors may improve screening accuracy, we found no relevant studies.

USPSTF Involvement

This review was funded by AHRQ. AHRQ staff and members of the USPSTF participated in developing the scope of the work and reviewed draft manuscripts, but the authors are solely responsible for the content.

Chapter 3. Results

This chapter provides a comprehensive presentation of the evidence from the 2006 report and our updated searches. The KQs in this update are similar to those in the 2006 report, and we added three descriptive contextual questions. The contextual questions describe techniques used for speech and language screening, risk factors associated with speech and language delays, and the role of the primary care provider in screening when the screening occurs in other venues, such as daycare. The inclusion criteria across the two reviews are generally the same. Exceptions include the type of screening studies allowed. In this review, we limited the administration time of the instrument when used by a primary care provider; included studies with a broad range of children's ages only if there were separate data for children age 5 years or younger; excluded studies of children with known conditions such as cleft palate; and required reference standards to be instruments known to be used by speech and language practitioners to diagnose speech and language delays or disorders in either research or clinical venues (**Table 1**). We limited treatment studies to RCTs, and only those with no treatment comparisons, because "usual care" implies inclusion of a treatment arm. To be comparable to the United States, we required the setting to be in countries with a very high Human Development Index.

We first report on the yields from our literature searches. The results presented below first summarize and then describe new studies identified by the updated search. Next, we summarize studies from the 2006 report that continue to meet inclusion and quality criteria. In relation to screening, we included 16 good- or fair-quality studies (in 26 publications) of the 35 studies included in the prior report, and in relation to treatment, we included seven good- or fair-quality studies of 14 earlier included studies. **Table 2** lists all studies included for analysis in this review. Reasons for study exclusion are detailed below. We follow with a synthesis of the overall (new, then old) evidence, noting results for subgroups when such data are available. **Appendix D** contains full evidence tables for each KQ.

Literature Search

Figure 2 illustrates the yield at each stage of the review process for the update search. We reviewed 1,497 titles and abstracts dually and independently, and identified 555 studies for full-text review. Evidence to answer KQs was obtained from 38 studies (in 40 articles) and two systematic reviews. Fifty-five additional studies were used solely to answer contextual questions. More specifically, of the 52 fair- or good- quality studies on screening or intervention included in the previous review, 27 studies (28 articles) met the inclusion criteria for this review. Four studies rated as good or fair quality in the earlier review were newly rated as poor quality and were not included in our analysis.[66-69] Eight new screening studies (in nine publications) and six new treatment studies met our inclusion and quality eligibility criteria following dual independent review.

Key Question 1. Does Screening for Speech and Language Delays or Disorders Lead to Improved Speech and Language Outcomes as Well as Improved Outcomes in Domains Other Than Speech and Language?

Although one new study met our inclusion criteria,[70,71] it was rated as poor quality, resulting in no evidence being available to answer this KQ. The study randomized a large sample of children in The Netherlands who attended regularly scheduled visits at child health centers. Children were randomized at age 15 months to receive screening/no screening at ages 18 and 24 months, and then followed to age 8 years. The study found no significant differences between the two arms in language performance at age 36 months. At age 8 years, children in the screening arm were less likely to be in a special school but not less likely to have repeated a grade because of language problems. A comparison of children screened versus not screened found that children who were screened were less likely to be in the lowest 10th percentile for oral language testing.

Of primary concern in this study was a large attrition rate. Of 6,485 children randomized to the screening group, 3,776 were fully screened. The study obtained outcomes for 3,118 children in this arm, only 1,980 of the children who had been fully screened. Of 4,955 children randomized to the control arm, outcome measures were obtained for 2,288 children.

Breaking the randomization, cohort analyses were conducted comparing children who were screened (a subgroup of the intervention arm) versus not screened (obtained from the intervention and control arms). This analysis did not control for other possible differences between children in the two groups that could result in poorer outcomes, such as autism spectrum disorder or hearing, developmental, and emotional problems that may have arisen following the initial screening.

Key Question 2. Do Screening Evaluations in the Primary Care Setting Accurately Identify Children for Diagnostic Evaluations and Interventions?

Key Question 2a. What Is the Accuracy of These Screening Techniques, and Does It Vary By Age, Cultural/Linguistic Background, Whether the Screening Is Conducted in a Child's Native Language, or How the Screening Is Administered?

Summary of Newly Identified Evidence on Accuracy of Screening

Fourteen new studies (15 articles) on the accuracy of screening instruments met our inclusion criteria since the prior review.[72-85] In addition, we found three older studies and a systematic review through hand searches/peer reviewer recommendation that were not included in the

previous review.[86-89] We used both the systematic review by Law et al[89] and the previous USPSTF review[90] to hand-search for relevant studies. Of the 14 newly identified studies, we rated eight as poor quality (**Appendix C**); two because the reference test was not independent of the screening instrument,[79,80] three because the reference test was inappropriate (i.e., either another screening instrument or a measure of cognitive ability),[81-83] two because an inappropriate reference standard was used and the reference was not independent of the screening instrument,[84,85] and one because no information was given on the reference standard and there was limited information on the screening instrument.[87]

Study Characteristics of Newly Identified Evidence on Accuracy of Screening

Characteristics of the eight newly identified studies rated fair- or good-quality are shown in **Table 3**. Of these, only the study by Sachse and Von Suchodoletz[76] was rated as good quality. Three studies[72-74] examined the accuracy of the ASQ, including a Spanish translation of the instrument. Five studies[73-76,78] examined different versions of the CDI, including translations in Spanish, German, and Swedish and shortened versions; two of these studies[73,74] also examined the ASQ. One of the studies[72] that reported on the ASQ also examined the accuracy of the Battelle Developmental Inventory Screening Test (BDIST) Communication Domain, the Brigance Preschool Screen (BPS), and the Early Screening Profile (ESP). One study by Rigby and Chesham[86] reported on a trial speech screening test. Another reported on the Infant-Toddler Checklist (ITC), a component of the Communication and Symbolic Behavior Scales–Developmental Profile.[88] As part of these studies, children ages 18 months,[78] 2 years,[74-76] 3 to 5 years,[73] and 4.5 years were screened.[72,86] Five of the studies were conducted in the United States; the remaining three were located in Canada, the United Kingdom, and Sweden. Recruitment techniques and venues included advertisements, birth registries, early childhood programs, medical practices, and university research programs. Venues for the studies included primary care practices, early childhood centers, health centers, hospitals, and university research laboratories.

Description of Previously Identified Studies on Screening That Continue to Meet Current Inclusion and Quality Criteria

We examined all 42 studies (in 43 articles) identified in the 2006 review. Of these 42 studies, 23 continued to meet the inclusion criteria for this update.[54,66-68,91-108] Nineteen studies were excluded at the full-text level. One study[109] was not original research but rather a letter to an editor, and another[110] examined the accuracy of a diagnostic test rather than a screening instrument. Eight studies[111-118] included children who either had a prior diagnosis or were older than our age criteria and did not include an analysis by subgroup that met our inclusion criteria. Six studies included screening instruments that did not focus on speech or language, did not have a speech and language component, or could not be administered or interpreted in the required timeframe. Three studies[119-121] did not include accuracy information about the screening instrument. We rated seven of the remaining 23 studies[66-68,96,101,107] as poor quality. Reasons for these ratings may be found in **Appendix C**.

Characteristics of the 16 good- or fair-quality studies included in our analysis are shown in **Table 3**. Three studies (in four articles)[54,98,102,122] examined the accuracy of the LDS. Two studies[95,104] examined the General Language Screen (GLS) (formerly known as the Parent Language Checklist). Two studies[92,105] examined the Fluharty Preschool Speech and Language Screening Test (FPSLST) and its earlier version, the Fluharty Preschool Screening Test. Two studies reported on the Structured Screening Test (SST)[99] and its previous version, the Hackney Early Language Screening Test (HELST).[100] No other screening instruments were examined in more than one study. Nine studies examined one or more instruments that were not assessed in any other study; many of these instruments have not been published or used widely outside of the study that reported their use or were older versions of a currently used instrument. These include the Davis Observation Checklist for Texas (DOCT),[91] the Northwestern Syntax Screening Test (NSST),[92] the Screening Kit of Language Development (SKOLD),[93] the Denver Developmental Screening Test (DDST),[94] the Denver Articulation Screening Exam (DASE),[97] the Developmental Nurse Screen (DNS) and the Parent Questionnaire,[103] the Sentence Repetition Screening Test (SRST),[106] and Ward's unnamed screening tool.[108]

The ages of the children screened in these studies varied; the majority focused on children ages 2 and 3 years. One study focused on children age 9 months,[108] and four were limited to those ages 4 and 5 years.[91,105,106] Nine of the studies were conducted in the United States, and the remaining seven in other English-speaking countries, including the United Kingdom, Canada, and Australia. Recruitment techniques and venues included advertisements, birth registries, early childhood programs, university research programs, medical practices, and school registration and entrance medical examinations.

Detailed Synthesis of Evidence on Screening

Table 4 provides a description of each screening instrument included in addressing KQ 2. We present the skills screened, the summary scores, time to complete, appropriate ages for administration, source of the screening information, and when available, reliability data. In some cases, we obtained the reliability information from test manuals. We review the evidence on the accuracy of screening by considering who does the screening and whether demographics, such as age, race, and ethnicity, and risk factors facilitate screening. **Table 5** provides accuracy statistics for parent-rated instruments, and **Table 6** provides statistics for those administered by trained examiners. We report sensitivity, specificity, prevalence, positive and negative predictive values, and positive and negative likelihood ratios (LRs), as well as 95% confidence intervals (CIs) for sensitivity and specificity. However, we caution that the positive and negative predictive values are virtually meaningless in studies where the prevalence exceeded 10 percent, because investigators chose a random sample from among children with negative screens to complete the reference measures. Therefore, we do not discuss them in the text. When accuracy statistics were not provided by the author, we calculated them ourselves using an online calculator[123] (**Appendix E**).

We calculated median test statistics across all parent-rated and trained examiner instruments separately. In some cases, a study calculated separate statistics for each reference measure; we calculated the median accuracy statistics across all measurements across all studies. We calculated the median rather than the mean because the accuracy statistics were somewhat

skewed. When more than one study examined the accuracy of an instrument, we determined the median of the accuracy statistics for that instrument and discuss it separately in the text. We report the accuracy statistics by age when there was variation by age at screening.

Parent-Rated Screening Instruments

Fourteen studies (in 16 articles)[54,72-78,88,95,98,102-104,108,122] examined the accuracy of screening instruments in which parents rated their child's speech and language skills (**Table 5**). The instruments included are the ASQ, CDI, GLS, ITC, LDS, Parent Questionnaire, and Ward's screening tool. Most children in these studies were age 2 or 3 years (toddlers). Cutoff scores for positive screening, when provided, varied as a function of the instrument but were usually the scores recommended by the developer.

Sensitivity for detecting a true speech and language delay or disorder using parent-reported instruments ranged from 50 to 94 percent, with a median of 80 percent, based on data from 19 measurements of accuracy that include 12 different reference standards in the 14 studies. Data from one study[98] were not included, as they concerned the same sample with a different cutpoint. The specificity of the screening test for detecting a child without a speech and language delay or disorder ranged from 45 to 96 percent, with a median of 81 percent. Based on the Michigan State University Evidence-based Medicine Course[124] criteria for interpreting LRs (**Appendix E**), we found a positive LR in at least one study investigating the ASQ, CDI, LDS, Parent Questionnaire, and Ward's screening tool. These results indicate that there was at least a moderate increase in the likelihood of a language delay using the results of each of these instruments. Inspection of the negative LRs suggests that in at least one study examining the CDI, ITC, and LDS, there was at least a moderate decrease in the likelihood of language delay.

Figures 3a and **3b** present CIs for sensitivity and specificity of the parent-rated instruments, by study. As **Figure 3a** demonstrates, the CIs for sensitivity of the different instruments overlap, suggesting no clear difference in sensitivity between them. In contrast, **Figure 3b** shows that the CI for the specificity of the Parent Questionnaire does not overlap with that of other instruments, suggesting that this measure is less able to detect children without language delays than the others.

Accuracy data for all screening instruments are presented in **Tables 5** and **6**. In addition, when there was more than one study that assessed an instrument, we provide results below.

Ages and Stages Questionnaire. Children in the three studies[72-74] evaluating the ASQ ranged in age from 24 to 54 months. The median sensitivity of the ASQ was 63 percent and the median across the different studies was 84 percent. In the two studies using the Spanish version of the ASQ,[73,74] the positive LR indicates moderate to large increases in the likelihood of a language delay for those children who screened positive.

MacArthur-Bates Communication Development Inventory. Five studies (six articles)[73-78] examined the accuracy of the CDI. This instrument has versions for infants, toddlers, and preschool children. In the toddler and preschool versions, parents report their child's use of words and sentences. All but one of the studies in this review[73] used the toddler version; children

ranged in age from 18 to 62 months. In addition to the original English-language version of the CDI, studies included translated versions in Spanish, German, and Swedish. The median sensitivity of the CDI across studies was 82 percent and the median specificity was 86 percent. The positive and negative LRs in the German version of the CDI[76,77] indicate a moderate increase in the likelihood of a language delay for those children who screened positive and a large decrease in the likelihood of language delay for those who scored negative. The CDI Words and Sentences[75] and the short form of the Spanish version of the CDI[74] also had moderately positive LRs; the Spanish short-form version also had a moderately negative LR.

General Language Screen/Parent Language Checklist. The Parent Language Checklist is an earlier version of the GLS and is essentially the same. Children in the two studies[95,104] evaluating this instrument were age 36 months. The median sensitivity across three measurements was 75 percent and the median specificity was 68 percent. The CI for the specificity of the Parent Language Checklist did not overlap with that of other parent-rated instruments, indicating that its specificity is lower than others.

Language Development Survey. Three studies (four articles)[54,98,102,122] reported on the LDS, in which parents indicate which of 310 words their child produces, as well as whether the child produces two-word and longer sentences. Children in these studies ranged in age from 24 to 34 months. The median sensitivity of the LDS was 91 percent, based on data from three measurements; data from Klee et al[98] were not included, as they concerned the same sample with a different cutpoint. The median specificity across three measurements was 86 percent. In one study of the LDS,[122] the positive LR was 24.1, indicating that children who screened positive were very likely to have a language delay. In addition, in each of the studies that investigated the LDS, the negative LRs were moderate to strong, indicating that children who screened negative on the LDS were highly likely not to have a language delay.

Accuracy of Parent-Rated Screening Instruments By Child Age

Ages and Stages Questionnaire. Comparison of the CIs of the ASQ in older children (age 4.5 years) in the Frisk et al study[72] with those in children ages 2 to 3 years in two other studies[73,74] suggests that there are few differences in sensitivity as a function of age. However, as the CIs indicate, specificity is higher for the Spanish ASQ in younger children: the median specificity for detecting the absence of speech and language delays or disorders in children ages 2 to 3 years was 94 percent compared with 74 percent in children age 4.5 years. Moreover, the positive LRs indicate at least a moderate increase in the likelihood of a language delay relative to children ages 2 to 3 years who screened negative, with only a small increase in the likelihood of delays for older children. The negative LRs were small and equivalent for both younger and older samples.

MacArthur-Bates Communication Development Inventory. Four of the five studies (five articles)[74-78] that examined the accuracy of the toddler version of the CDI included children ages 18 to 36 months. One study[73] used the preschool version with children ages 36 to 62 months. Comparison of the accuracy of the toddler version with the preschool version indicates that they are fairly comparable. The median sensitivity of the toddler version was 84 percent compared with 82 percent for the preschool version; the median specificity was 87 percent for the toddler

version versus 81 percent for the preschool version. However, as **Figures 3a** and **3b** show, sensitivity was lower in one study[78] of toddlers than in all the others.

Infant-Toddler Checklist. The one study of the ITC[88] included separate accuracy statistics for children in two age groups: younger toddlers (ages 12 to 17 months) and older toddlers (ages 18 to 24 months). Accuracy results were similar, as shown in **Figures 3** and **3b**. Sensitivity was 89 percent for younger toddlers and 86 percent for older toddlers. Specificity was 74 percent for younger toddlers and 77 percent for older toddlers. In both samples, negative LRs indicate a moderate decrease in the likelihood of language delay in those children who tested negative.

Accuracy of Parent-Rated Screening Instruments By Child Race/Ethnicity

No studies provided evidence for accuracy as a function of race/ethnicity.

Accuracy of Parent-Rated Screening Instruments By Prediction Length

Two studies in four articles[76,77,98,122] examined the accuracy of screening instruments for predicting future language delay or disorder. In both studies, the accuracy of the instrument administered at age 2 years was examined in relation to the reference standard at both ages 2 and 3 years, allowing a comparison of longer-term versus more immediate sensitivity and specificity. In a study (one of two articles)[122] that examined the LDS, sensitivity for detecting a language delay or disorder at age 3 years was 67 percent compared with 91 percent at age 2 years. Specificity for detecting typical language at age 3 years was 93 percent compared with 96 percent at age 2 years. In a second study that examined the German version of the CDI, sensitivity for detecting a language delay or disorder at age 3 years was 94 percent compared with 93 percent at age 2 years. Specificity for detecting typical language at age 3 years was 61 percent compared with 88 percent at age 2 years.

Trained Examiner Screening Instruments

Twelve studies[72,86,91-94,97,99,100,103,105,106] examined the accuracy of screening tests designed to be completed by trained examiners, including nurses, primary care providers, teachers, and paraprofessionals (**Table 6**). Evidence includes data on the following instruments: the BPS, BDIST Communication Domain, DOCT, DASE, DDST Language, DNS, ESP, FPSLST, NSST, SRST, SKOLD, SST, and Rigby's trial speech screening test. Several studies included more than one screening instrument. All but two of the instruments (DNS[103] and DOCT[91]) require at least some direct testing of the child; DNS and DOCT are completed after observing the child. In comparison with the studies of parent-rated instruments, these studies tended to focus on older preschool-age children, ranging from 18 to 72 months. Three studies[99,100,103] focused on children ages 2 to 3 years, one study[92] included children ages 3 to 4 years, five studies[72,86,91,105,106] included children ages 4 to 5 years, and three studies[93,94,97] included children across the age span.

Four instruments included at least a component to screen for articulation delays or disorders (FPSLST, DASE, SRST, and Rigby's trial speech screening test). Four instruments included separate components for language expression and language comprehension (SKOLD, BDIST Communication Domain, BPS, and SST). Two instruments measured grammar (NSST and

SRST), and one assessed vocabulary knowledge (ESP). Two instruments measured global speech and language skills (DOCT and DDST Language). The DNS includes a single question about the child's communication that is answered after a period of observation.

Many studies either included multiple screening instruments or examined accuracy in relation to more than one reference test; we include all of these measurements in our analysis. Based on 27 measurements (in the 11 studies using accuracy from all reference tests), sensitivity of a screening test administered by a trained examiner for detecting a true speech and language delay or disorder ranged from 17 to 100 percent (median, 74%); specificity ranged from 46 to 100 percent (median, 91%). In studies of the BDIST,[72] DOCT,[91] SKOLD,[93] SRST,[106] SST,[99] and Rigby's trial speech screening test,[86] positive LRs indicated at least a moderate increase in the likelihood of language delay for children who screened positive; studies of the BPS,[72] DOCT,[91] ESP,[72] NSST,[92] SKOLD,[93] and HELST[100] indicated at least a moderate decrease in the likelihood of language delay for those who screened negative. Accuracy results for instruments that appeared in more than one study are presented below.

Figures 4a and **4b** display the sensitivity and specificity of the trained examiner screening instruments. The CIs for sensitivity indicate great variability among the instruments. However, the CIs for the Standard English (SE) version of the SKOLD and the HELST did not overlap with those of several other instruments (BDST Receptive, BDST Expressive, BPS Receptive, DDST, FPST, SRST, SST, and Rigby's trial speech screening test), indicating that the latter are less sensitive than SKOLD and HELST for detecting language delays. The figures also show that the DDST is less sensitive than several other instruments. CIs around the specificity point estimates were somewhat tighter. Some instruments demonstrated better ability to detect typical speech or language compared with others; namely, the SE version of the SKOLD-30, DOCT, DSST, SRST (for typical articulation), SST, and Rigby's trial speech screening test demonstrated better ability to detect typical speech or language delays compared with the BDST (for typical receptive language), BPS, ESP (for typical receptive language), NSST, and HELST.

Fluharty Preschool Speech and Language Screening Test. Two studies[92,105] examined the accuracy of the FPSLST and its precursor, the Fluharty Preschool Screening Test, in children ages 3 and 4 to 5 years. The FPSLST provides separate scores for articulation and language and an overall composite. Across the five measurements (all reference tests included) in these two studies, sensitivity ranged from 17 to 74 percent, with a median of 43 percent; specificity ranged from 81 to 97 percent, with a median of 93 percent.

Structured Screening Test. Two studies evaluated the SST and its precursor, the HELST,[99,100] each in children age 30 months. Designed for health visitors to administer during routine developmental assessments, this instrument includes items measuring language expression and comprehension. In the two studies, sensitivity was 66 and 98 percent (median, 82%) and specificity was 89 and 69 percent (median, 79%) for the SST and HELST, respectively. It should be noted that the SST maximized specificity rather than sensitivity.

Accuracy of Trained Examiner Screening Instruments By Child Age and Language Dialect

Screening Kit of Language Development. One study[93] assessed the SKOLD in children ages 30

to 48 months. The SKOLD measures both language comprehension and expression, and includes separate subtests for different ages and for speakers of African American dialect and SE. Because the instrument has separate subtests by age and linguistic background, we could examine accuracy as a function of these two characteristics.

Across the two dialect versions, the median sensitivity was 94, 94, and 97 percent for children ages 30 to 36 months, 37 to 42 months, and 43 to 48 months, respectively; the median specificity was 92, 88, and 85 percent, respectively.

Across the three age levels, the median sensitivity for SE subtests was 100 percent compared with 88 percent for African American dialect, and the median specificity for SE was 93 percent compared with 86 percent for African American dialect. As noted above, the SE version of the SKOLD displays higher sensitivity for detecting language delays than several other measures.

Except for African American children screened at ages 43 to 48 months, positive LRs indicate a large increase in the likelihood of a language delay among children who scored positive in any age/dialect group. Across all ages and both dialect groups, negative LRs indicate a large decrease in the likelihood of a language delay among those children who scored negative.

No other screening instrument provided separate data by racial/age groups.

Key Question 2b. What Are the Optimal Ages and Frequency for Screening?

There is no evidence to answer this question.

Key Question 2c. Is Selective Screening Based on Risk Factors More Effective Than Unselected, General-Population Screening?

There is no evidence to answer this question.

Key Question 2d. Does the Accuracy of Selective Screening Vary Based on Risk Factors? Is the Accuracy of Screening Different for Children With an Inherent Language Disorder Compared With Children Whose Language Delay Is Due to Environmental Factors?

There is no evidence to answer this question.

Key Question 3. What Are the Adverse Effects of Screening for Speech and Language Delays or Disorders?

There is no evidence to answer this question.

Key Question 4. Does Surveillance (Active Monitoring) By Primary Care Clinicians Play a Role in Accurately Identifying Children for Diagnostic Evaluations and Interventions?

There is no evidence to answer this question.

Key Question 5. Do Interventions for Speech and Language Delays or Disorders Improve Speech and Language Outcomes?

In this review, we organize our summary of treatment evidence around three broad outcome categories: language (including expressive and receptive language and more specific aspects of language, such as vocabulary, syntax/morphology, and narratives), speech sounds (including articulation, phonology, phonological awareness, and speech intelligibility), and fluency (stuttering). Among both the newly and previously identified evidence, some studies report outcomes in more than one of these three broad categories.

Summary of Newly Identified Evidence on Treatment

We include in our analysis six trials testing treatment for speech and language delays or disorders that met the inclusion criteria and were not included in the previous review.[125-130] Also, we identified one systematic review of the literature on treatment of childhood apraxia of speech.[131]

We identified two additional studies that we rated as poor quality (**Appendix C**). One study did not state how the groups were randomized or whether the researchers used any procedures to address missing data and intention to treat, and presented no participant characteristics beyond pretest scores.[132] The other study did not state how study assignments were made and did not include baseline characteristics or independent measures of the outcome.[133]

Study Characteristics of Newly Identified Evidence on Treatment

The newly identified evidence includes one good-quality cluster RCT[128] and five fair-quality parallel RCTs[125-127,129,130] (**Table 7**). The systematic review of the literature on treatment of childhood apraxia of speech found no studies that met the inclusion criteria.

Among the six newly identified trials, four examined language outcomes,[125,128-130] including three that also examined aspects of speech sound outcomes.[125,129,130] The other two newly identified studies focused on fluency outcomes (**Table 8**).[126,127]

Summary of Previously Identified Studies on Treatment That Continue to Meet Current Inclusion and Quality Criteria

Of the 14 fair- or good-quality trials identified in the previous review (two of which we concluded were the same study), seven trials reported in eight publications met the inclusion criteria for this update[134-141] (**Table 7**). One of these was evaluated as being of good quality.[135]

We excluded five treatment studies that were included in the 2006 review because we considered them to be comparative effectiveness studies.[142-146] One additional article from the previous review was excluded because it was irretrievable.[147]

Language Outcomes

New Studies

Wake et al[128] tested the effects of a modified Hanen Parent Program called "You Make the Difference"[148] for children served by maternal and child health centers in Melbourne, Australia. Child eligibility at age 18 months was based on a score at or below the 20th percentile on a parent-completed vocabulary checklist; 301 children were randomized by the maternal and child health center in which they were served. Treatment was provided by three professionals trained in the intervention model (one speech-language pathologist and two psychologists) through six weekly 2-hour parent group sessions. For the first 1.5 hours, the group leader facilitated a review of the previous week's home practice, followed by a participatory presentation on optimizing responsive interactions and providing a rich language environment for young children. For the last 30 minutes, parents were videotaped practicing new strategies with their children, with coaching as needed from the group leader. The report does not state if any children received speech/language services in the community. Outcomes were measured at ages 2 and 3 years, and included broad measures of expressive and receptive language (the Preschool Language Scale expressive communication and auditory comprehension subscales) and the Expressive Vocabulary Test.

Fricke et al[125] recruited 180 children (mean age, 4 years) with the lowest scores on a composite measure of expressive language from nursery school programs in Yorkshire, England. For children in the treatment group, teaching assistants provided a 30-week manualized oral language program modified from a previous intervention study.[149] This program was compiled from a variety of sources and has not been widely disseminated or evaluated as a specific treatment package outside of the studies conducted by this group of researchers, thereby limiting its immediate applicability to other settings. Lessons covered vocabulary and narratives, and in the last 10 weeks of the program, also covered the emergent literacy skills of letter sounds and phonological awareness. The children participated in three 15-minute small-group sessions per week for 10 weeks in nursery school classrooms (for children ages 3 and 4 years), and three 30-

minute small-group sessions and two 15-minute individual sessions per week for 20 weeks in reception classrooms (in which children are enrolled the year they turn age 5). A large number of individual language outcome measures were gathered, and through latent variable analysis, the researchers identified four constructs (language, narrative, phoneme awareness, literacy) for which effects were examined at immediate posttest and at a maintenance followup 6 months after the end of the intervention. No information was provided regarding whether any children received speech/language treatment in the community.

Wake et al[130] recruited 200 children at age 4 years from the greater Melbourne, Australia area. Eligible children had receptive and/or expressive language scores at least 1.25 standard deviations below the mean on the Clinical Evaluation of Language Fundamentals–Preschool, second edition. Children were excluded if they had a known intellectual disability, major medical condition, autism spectrum disorder, hearing loss greater than 40 dB in the better ear, or parents with insufficient English to participate. Children were randomized to an intervention (n=99) or control (n=101) group. The intervention was planned to comprise 18 1-hour sessions, occurring in three blocks of six 1-hour sessions across 6 weeks, with a 6-week break between session blocks. The intervention was adapted from a manualized program developed for an earlier RCT by a different team of investigators.[150] Trained language assistants provided the intervention, which included phonological awareness activities and storybook reading targeting print awareness, initial phoneme isolation, and letter knowledge for all children, and also included specific language targets selected for each child individually based on the child's language profile. Examples of individualized targets include vocabulary expansion, sentence structure, and comprehension and use of morphological markers (e.g., plurals, possessives, past-tense verb endings). The intervention manual supported implementation of the intervention by the language assistants, who were trained and had ongoing guidance from a supervising speech pathologist. Parents of children in the control group were informed by mail of group allocation and the availability of local speech pathology services. However, no data were reported on local speech pathology services actually received by the control group or on community speech pathology services received by the experimental group, if any.

Yoder et al[129] recruited 52 preschool children with specific speech and language impairments (mean age, 43.8 months). Included children a had nonverbal IQ above 80 and scores at least 1.3 standard deviations below the mean on either a mean length of utterance measure or the expressive subscale of the Preschool Language Scale, third edition,[151] and a score of at least 1.3 standard deviations below the mean on the Arizona Articulation Proficiency Profile.[152] The intervention consisted of broad target recasting, a strategy characterized by an interventionist providing additional information when a child uses an immature form of speech or language. Interventionists provided speech recasts (providing an appropriately articulated repetition of an utterance the child used with immature articulation, but without adding additional grammatical structure) or sentence-length recasts (expanding a syntactically immature structure used by the child to a syntactically complete sentence). Individualized treatment was conducted three times per week for 30 minutes per session for 6 months. Intervention effects were examined at immediate posttreatment and 8 months after the treatment ended. All study participants were free to participate in community interventions. The treatment and control groups did not differ in the amount of speech and language treatment they received in the community, but the control group participated in more treatments targeting areas other than speech and language.

Studies From the Previous Review

All seven previously identified trials included in this update reported language outcomes.[134-137, 139-141]

One trial by Glogowska et al examined children younger than age 42 months (n=159) who were identified as having a delay in general language, expressive language, or phonological development at any of 16 clinics in Bristol, England.[135] Treatment consisted of immediate speech and language therapy services, usually provided by the clinic. Some children in both arms did not fulfill the protocol. In the therapy group, three of 71 children failed to attend any therapy sessions; in the control group (n=88), one family requested therapy within 1 month of randomization and 17 requested therapy at the end of 6 months. Intervention treatment services were provided for an average of 8.4 months (range, 0.9 to 12), for 8.1 contacts (range, 0 to 17) and 6.2 total hours per participant (range, 0 to 15). Outcome measures were collected at 6 and 12 months after randomization.

Robertson and Ellis Weismer[139] examined the effects of a clinician-delivered intervention on the expressive and receptive language skills of toddlers (ages 21 to 30 months) who were identified as late talkers based on parent-reported expressive vocabulary scores below the 10th percentile (n=21). Speech-language pathologists directed therapy in small groups of no more than four children for 150 minutes per week for 12 weeks. Aspects of the intervention included establishing routines, using theme-based materials, increasing the salience of linguistic input through modifications of stress vocabulary and pitch, modeling language, and providing interaction opportunities and feedback. Three key strategies used for language modeling were 1) parallel talk, or providing a verbal description of the child's actions in the absence of a child verbalization; 2) expansion/expatiation, or repeating a child's utterance with the addition of content that extends that given by the child; and 3) recast, defined here as repeating a child's utterance with modification of syntactic elements of modality or voice.

One previously included Canadian trial evaluated the effects of the Hanen Parent Program on language outcomes[137] among children ages 23 to 33 months with expressive language delays (i.e., at no higher than the one-word stage). The Hanen Parent Program comprises eight parent group sessions of 2.5 hours each and three home visits. Parents were taught to provide linguistic input to their children contingent on their child's interests. For this study, the usual Hanen Parent Program was modified to coach parents on focused stimulation of 10 target words; replacing acquired words with new, parent-identified target words; and modeling two-word utterances.

Gibbard[136] evaluated a parent training program for parents of toddlers ages 26 to 39 months with limited expressive vocabulary (30 words or less) but without evidence of global developmental delays. Parents attended sessions for 60 to 75 minutes every other week for 11 weeks. The primary objective for parents was to increase their child's language development to the point that the child was producing three- to four-word utterances. During the parent group meetings, the group leader emphasized games and activities that could be used to help the children meet these objectives and how to transfer the language skills achieved during the games to daily life activities.

A second trial conducted by Robertson and Ellis Weismer[140] randomized 20 children ages 44 to 61 months with an SLI to a peer model or control group. All children were enrolled in a language-based early childhood classroom throughout the study. Children in the peer model group played house in their classroom with language-typical peers at least four times for 15 minutes per play session over a 3-week period. Children in the control group were monitored to ensure that they played in the house area at least 60 minutes during the same 3-week interval, but without language-typical peer models. Language measures were all tied to the play house scripts and included gain scores in 1) the number of words included in a script describing how to play house, 2) the number of different words in the script, 3) the number of play-theme–related acts described in the script, and 4) the number of linguistic markers used in the script. Group comparisons were made on these content and structural indexes at immediate posttest and at 3-week followup. No comparisons were made on language measures apart from those in the play house scripts, which were tied to the specific context in which the experimental group interacted with language-typical peer models.

Finally, two studies that focused on treating children with speech sound disorders also included language outcome measures.[134,141] These studies are described in more detail in the section on speech sound outcomes. Almost and Rosenbaum[134] included mean length of utterance as an outcome measure of expressive language. Shelton et al[141] included the NSST[153] and the Auditory Association Subtest of the Illinois Test of Psycholinguistic Abilities as language outcome measures.

Speech Sound Outcomes

New Studies

Three of the new studies described in the section on language outcomes included speech sound outcome measures as well.[125,129,130] In their study of broad target recast treatment, Yoder et al[129] evaluated speech intelligibility, measured as acceptable ("intelligible") word approximations in a 20-minute speech sample. Two other new studies examined outcomes related to phonological awareness.[125,130] Phonological awareness is the ability to recognize the variety of sound units that make up spoken words. Slow development of phonological awareness often occurs in children with other speech and language delays or disorders, and is associated with difficulty in the development of early literacy skills.[154,155]

Studies From the Previous Review

Three of the trials described in detail in the section on language outcomes also reported speech sound outcomes. Glogowska et al[135] included a phonology error rate[156] to measure the effects of usual speech and language therapy services on speech sounds. Girolametto et al[138] evaluated the effects of the Hanen Parent Program, adapted to include focused stimulation of language targets on three measures related to speech sounds: syllable structure level, consonant inventory, and percentage of consonants correct. Robertson and Ellis Weismer[139] included a measure of percentage of intelligible utterances in their study of small-group language therapy for late-talking toddlers.

Two additional trials focused primarily on speech sound outcomes,[134,141] although both included measures of language outcomes as well. Almost and Rosenbaum[134] evaluated the efficacy of a modified "cycles" approach to phonological therapy,[157] wherein rule-based errors in the child's speech sound production are treated through recursive cycles of therapy targeting particular rules (also known as phonological processes). In a trial of 26 children with severe phonological disorders, outcomes were measured for those randomized to the intervention group following 4 months of treatment. Speech sound outcome measures included the Assessment of Phonological Processing–Revised,[158] the Goldman-Fristoe Test of Articulation,[159] and percentage of consonants correct.

Shelton et al[141] identified 45 preschoolers (mean age, 47 months) through articulation screening, matched trios of children on a measure of receptive vocabulary, and then randomly assigned each member of the trio to one of three groups: a listening intervention that focused on speech sound discrimination activities, a reading and talking intervention that focused on storybook interactions, or control. Parents conducted activities with their children in the two active treatment groups for 57 days, for 5 minutes per day in the listening group and 15 minutes per day in the reading and talking group. Speech sound outcomes included measures of speech sound discrimination in quiet and in noise, speech sound error recognition, and articulation.

Fluency Outcomes

New Studies

Two newly identified studies focused only on fluency outcomes.[126,127] Both of these studies examined the Lidcombe Program of Early Stuttering Intervention.[160] The manual for the Lidcombe program can be downloaded from the Web site of the Australian Stuttering Research Centre (www.fhs.usyd.edu.au/asrc). In this program, parents are trained to provide differential verbal contingencies for stutter-free speech and for unambiguously stuttered speech for prescribed periods each day. In the original version of the program, the parent and child attend sessions with a speech-language pathologist for up to 1 hour per week during stage 1 of the treatment, in which the parent learns and practices the contingencies and learns to rate the severity of the child's stuttering. The speech-language pathologist also evaluates the child's stuttering during each weekly visit, using a measure of percentage of syllables stuttered. When the child is stuttering on less than 1 percent of all syllables uttered, the treatment progresses to stage 2. During stage 2, the parent gradually withdraws the contingencies, and clinic visits decrease in frequency over a period of at least 1 year. If the child's percentage of syllables stuttered is greater than 1 percent for two consecutive visits, then the treatment returns to stage 1 until stuttering again decreases to the criterion level.

Jones et al[126] evaluated the Lidcombe program in New Zealand based on a trial that recruited 54 children ages 36 to 72 months. The control group parents were told they would receive the Lidcombe intervention at the end of the trial should it prove to be efficacious and their children were still stuttering; they were also free to seek other treatment for their children during the trial, provided it was not the Lidcombe program. In violation of the protocol, four of the 25 children in the control group received some Lidcombe treatment; three others received alternative treatments for stuttering. Outcomes were measured at 9 months after randomization.

The second study of the Lidcombe program was conducted in Australia and involved telehealth delivery of the treatment.[127] The 22 included children were ages 36 to 54 months, with a history of stuttering for longer than 6 months and no previous or current treatment for stuttering. Adaptations for telehealth delivery of the intervention included regularly scheduled telephone consultations in place of weekly clinic visits, videotaped demonstrations of the use of contingent feedback, parent training in rating stuttering severity via audiotaped speech samples and telephone conversations, audio-recorded parent-child interactions mailed to the speech-language pathologist for evaluation of parent implementation, and audio-recorded speech samples of the child mailed to the speech-language pathologist for computation of the percentage of syllables stuttered. Although parents of children in the control group were offered the Lidcombe program after the posttest, unlike in the Jones study, it was not reported whether any families sought other treatment during the trial.

Studies From the Previous Review

No previously included trials measured fluency outcomes.

Detailed Synthesis of Prior Evidence With New Findings on Treatment

In synthesizing the evidence across studies, we first organized the trials based on the type(s) of outcomes reported—language, speech sounds, or fluency. Within each group of studies reporting the same type of outcomes, we considered treatment heterogeneity, including the agent (teacher/clinician, parent, peer), strategies, and dosage/intensity. We also considered the characteristics of the children, including age range, and their speech and language abilities and disabilities.

In our synthesis, to aid in readability, we refer descriptively to the types of outcomes but in general do not name each specific outcome. Details for results of specific outcome measures are given in **Table 8**. In addition, we characterize outcomes as statistically significant or nonsignificant, and we use Cohen's[161] conventions for referring to effect sizes as small, medium, or large based on the variance explained by treatment group assignment. For Cohen's d, a statistic representing the distance in standard deviation units between two means, the conventions we use are: small (0.2 to <0.5), medium (0.5 to <0.8), and large (≥0.8). For odds ratios giving the differential likelihood of a dichotomous outcome, the conventions we use are: small (1.44 to <2.47), medium (2.47 to <4.25), and large (≥4.25). Although we use Cohen's conventions for characterizing effect sizes as small, medium, or large, we acknowledge and agree with the caution that these conventions may not be equated with the clinical significance of the differences.[162] When standardized effect sizes were provided in the publications, we used the reported effect size. For trials not reporting standardized effect sizes, we computed effect sizes when the published data permitted these computations.

Table 7 provides information on specific ages of children in the included trials. In the text, we use "toddlers" to refer to children younger than age 3 years and "preschoolers" to refer to children ages 3 to 6 years.

Studies Reporting Language Outcomes

Eleven trials reported on language outcomes (**Table 8**). Among these, four used parents as the primary intervention agent.[128,136,137,141] Two trials tested the effects of variations of the Hanen Parent Program[128,137] on outcomes of toddlers with language delays, with divergent findings. The trial by Girolametto et al[137] (n=25) found moderate to large effects favoring the treatment group on five of six expressive language outcome measures, in contrast with no significant differences and negligible effect sizes on three expressive language measures and one receptive language measure in the trial by Wake et al[128] (n=301). Compared with the trial by Girolametto et al, the trial by Wake et al[128] provided a lower dosage of parent training (720 vs. >1,200 minutes), enrolled younger children (age 18 vs. 23 to 33 months) who were selected based on less stringent criteria for language delay (lowest 20th vs. lowest 5th percentile for expressive vocabulary), and did not include any home visits for coaching purposes but included some individual parent coaching at the end of the parent group meetings. In the study by Girolametto et al, the parent group facilitators made three home visits. The differences in eligibility criteria for the two studies may be relevant to the divergent findings. Whereas Wake et al considered the possibility that the tested treatment was not sufficiently intensive to produce an effect, they concluded that the null findings in their study were more likely the result of natural resolution of the initial symptoms of delayed language, based on finding that the mean language scores were in the normal range (and very close to the standardized mean scores) for children in both groups at age 3 years. Children in the study by Girolametto et al, who were selected based on expressive vocabulary in the lowest 5th percentile, may have been less likely to experience a natural resolution of their language delay than those in the trial by Wake et al.

In a small trial involving parent training (n=36), Gibbard[136] tested group training for parents of toddlers (ages 27 to 39 months) with limited expressive language. The total intensity of the intervention was relatively low, similar to that in the study by Wake et al[128] (780 to 975 minutes), although the parent group meetings in the Gibbard trial were scheduled over a 6-month period compared with a 6-week period in the study by Wake et al.[128] The content of the training was focused on activities parents could do with their children to promote specific language objectives, an approach that seemed more similar to the adaptation of the Hanen Parent Program by Girolametto et al[137] than to the trial by Wake et al,[128] which focused on more general language stimulation strategies. However, we could not fully assess the comparability of the content of the Gibbard intervention with that of either adaptation of the Hanen Parent Program from information available in the publication or online. Similar to Girolametto et al and in contrast to Wake et al, Gibbard reported large effects across seven language outcome measures, including six measures of expressive language and one of receptive language.

Shelton et al[141] also had parents provide interventions for their children (ages 27 to 55 months) in a small trial (n=45 in three groups). They were primarily interested in the treatment of children with speech sound disorders; however, in addition to a listening treatment group exposed to speech discrimination activities designed to target speech sound outcomes, they included a second reading and talking treatment group, in which parents read and talked about storybooks with their children, a treatment that might be expected to positively affect children's language outcomes. No significant effects were found for either treatment group compared with the control group on expressive syntax (small effect sizes favoring the control vs. listening group,

and favoring the reading and talking vs. control group). Also, no significant effects were found on an auditory association measure tapping children's semantic knowledge (medium effect sizes in favor of the listening vs. control group, as well as for the reading and talking vs. control group).

Two trials tested treatments primarily or exclusively delivered in a small-group format to toddlers[140] and preschoolers[125] with speech and language delays or disorders. In addition to small-group intervention, the trial by Fricke et al included two 15-minute individual treatment sessions per week during the last 20 weeks of the 30-week program. The intensity of both interventions was relatively high—2,850 total minutes in the trial by Fricke et al[125] and 1,800 minutes in the trial by Robertson and Ellis Weismer.[139] In both studies, the researchers specified the components of the intervention and trained the interventionists (teaching assistants in Fricke et al and speech-language pathologists in Robertson and Ellis Weismer) to implement the program. Both trials reported significant and large effects on measures of language skills. Fricke et al also reported a significant but small effect for a construct measuring narrative language.

Four trials reporting language outcomes tested treatments provided to children on an individual basis by research staff or speech-language pathologists[129,135] but are not otherwise very comparable with one another. Glogowska et al[135] examined the effects of providing young children (ages 18 to 42 months) with clinically significant delays in language or phonological development immediate access to usual speech-language therapy services in the community. Over the 12 months of the trial, children received an average of 372 minutes of treatment and showed significant but small gains relative to the control group in receptive language, with a small effect size (d=0.3), but did not differ at the end of treatment on expressive language measures, for which effect sizes were negligible. Wake et al[130] tested a manualized intervention for 4-year-olds with specific language impairments that included a focus on phonological awareness, print awareness, and letter knowledge for all children but also addressed individualized language goals based on each child's profile of language impairments. Children received an average of 1,020 minutes of treatment over a 30-week period (approximately 7 months). The intervention had no significant effect on the primary outcomes of expressive or receptive language or on the secondary outcome of pragmatic language, with small to negligible effect sizes for all three variables. Yoder et al[129] tested the effects of an intervention strategy called recasting (repeating what is said by a child, but with correct articulation or with a grammatical expansion of the child's utterance). The total amount of treatment was 2,340 minutes provided over 6 months. The intervention had no significant effect on the outcome measure of language (mean length of utterance); the publication did not report data sufficient to allow for the computation of an effect size. Yoder et al reported an interaction between the treatment group and the pretreatment articulation skills of the child, with a significant treatment effect on mean length of utterance at posttest and at followup for children with the lowest baseline articulation skills. Almost and Rosenbaum[134] tested whether an individualized treatment for children with speech sound disorders had an effect on the language outcome measure of mean length of utterance but found no significant language effect (small effect size). More information about this study is provided in the following section.

Finally, the trial in which preschoolers with language impairments play with peers with age-appropriate language skills in the house play area of the preschool classroom at least four times

over a 3-week period found large and significant effects on four measures of expressive language taken from samples in which the children were asked to specifically talk about playing house.[140]

Studies Reporting Speech Sound Outcomes

We included eight trials that reported outcomes related to speech sounds (measures of articulation, phonology, phonological/phonemic awareness, or intelligibility)[125,129,130,134,135,138,139,141] (**Table 8**). All of these trials also reported language outcomes.

In two trials, the treatment was parent mediated. Girolometto et al[138] examined speech sound outcomes in addition to language outcomes for toddlers whose parents participated in the modified Hanen Parent Program. They reported significant effects on consonant inventory and syllable structure for the treatment group compared with the control group, and the effect sizes were large in both cases. Although parent mediated, the approach examined by Shelton et al[141] was quite different in content. The primary research question in their study was whether children (ages 27 to 55 months) would benefit from a listening treatment in which parents focused the child's attention on consonant sounds in syllables and words, and engaged the child in activities directed at discrimination of sounds, including correctly and incorrectly articulated sounds. The total intensity of the treatment was 1,425 minutes, delivered 5 minutes per day 5 days per week for a total of 57 sessions. One significant difference emerged in comparing the listening treatment with a control condition: children in the control condition made more improvements in auditory discrimination in noise. Although effects on articulation were nonsignificant, there was a medium-sized effect in favor of the listening group on one articulation measure (Templin-Darley Articulation Screening Test), but only a small effect on a second articulation measure (McDonald Screening Deep Test of Articulation). Shelton et al also reported results on articulation measures for the reading and listening treatment, described in the section on language outcomes; this group did not differ significantly from the control group on articulation outcomes, with small effects for both measures. Further, the effect favored the control group for one measure (McDonald Screening Deep Test of Articulation).

Robertson and Ellis Weismer[139] evaluated a speech sound outcome (percentage of intelligible utterances) for toddlers who participated in a small-group speech and language program provided by speech-language pathologists. They found a significant effect of large magnitude in favor of the treated children compared with the control group.

Two studies examined effects on speech sounds for children treated individually by speech-language pathologists. Almost and Rosenbaum[134] examined the effects of a now well-known "cycles" approach to phonological therapy for preschoolers with severe phonological disorders. The treatment was provided by speech-language pathologists in 30-minute sessions twice a week across 4 months (total of 1,040 minutes of treatment). There were significant effects, with large effect sizes, on three speech sound outcome measures, including two standardized tests, as well as the percentage of consonants correct during a speech sample. Glogowska et al[135] found no improvement in phonology error rate for young children randomized to usual community speech-language pathology services for a year; however, after 12 months, treated children were 2.7 times more likely than control children to no longer exhibit the criterion severity of speech sound problems used to initially determine eligibility for the trial, a significant effect of medium size.

As mentioned previously, the total average amount of treatment time in that trial was less than 7 hours.

The individual treatment trial of preschoolers by Yoder et al[129] included the strategy of speech recast, which involved repeating a child's incorrect speech production with correct articulation. There were no main effects of treatment on child intelligibility; however, there was an interaction between treatment and the pretreatment articulation skills of the child, with a significant treatment effect on intelligibility at followup for children with the lowest baseline articulation skills.

Two studies that focused primarily on language outcomes examined the effects of speech and language interventions on phonological/phonemic awareness skills as secondary outcomes for preschoolers.[125,130] The study by Fricke et al,[125] in which preschoolers participated in small-group and individual speech and language lessons delivered by teaching assistants, found significant effects, with a small to medium effect size both in the immediate posttest and at 6-month followup for a construct representing measures of phonemic awareness. Phonological awareness was also measured in the study by Wake et al,[130] in which language assistants provided individual home-based intervention focusing on language and emergent literacy skills to preschoolers with language impairments, with findings of a significant effect of moderate size on this outcome.

Studies Reporting Fluency Outcomes

Two trials focused only on fluency outcomes[126,127] (**Table 8**), examining the Lidcombe Program of Early Stuttering Intervention.[160]

Jones et al,[126] who delivered the treatment to parents and their children ages 3 to 6 years in a clinic setting, found that the Lidcombe group showed a greater decrease in the percentage of syllables stuttered than the control group after 9 months; children in the Lidcombe group were almost 8 times more likely to have reached the criterion of stuttering on less than 1 percent of syllables. The odds ratio for this finding is large, with children in the Lidcombe program 7.7 times more likely than those in the control group to stutter on less than 1 percent of syllables after 9 months.

The trial by Lewis et al,[127] using telehealth delivery of the Lidcombe program to parents and their preschool children, found that the treatment group showed a significantly greater reduction in the percentage of syllables stuttered, 69 percent less than in the control group (95% CI, 13 to 89).

Key Question 6. Do Interventions for Speech and Language Delays or Disorders Improve Other Outcomes, Such as Academic Achievement, Behavioral Competence, Socioemotional Development, or Health Outcomes, Such as Quality of Life?

Summary of Newly Identified Evidence on Other Outcomes

We identified three trials that met the inclusion criteria, contribute evidence relevant to this KQ, and were not included in the previous review.[125,128,130] All three trials examined speech or language measures as primary outcomes, and thus they were included in the synthesis of evidence related to KQ 5 (**Table 7**).

Study Characteristics of Newly Identified Evidence on Other Outcomes

Two newly identified trials, both rated fair-quality, measured outcomes related to literacy.[125,130] One of these trials also included a secondary measure of health-related quality of life.[130] That trial and one other[128] included outcomes related to child problem behaviors.

Description of Previously Identified Studies on Other Outcomes That Continue to Meet Current Inclusion and Quality Criteria

Two previously identified studies met inclusion criteria for the current review[135,139] and provide evidence relevant to this KQ. Both also measured speech or language outcomes and thus were included in the results for KQ 5. Glogowska et al[135] measured well-being, attention level, play level, and adaptive socialization skills as secondary outcomes. Robertson and Ellis Weismer[139] measured adaptive socialization skills and parental stress as outcomes.

Detailed Synthesis of Prior Evidence With New Findings on Other Outcomes

Two trials examined the effects of language treatments on socialization, either among children receiving community-based speech-language pathology services[135] or among language-delayed toddlers receiving small-group therapy.[139] The former trial produced no significant differences between children in the treatment and control groups in socialization outcomes, while the latter produced significant differences in favor of children in the treatment group, with large effect sizes.

Of the two trials reporting outcomes related to child behavior problems, one was a low-intensity parent group program for parents of slow-to-talk toddlers,[128] and the other provided up to 18 1-hour in-home speech and language treatment sessions for preschoolers with a SLI, with the

sessions conducted by a language assistant.[130] Neither found treatment to have a significant effect on children's problem behaviors, with very small effect sizes. Similarly, two trials reporting secondary outcome measures of well-being (in toddlers)[135] and health-related quality of life (in preschoolers)[130] reported nonsignificant effects of treatment and very small effect sizes in both cases.

Contrasting with these null findings, two trials measured outcomes related to emergent literacy skills for speech and language treatments conducted in preschoolers[125,130] and found significant improvement in letter knowledge in both cases, with small effect sizes. Although one of these studies failed to find a significant treatment effect for a broader construct of literacy,[125] the researchers found a significant treatment effect of moderate size on a measure of reading comprehension first administered at a 6-month followup. Further, these differences were mediated by differences in oral language associated with being in the treatment group.

Several other outcomes were examined only in single trials. Glogowska et al[135] found no significant advantages in favor of toddlers randomized to receive speech-language pathology services versus those in the control condition on measures of well-being, attention level, or play. Robertson and Ellis Weismer[139] found that parents of language-delayed toddlers randomized to participate in small-group language therapy reported significantly greater improvements in parental stress than parents of toddlers in the control condition; the effect size for this finding was large.

Key Question 7. What Are the Adverse Effects of Interventions for Speech and Language Delays or Disorders?

Three studies examined potential adverse effects of interventions.[135,139] The small-group intervention study conducted by Robertson and Ellis Weismer found greater improvement in parent stress, as measured by the Parental Stress Index, in the intervention group. Glogowska et al[135] found no differences in well-being between a group receiving individual treatment and the control, and Wake et al[130] found no differences in health-related quality of life.

Chapter 4. Discussion

In this chapter, we summarize the findings of the 2006 report[64] about screening preschool children for speech and language delays. We note the 2006 USPSTF recommendations and comment on the implications of this new synthesis for previous conclusions. Then we discuss the context for these updated results, applicability, limitations of the review and the literature, research gaps, and conclusions.

Overall, the USPSTF issued an I recommendation following the 2006 review, concluding that "the evidence is insufficient to recommend for or against routine use of brief, formal screening instruments in primary care to detect speech and language delay in children up to 5 years of age."

Speech and language delays affect 5 to 8 percent of preschool children, often persists into the school years, and may be associated with lowered school performance and psychosocial problems. The USPSTF found insufficient evidence that brief, formal screening instruments that are suitable for use in primary care for assessing speech and language development can accurately identify children who would benefit from further evaluation and intervention. Fair evidence suggested that interventions can improve the results of short-term assessments of speech and language skills; however, no studies assessed long-term outcomes. Furthermore, no studies assessed any additional benefits that may be gained by treating children identified through brief, formal screening who would not be identified by addressing clinical or parental concerns. No studies addressed the potential harms of screening or interventions for speech and language delays, such as labeling, parental anxiety, or unnecessary evaluation and intervention. Thus, the USPSTF could not determine the balance of benefits and harms of using brief, formal screening instruments to screen for speech and language delay in the primary care setting.

Summary of Review Findings

Key Question 1

The 2006 report found no studies that met the inclusion criteria to answer the question: "Does screening for speech and language delays result in improved speech and language, as well as improved other nonspeech and language outcomes?" The update changed the wording of the question to specify disorders as well as delays: "Does screening for speech and language delays or disorders lead to improved speech and language outcomes, as well as improved outcomes in domains other than speech and language?" Although one new RCT met our inclusion criteria[70,71] by randomizing a large national sample of children who received regularly scheduled care at child health centers to early screening and measuring outcomes in both groups at age 8 years, the study was not included in our analysis because it was rated as poor quality due to various flaws. The most serious flaw is the large attrition, with less than 60 percent of the intervention group being fully screened and only about half of the fully screened group contributing outcomes. The study obtained outcomes on an even smaller percentage of children in the control group. Other flaws included not using a standard instrument for measuring speech and language at the endpoint but rather using a more indirect measure based on self-report, and then not conducting

an analysis that considered other possible diagnoses that may have occurred unevenly in the two groups over the long followup period and influenced the findings, including autism spectrum disorder and other developmental or emotional delays or disorders. Nevertheless, we acknowledge the difficulty in conducting and maintaining a study of this kind (**Table 9**).

Key Question 2

Prior Review Findings on Screening

The 2006 review examined several aspects of the question of whether screening evaluations in the primary care setting accurately identify children for diagnostic evaluations and interventions.

The first was whether identification of risk factors improves screening. The 2006 review found 16 studies that met its inclusion criteria and concluded that a small number of characteristics, such as male sex, family history, and parental education, were linked to language delay. We discuss these and other risk factors as part of Contextual Question 2. However, we found no studies that used these risk factors to improve accuracy, nor did we find any studies that examined the role of child race and ethnicity on the accuracy of speech-language screening results.

The second and third subquestions addressed screening techniques, how screening differed by age, screening accuracy, and how accuracy differed by age. The 2006 review evaluated the performance characteristics of instruments to screen for speech and language delay. It included studies of instruments that took 30 minutes or less to administer. The included studies were generally focused on children age 5 years or younger who did not have a previously diagnosed condition such as autism, mental retardation, or orofacial malformations.

The 2006 review included a total of 43 studies that described 32 instruments taking no more than 30 minutes to administer. (Note: The 2006 review counted a study[90] with two substudies as two separate studies; we count it as one study.) In the good- or fair-quality studies of instruments, sensitivity for detecting a speech or language delay ranged from 17 to 100 percent, and specificity for detecting typical language ranged from 45 to 100 percent. The previous review further identified the Early Language Milestone Scale, Clinical Linguistic and Auditory Milestone Scale, LDS, SKOLD, and Levett-Muir Language Screening Test as the five instruments with the highest sensitivity and specificity. However, the reviewers concluded that the best methods and ages for screening could not be determined from the studies included in the review because of a number of factors (e.g., instruments were not designed for screening or lacked comparisons across populations, venues were outside the primary care setting, speech and language delays have no gold standard reference). The fourth subquestion examined the optimal ages and frequency for screening. No studies addressed this question.

The USPSTF found insufficient evidence that brief, formal screening instruments that are suitable for use in primary care for assessing speech and language skills can accurately identify children who would benefit from further evaluation and intervention.

Implications of the New Synthesis on Prior Conclusions on Screening

Of the 42 studies (43 articles) identified in the 2006 review, 16 studies (17 articles) continued to meet the inclusion criteria for this update and were determined to be of good or fair quality.[54,91-95,97-100,102-106,108,122] In the current review, we included only studies that provided accuracy statistics or data that allowed us to calculate accuracy. We were stricter in determining whether a study met the population inclusion criteria. We excluded studies if some children in the population were outside the age range or had a previously diagnosed condition and the study did not stratify for age and condition. We used the most recent USPSTF criteria for determining quality of studies. To these previously included 16 studies, we added an additional eight newly found studies (nine articles). In doing so, we were able to address one identified limitation of the previous review—namely, the lack of studies comparing the same instrument in different populations. We also examined the studies in our review by considering parent-rated screening instruments separately from those that are administered by trained examiners, including those in primary care. The current review also included one study that examined screening for preverbal language[88] (**Table 10**).

Altogether, 14 studies (in 16 articles)[54,72-78,88,95,98,102-104,108,122] examined the accuracy of screening instruments in which parents rated their young children's speech and language skills. Sensitivity ranged from 50 to 94 percent, and specificity ranged from 45 to 96 percent.

Nine of the parent-rated screening studies (11 articles) examined three instruments widely used in the United States—the ASQ Communication Domain, CDI, and LDS. Several of these instruments exhibited LRs suggesting that there is a moderate to large increase in the likelihood of language delays in children who screen positive or a moderate to large decrease in the likelihood of language delays in children who screen negative. Although the LRs tended not to be consistent across all studies that included a particular instrument, both the positive and negative LRs were moderate to large in two studies examining the CDI.[74,76,77] Another parent-reported instrument, the ITC, is also used in the United States but in a somewhat younger population (i.e., ages 6 to 24 months).

Because the ASQ and CDI have versions for infants, toddlers, and preschool-age children, we were able to examine the accuracy of the instruments at different ages. Studies examining the ASQ in children ages 2 years,[74] 3.5 years,[73] and 4.5 years[72] reported comparably low sensitivity at all three ages (ranging from 50% to 59%), and better specificity for the 2- and 3.5-year-old samples (95% and 92%) than for the older sample (79% and 83%). These results suggest that use of the ASQ for screening for language delays, especially in preschool-age children, may result in many false-negatives. Comparisons indicated that sensitivity and specificity of the toddler and preschool CDI versions were fairly close, suggesting that the CDI is robust in its ability to detect a language delay across the toddler and preschool years. The study examining the ITC subdivided the sample into two age groups—younger and older toddlers. Sensitivity, specificity, and LRs were nearly identical in the two age groups.

However, studies indicate that the screening accuracy of parent-reported instruments diminishes somewhat over time. Two studies (in four articles)[76,77,98,122] examined the accuracy of screening instruments completed by parents of children age 2 years in relation to language assessments

administered to the children at both age 2 and 3 years. In one study[122] that evaluated the LDS, sensitivity was reduced after a year, but specificity remained the same. In the second study,[76,77] which evaluated the German version of the CDI, sensitivity was about the same at ages 2 and 3 years, but specificity was reduced at 3 years. Forty-four percent of the children who had been classified as having a language delay at age 2 years had typical language at age 3 years. The reduction in specificity over time illustrates the finding that some children with language delays will "catch up" and display more typical language skills with development.[3]

We reviewed 12 studies[72,86,91-94,97,99,100,103,105,106] that examined the accuracy of screening tests administered by trained examiners, all but two of which require direct testing of the child. The variability in accuracy across these instruments was greater than the variability across the parent-rated instruments; sensitivity ranged from 17 to 100 percent and specificity ranged from 48 to 100 percent. Several of the trained examiner instruments also had moderate or large LRs, indicating an increase in the likelihood of a language delay for children who screened positive or a decrease in the likelihood of a language delay for those who screened negative. Many of the screening instruments performed as well as the parent-rated instruments, but aside from the DDST (now known as the Denver II), most are not used in primary care offices and would require a dedicated, trained professional or paraprofessional to directly test the child. The study of the original version of the DDST found excellent specificity (100%) but poor sensitivity (46%); no studies provided information on the accuracy of the language component of the current version.

Because few studies of screening instruments administered by trained examiners examined the same instrument with different populations or with different ages, it is unclear how instruments for multiple ages fare more broadly or whether there is an optimal age for screening. We were able to examine cross-age accuracy with only two instruments that are published and used in the United States. Two studies[92,105] examined the FPSLST in children age 3 years and in children ages 4 to 5 years. Specificity was greater in the study[105] in older children (ranging from 85% to 95% in two samples with two reference measures each) than the study of younger children[92] (81%), but sensitivity was generally low in both studies (17% to 74% in the older cohort and 60% in the younger group).

A second study,[93] which reported on an instrument (the SKOLD) designed for children ages 2 to 5 years, provided separate accuracy statistics for each of three age groups (ages 2.5 to 3, 3 to 3.5, and 3.5 to 4 years) and for speakers of African American dialect and SE, and generally found excellent sensitivity and specificity for each age and linguistic group. Although the accuracy of this instrument suggests that it is a good candidate for screening children ages 2.5 to 4 years, particularly speakers of African American dialect, its widespread utility may be limited by the necessary training. The developers of the instrument[93] caution, "For successful administration and scoring, screeners need an understanding of normal and impaired language development, black English, and familiarity with administration and scoring procedures of SKOLD. Ideally, paraprofessionals should be trained by speech-language pathologists in the above areas."

The 2006 review concluded that, despite the availability of brief screening instruments, screening for speech and language delays has serious limitations. For example, optimal screening methods had not been established, an accepted gold reference standard was lacking, data comparing an

instrument across different populations and different ages were limited, and sensitivity and specificity varied. With the addition of eight newly identified studies and the exclusion of 14 of the 35 studies from the 2006 review, the evidence in this review differs somewhat. We identified several studies that speak to the accuracy of the CDI and LDS in multiple populations and multiple ages. Although there is no gold standard for speech and language assessment, the reference standards used in these studies are well-regarded instruments that speech-language pathologists routinely use. The sensitivity and specificity of these instruments are acceptable,[163] and because parents complete them, adopting them in a screening program should not burden a primary care practice with training someone in test administration. The findings related to the CDI and LDS point to the importance of involving parents in identifying young children with speech and language delays and disorders. In addition, each of these instrument focuses on language, and the more extensive information that parents provide specifically related to their children's language skills may help explain the fact that the CDI and LDS are more accurate in identifying children with speech and language delays or disorders than broad-based instruments that include fewer items to screen for speech and language problems. In summary, this synthesis yields evidence that two parent-rated instruments, the CDI and LDS, would likely be interpreted with little difficulty in the primary care setting and can accurately identify children for diagnostic evaluations and interventions. Our findings do not address the importance of speech and language assessments for children with intellectual disabilities, sensory or motor impairments, or structural abnormalities of the head or neck.

Key Question 3

The 2006 review found that no studies addressed the question of adverse effects of screening. The authors suggested potential adverse effects, such as false-positive and false-negative results, which would have deleterious consequences, such as erroneously labeling a child with typical speech and language as having a delay or disorder, or missing a child with a true speech and language impairment who then fails to benefit from timely intervention services. We also found no evidence to address this question.

Key Question 4

The 2006 study found no studies examining the role of enhanced surveillance by a primary care clinician once a child is identified as possibly having a speech and language delay. We asked a related question: "Does surveillance (active monitoring) by primary care clinicians play a role in accurately identifying children for diagnostic evaluations and interventions?" We found no evidence to answer this question.

Key Question 5

Prior Review Findings on Speech and Language Outcomes of Treatment

In the 2006 review, studies evaluated the effects of individual or group interventions directed by clinicians or parents that focused on specific speech and language domains. These domains included expressive and receptive language, articulation, phonology, and syntax. Interventions

were short term, commonly lasting from 3 to 6 months, and took place in speech and language specialty clinics, community clinics, homes, and schools. Outcomes were measured by subjective reports from parents and by scores on standardized instruments.

Eight fair- or good-quality studies focusing on the treatment of children age 3 years or younger found mixed results, with five studies reporting improvement on a variety of speech and language domains, including clinician-directed treatment to improve expressive and receptive language delay, parent-directed therapy to improve expressive delay, and clinician-directed therapy to improve receptive auditory comprehension. Results were also mixed for seven fair-quality studies focusing on children ages 3 to 5 years; five found significant improvement and two reported no differences.

Implications of the New Synthesis on Prior Conclusions on Speech and Language Outcomes of Treatment

The previous review reported significant effects of treatment on speech and language outcomes across the age range of 2 to 5 years, although significant findings were not universal across included trials. We did not include six of the previously included studies in our review because we considered them to be comparative, examining the relative merit of a new intervention compared with treatment as usual. One newly identified trial was unique in examining the treatment of children who were all younger than age 2 years;[128] no significant effects on language outcomes were detected, but it is not possible to evaluate whether this finding was related to the young age of the children or other factors.

The evidence of maintained benefits of a school-based language treatment program for preschoolers with low language scores[125] is an important addition to this update. The current review also adds evidence from two small trials for the potential effectiveness of treating preschool children who stutter, with both trials testing the same treatment, the Lidcombe Program of Early Stuttering Intervention.[126,127] Thus, there is some cumulative evidence for benefits of targeting outcomes in the areas of language (six of 11 trials reporting significant positive results), speech sounds (six of eight trials reporting significant positive results), and fluency (two of two trials reporting significant positive results) among toddlers and preschoolers with speech and language delays or disorders.

The addition of new evidence related to the treatment of speech and language problems in children does little to clarify the characteristics of effective treatments. Two of the three largest trials included in this review, and the only two of good quality, reported limited to no benefits associated with treatment.[128,135] A potential explanation for these results is that the trials examined the lowest-intensity treatments evaluated in any of the studies included in our review (about 6 hours of individual speech and language therapy in one case and 12 hours of parent group meetings in the other). The addition of findings from a second trial of low-intensity treatment provides more reason to question the benefits of such low-intensity treatments for young children with speech and language delays. However, because the heterogeneity across the included studies related to many factors in addition to intensity, it is not possible to be certain that treatment intensity explains the null findings. In fact, one trial entailing only 13 to 16 hours of parent group meetings produced large effects on language outcomes,[136] and another study that

provided the second most intensive treatment of any of these trials (individual treatment) found no main effects on child language or intelligibility.[129] Thus, we are unable to comment on the minimum amount of intensity required for a treatment to likely be effective, and intensity alone cannot account for either positive or null findings among these trials.

This review also includes a study that identified an interaction between a child's baseline characteristic and the response to a particular treatment strategy (recasting).[129] Although the generalizability of this specific finding is limited, it is the only evidence related to the benefits of matching treatments to individual child characteristics. Given the improbability that a treatment for any condition will benefit everyone with the condition, there is a need for such evidence.

We grouped outcome measures into the broad categories of language, speech sounds, and fluency. We generally would anticipate correlations of at least moderate size among different measures within one of these broad categories. For example, children who are slow to acquire vocabulary generally will also have relatively short mean lengths of utterances; children who make many errors on consonant sounds generally will be less intelligible than children who make few errors. However, the strength of these correlations for any given subpopulation of children with speech or language disorders is an empirical question—that is, we cannot assume that one measure within a category such as language will be equivalent to another measure in that category, or that the effects of a treatment on one measure will be generalizable to other measures within the outcome category. Across the trials that report outcomes within the categories of language and speech sounds, diverse outcome measures were used, with no single measure used in a majority of trials. For example, among the trials that report on language outcomes, the most often used measure was mean length of utterance, an index of expressive language structural complexity; however, this measure was used in only four of 10 trials reporting language outcomes.

Trials also varied in the way outcomes were reported. For example, most trials omitted information about effect sizes, and some did not report the statistics needed to compute effect sizes. In a few cases, outcome measures were reported that speak directly to clinical significance, such as the relative number of children in treatment versus control who reduced stuttering to less than 1 percent of syllables[126] or improvement on the clinical criteria used for study entry.[135] In most cases, however, outcomes were not reported in terms that are easily interpreted with respect to their clinical or functional effects.

In summary, the majority of the 13 trials that met inclusion criteria for this review offer evidence supporting the effectiveness of treating speech and language delays and disorders in young children. Positive findings have emerged from studies examining various service delivery models, including individual and small-group treatment, and various intervention agents, including parents supported/trained by professionals, speech-language pathologists, and trained teaching or therapy assistants. Some included trials reported null findings for language and speech sound outcomes. Confident interpretation of this body of evidence on the treatment of speech and language delays is limited by multiple factors, including 1) the small size of many of the trials, which constrains the examination of moderators and mediators of treatment effectiveness; 2) the lack of replicated positive findings for any treatment approach except the Lidcombe program for stuttering; 3) the wide variability across trials in the age of children

treated and intervention agents (e.g., speech-language pathologists, teaching assistants, parents, research staff), intensity, content, and strategies; 4) the relatively small number of trials that have examined manualized treatments or otherwise provide enough details of the treatment approach to permit replication; 5) a corresponding lack of reporting of treatment fidelity in many trials; and 6) the lack of common outcome measures and the inconsistency in how results are reported across trials. Because of these constraints, the current body of evidence does not lend itself to meta-analysis and offers little guidance on the specific factors associated with effective treatments for young children with speech and language delays or disorders.

Key Question 6

Prior Review Findings on Other Nonspeech and Language Outcomes of Treatment

In the 2006 review, four good- or fair-quality studies included functional outcomes other than speech or language. However, the interventions and outcomes varied across the studies and lacked appropriate comparison cohorts. The 2006 review also examined "additional" outcomes and cost-effectiveness issues but did not find any studies that addressed these questions.

Implications of the New Synthesis on Prior Conclusions on Other Nonspeech and Language Outcomes of Treatment

As in the previous review, few trials examined other outcomes of speech and language treatment in children (i.e., outcomes beyond speech and language). One new trial provided evidence supporting the contributions of oral language to proficiency in early reading comprehension.[125] Although this is widely assumed to be the case based on prior longitudinal correlational research, the trial provides better evidence for a causal relationship. The other outcomes measured in the four trials that included nonspeech and nonlanguage outcomes are disparate and thus allow no synthesis of findings across studies.

Key Question 7

The 2006 review found no studies that addressed this question. The update found insufficient evidence to address this question (one outcome in each of two studies).

Applicability of Findings

The included studies have mixed applicability for primary care settings. In a few studies, screening occurred in primary care settings,[78,86,99,100,103] and in two cases, primary care providers administered the screening to the children.[86,103] It should be noted that none of these studies occurred in the United States, and the extent to which conclusions reached from screening in primary care settings in Sweden, Australia, and the United Kingdom are transferable to primary care settings in the United States is not known.

Other settings for screening included early childhood care centers, preschools, and elementary

schools; developmental evaluation centers; university research laboratories; and hospitals. Whether it is realistic for screening to occur in another setting and to have the results sent to a primary care provider is not known, although with training and supervision, a staff member in the primary care setting could administer some of the screening instruments. In some studies, parent-rated instruments were completed at home and mailed or brought to the investigator, and in other cases, they were completed when the child was seen for the administration of the reference test. Either of these settings appears to be applicable to the primary care setting. However, aside from the ASQ, which is used in the primary care setting, parent-rated instruments have not been widely adopted in the United States.

Most of the intervention trials (eight of 12) were conducted in countries other than the United States; three in the United Kingdom,[125,135,136] two in Australia,[127,128,134,137,138] and one in New Zealand.[126] As with the screening studies, whether conclusions reached from trials conducted in countries with different medical, health insurance, and school systems are applicable to the United States is debatable.

Many screening studies examined accuracy in only a subset of children—those who scored positive on the instrument and either a random selection of children who scored negative or a separate cohort of children with typical language. The applicability to an unselected group of children in a primary care setting is not known. However, it is highly likely that the positive and negative predictive values that we calculated are inaccurate because of an incorrect prevalence estimate. An important next step is to conduct screening studies in a general population of preschoolers, in which the prevalence of language delay is closer to the 8 percent found in prevalence studies.

There is also mixed applicability for the interventions in community settings. One study explicitly tested the effectiveness of immediately referring young children identified with speech or language delays/disorders to usual community speech-language therapy services compared with a control condition (watchful waiting).[135] This test is valuable in providing information on whether it is helpful for a primary care provider to refer children with speech and language delays or disorders for speech-language pathology treatment. However, the question this study answers is similar to asking, "Is it effective for a person with symptoms of illness to go to a physician?" Speech-language pathology services entail a diversity of treatments that are individualized to a child's symptoms and ability to participate in different types of interventions, and will also be influenced by the training, experiences, and preferences of the speech-language pathologist serving the child. The rigor of an RCT is unlikely to be relevant to clinical treatment, where it is important to recognize the individual's needs.

Some trials evaluated manualized programs for which resources and training are available (e.g., Lidcombe Program of Early Stuttering Intervention, Hanen Parent Program, the cycles approach to phonological therapy). Using the Hanen program requires certification, which is relatively expensive (**Appendix F**). The treatments used in most trials would be difficult to replicate in the community because of insufficient published information on the program, as well as the difficulty that community practitioners have in accessing information in many peer-reviewed journals.

Context for Findings

Contextual Question 1. Techniques for Screening for Speech and Language Delays or Disorders and Differences by Age and Cultural Background

In the 2006 review, the question concerning techniques for speech and language screening was examined as part of addressing accuracy in KQ 2. The 2006 review, which considered all techniques taking 30 minutes or less to complete as having potential for screening, found 43 articles describing the characteristics of 51 speech and language screening instruments. (Note: The 2006 review counted a study[164] with two substudies as two separate studies; we count it as one study.) The conclusion was that there was no gold standard and that studies using these instruments provided limited details about the participants.

In the current review, we limited our focus to instruments that either take no more than 10 minutes to administer in the primary care facility or, if administered outside the primary care practice, could be interpreted in 10 minutes or less. We also limited it to instruments that we used to address KQ 2. We found 20 studies that described instruments that met criteria for addressing KQ 2. Descriptions of the screening instruments are in **Table 4**. Both parent-rated and trained examiner tools are included, with the latter appropriate for children who are somewhat older.

Contextual Question 2. Risk Factors Associated With Speech and Language Delays or Disorders

We searched the evidence for consistent, reliable, and valid risk factors that clinicians could use to identify children at highest risk for speech and language delays (**Tables 10** and **11**). The ability to reliably stratify children by risk could promote efficiencies in screening activities, ideally assisting in earlier identification of children with speech and language disorders that would translate into earlier intervention and improved speech and language outcomes. Predicting which children are at high risk for speech and language disorders is complicated, however, by the many types of speech and language disorders, heterogeneity in populations across studies, inconsistent identification of potential risk factors across studies, and inconsistent adjustment for potential confounders (i.e., other characteristics that may simultaneously be related to a child's risk for a speech and language problem). To adjust for confounders, all but six studies[165-170] included multivariate analyses of cohorts or a case-control design. We limit our report of cohort studies to their multivariate findings, where available.

Evidence for valid risk factors is also limited by lack of discussion of causal links describing how an associated risk factor may lead to a speech or language delay. For example, male sex is listed as a risk factor for speech and language delays in a number of studies, but it is unclear how and why male sex may contribute to speech and language delay. We aimed to update the evidence on risk stratification.

Our review includes 38 studies conducted in 28 cohorts and one review of studies on characteristics of late-talking toddlers.[171] Twenty-one of the cohorts were English-speaking and seven were non-English speaking.

Among studies in English-speaking populations, sample sizes ranged from 60[165] to 11,383[172] subjects. Most studies evaluated outcomes measuring language delay with or without speech delay. Speech and language outcome domains included expressive and receptive language and vocabulary, number of words, early language and communication difficulty, stuttering, and parental report of speech and language impairment. Male sex was a significant risk factor in 11 of the 14 studies examining it.[83,167,173-181] Only one large cohort study of children age 5 years in Britain reported that male sex decreased the probability of both SLI and nonspecific language impairment.[46] In these multivariate analyses, proximal factors such as family overcrowding, the child being in preschool, and the parent being a poor reader were found to be significant risk factors for poorer outcomes. Family history of speech and language impairment was also a consistent risk factor, significantly associated with delay in seven of nine studies.[166,168,173,175,176, 178,182] However, family history was generally measured by self-report and described nonspecifically (i.e., family members who were late talkers or had language disorders and speech problems). Family history was not found to be a risk factor for stuttering onset in one cohort that measured outcomes at ages 3 and 4 years.[177,181] Parental education had an inconsistent association with speech and language delay. Nine of 15 studies reported a significant association between lower parental education level (either mother or father) and speech and/or language delay.[46,167,168,172,173, 179,182,183] The study of risk factors related to stuttering onset found that stuttering was associated with the mother having a higher level of education.[177,181] Other risk factors identified in two or more studies among English-speaking populations included lower socioeconomic status, earlier identified speech and language delays, poorer parenting practices, greater parental stress, and poorer maternal mental health. Minority race was significant in two of the five studies that examined it.[180,184]

Four studies examined speech and language delays in preterm birth cohorts, measured at ages 18 months to 4 years; studies mostly examined nonoverlapping sets of risk factors.[83,180,184,185] However, two of the studies found that males were at higher risk for poor outcomes.[83,180] Perinatal risk factors were inconsistently measured across other cohorts and included prematurity, low birth weight, being born late in the family birth order, less breastfeeding, maternal alcohol consumption during pregnancy, and younger maternal age at birth. Perinatal factors determined to be risk factors in at least one study that measured them were maternal binge drinking, prematurity, low birth weight, and younger maternal age.

The 13 studies assessing risk in non–English-speaking populations, conducted in eight cohorts, included sample sizes from 24 to 42,107 subjects and evaluated various types of delay, including vocabulary, communication, word production, speech, stuttering, and expressive and receptive language. Significant associations were reported in five studies in four cohorts evaluating risk associated with male sex[57,58,186,187] and two studies evaluating family history of speech and language concerns.[187,188] Perinatal risk factors were examined in a Netherlands study comparing a preterm and term cohort; the study found prematurity to be associated with communication delays at age 4 years.[186,189-191] Several studies, including one based on a large Finnish cohort (n=8,276) found that low birth weight was also associated with poorer speech and language

outcomes.[58,192,193] Other associated risk factors reported less consistently include parental education level and family factors such as size and overcrowding. These studies did not find associations with the mother's stuttering or speaking style or rate, mother's age, or child's temperament.

A review of late-talking toddlers ages 18 to 34 months found a statistically significant association with family history of language disorders, socioeconomic status, and parental stress but no association with parents' education level.[171] The review identified some of the challenges inherent in identifying risk factors for speech and language disorders. First, some studies are limited to children with an expressive vocabulary delay, excluding children with receptive language deficits, even though many children age 2 years have deficits of both comprehension and expression.[171] Also, the instruments used to measure expressive vocabulary across studies are inconsistent. The review author concluded that future research should take into account the lack of homogeneity observed within the population of children with a vocabulary delay at age 2 years and consider a multifactorial perspective of child development to further understand this phenomenon.

Although more recent studies examine more proximal risk factors, such as social determinants of health, rather than distal risk factors such as race, speech and language studies continue to have dissimilar inclusion and exclusion criteria and assess dissimilarly measured risk factors and outcomes. Because of these dissimilarities, it is difficult to determine which of these more proximal factors may be the attributable factor for the speech and language disorder.

Contextual Question 3. Role of Primary Care Providers in Screening in Children Age 5 Years or Younger That Is Performed in Other Venues

The 2006 review did not address the role of primary care providers in screening in children age 5 years or younger that is performed in other venues (such as Head Start or preschool). We found two studies[91,194] that examined screening in preschool venues; however, neither discussed the role of the medical provider. Thus, we have no evidence on the interface between this aspect of the screening process and primary care providers.

Limitations of the Review

The 2006 review identified a number of limitations of the literature base, including a lack of studies specific to screening; inconsistencies in terminology across studies; assessment instruments and interventions that address specific aspects of language development rather than a common, global indicator of speech or language; and difficulties evaluating the effects of complex interventions, especially those related to screening. Many of these issues continue to plague the field.

We found additional limitations. One difficulty in drawing conclusions about whether screening for speech and language delays or disorders leads to improved outcomes is the lack of well-designed studies that address this overarching question. The ideal study would randomize children to screening and no screening; follow up with those who are screened, both positive and

negative results; and at some later point, assess all children, while collecting enough data to understand what occurred during the intervening time. Although de Koning et al[70] designed a randomized trial of screening versus no screening, their study had a large attrition, and they did not use a uniform method of assessing language outcomes. Thus, this trial did not provide evidence about screening.

We are beginning to answer the question of whether screening can accurately identify children and have identified some candidate measures. Yet many studies included in the review are less than ideal because they include selected groups of children; that is, many studies include a sample of children with and without language delays. Use of such predetermined samples makes it difficult to examine whether screening is accurate in unselected samples, the likely target for such activities. In addition, because such studies tend to have a greater number of children with language delays or disorders, estimates of prevalence are skewed, leading to inaccurate estimates of positive and negative predictive values. Only a few studies examined how well screening instruments detect speech and language disorders over the long term. Such studies are critical in calculating the real benefit of early detection. Examining long-term outcomes may identify children with a language impairment rather than a transient language delay, enabling providers to target intervention resources to those who have a greater need.

We also encountered studies that purported to screen for speech and language delays but used instruments that were not specific to linguistic skills, instead screening for developmental delays. Other studies validated instruments by examining their accuracy in relation to other instruments, not to recognized reference standards. The issue is not that the instruments are deficient; rather, it is the study designs that are deficient.

One limitation of the included intervention trials was that the studies often did not include information on whether the children were receiving community services for their speech and language symptoms outside of the study. Exceptions[126,129,135] provided information about community speech and language services. Understanding what services children in both arms of the intervention study receive is critical to interpreting treatment effects, or lack thereof.

It is challenging, at least in the United States, to conduct an RCT comparing speech and language treatment versus no treatment in children with severe enough symptoms to be identified as having a speech and language delay or disorder. Under IDEA, children from birth to age 5 years with special needs are entitled to services through the early intervention programs in their resident State. States have some latitude in setting eligibility criteria for these services, and as funding has become tighter, the trend is to limit eligibility, requiring that the children served have more severe problems. The result of this law and the associated policies in the United States is that children with more significant problems will likely receive public early intervention/preschool services, making it unlikely that researchers could conduct an RCT that compares children receiving a speech-language treatment with children not receiving any speech-language treatment. Although it may be possible to conduct such trials in children who have milder symptoms that do not qualify them for public services, such trials would not be representative of the full population of children with speech and language delays and disorders, and would largely exclude the children with the greatest needs.

Across the included trials, the majority of control groups offered intervention to children on a delayed schedule. This condition would likely make parents more willing to consent to their child participating in an RCT, but constrains our ability to examine long-range outcomes for treated versus untreated children.

Future Research Needs

In order to sufficiently answer the question, "Does screening for speech and language delays or disorders lead to improved speech and language outcomes, as well as improved outcomes in domains other than speech and language?", studies need to be specifically designed and executed for this purpose. Neither the current review nor the 2006 review could answer this question directly; rather, both addressed the question by considering subquestions. This research gap presents an opportunity for a large study to test the efficacy of systematic routine screening for speech and language delays and disorders compared with not implementing routine screening in primary care. In tandem with this, the field would benefit from a study to examine the feasibility of speech- and language-specific screening as part of the more general developmental screening that is already recommended.[49] Better designed studies of risk factors, including children's background characteristics, would also facilitate clinicians' ability to identify children who are at highest risk for speech and language delays.

Only a few of the screening studies included children who were speakers of languages other than English. Future studies should include such children in studies of both language screening and language intervention.

Given Federal mandates under IDEA that all children with a documented speech or language delay receive early intervention, going forward, it may be difficult to conduct RCTs to examine the efficacy of interventions. Future research protocols may adopt quasiexperimental designs of sufficient rigor to answer intervention questions. For example, regression discontinuity designs seem applicable to addressing treatment efficacy because they can be used when there is a cutoff in a continuous measure that is used to identify children who are eligible for the treatment. The effect size is evaluated at the point of discontinuity, dividing those who met by those who did not meet eligibility criteria. Well-designed and implemented regression discontinuity designs can now meet standards for rigor without reservation for the U.S. Department of Education, whose Institute of Education Sciences sponsors evaluations of evidence.

We recommend that stakeholders with an interest in screening develop research agendas and funding targeted to answer the important questions that could not be addressed in this review. To build the necessary evidence that screening children for speech and language delays and disorders can lead to improved outcomes, it will be necessary to design and conduct studies that can specifically address that question.

Conclusion

We found no evidence to answer the overarching question of whether screening for speech and

language delays or disorders leads to improved speech and language outcomes. However, this should not be interpreted to mean that screening for speech and language delays is not beneficial; rather, we do not know whether there is a benefit because of a lack of evidence to answer this question. The studies from the 2006 review, as well as the newly identified studies, suggest that some screening instruments for detecting speech and language delays and disorders are accurate. Although these parent-rated instruments require only that the primary care provider interpret the findings, studies have not examined how receptive providers are to doing so. As in the 2006 review, we found no studies that addressed the harms of screening for speech and language delays, nor did we find any evidence about the role of enhanced surveillance by a primary care clinician once a child is identified as possibly having a speech and language delay. Building on the studies identified in the 2006 review, we found evidence supporting the effectiveness of treating speech and language delays and disorders in children. However, the body of evidence does not provide guidance regarding the specific factors associated with effective treatments for young children with speech and language delays or disorders. Finally, this review found no evidence relating to the harms of treating speech and language delays or disorders.

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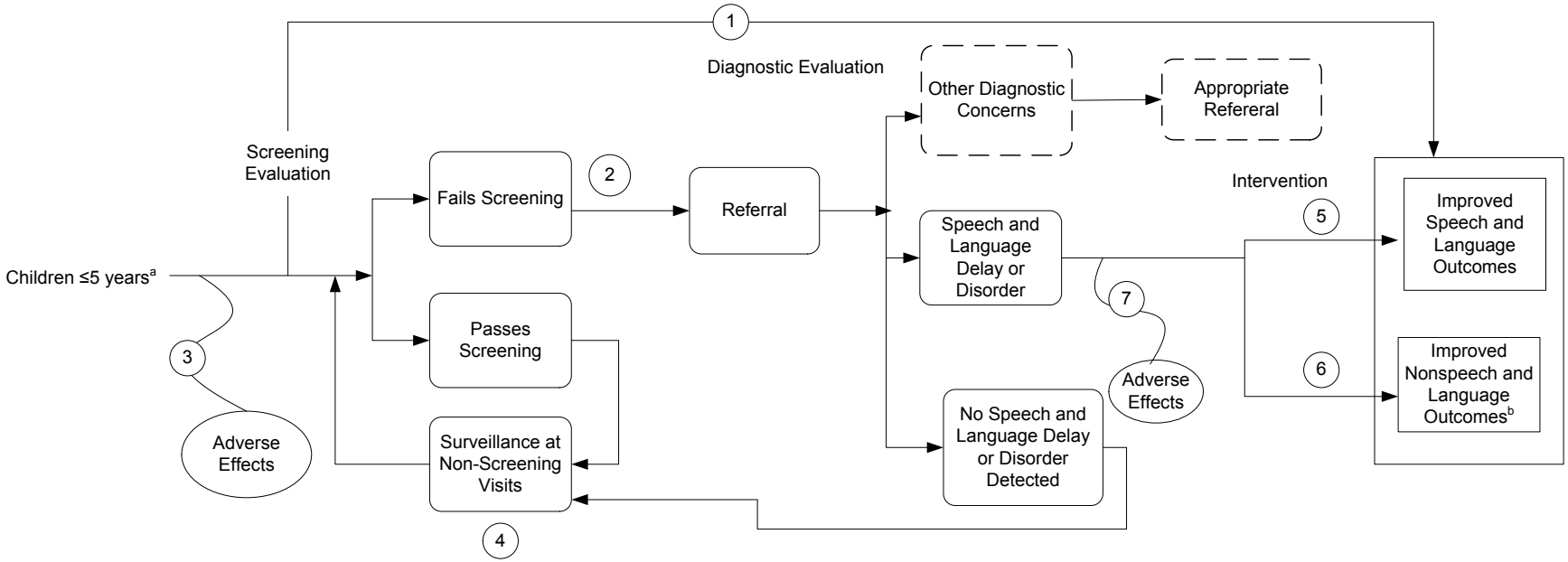
Figure 1. Analytic Framework



[a]Excluding children with diagnosed disorders including autism, mental retardation, Fragile X, hearing loss, degenerative and other neurologic conditions.
[b]School performance, behavioral competence, socioemotional development, quality of life, and others.

Figure 2. Preferred Reporting of Systematic Reviews and Meta-Analysis (PRISMA) Tree

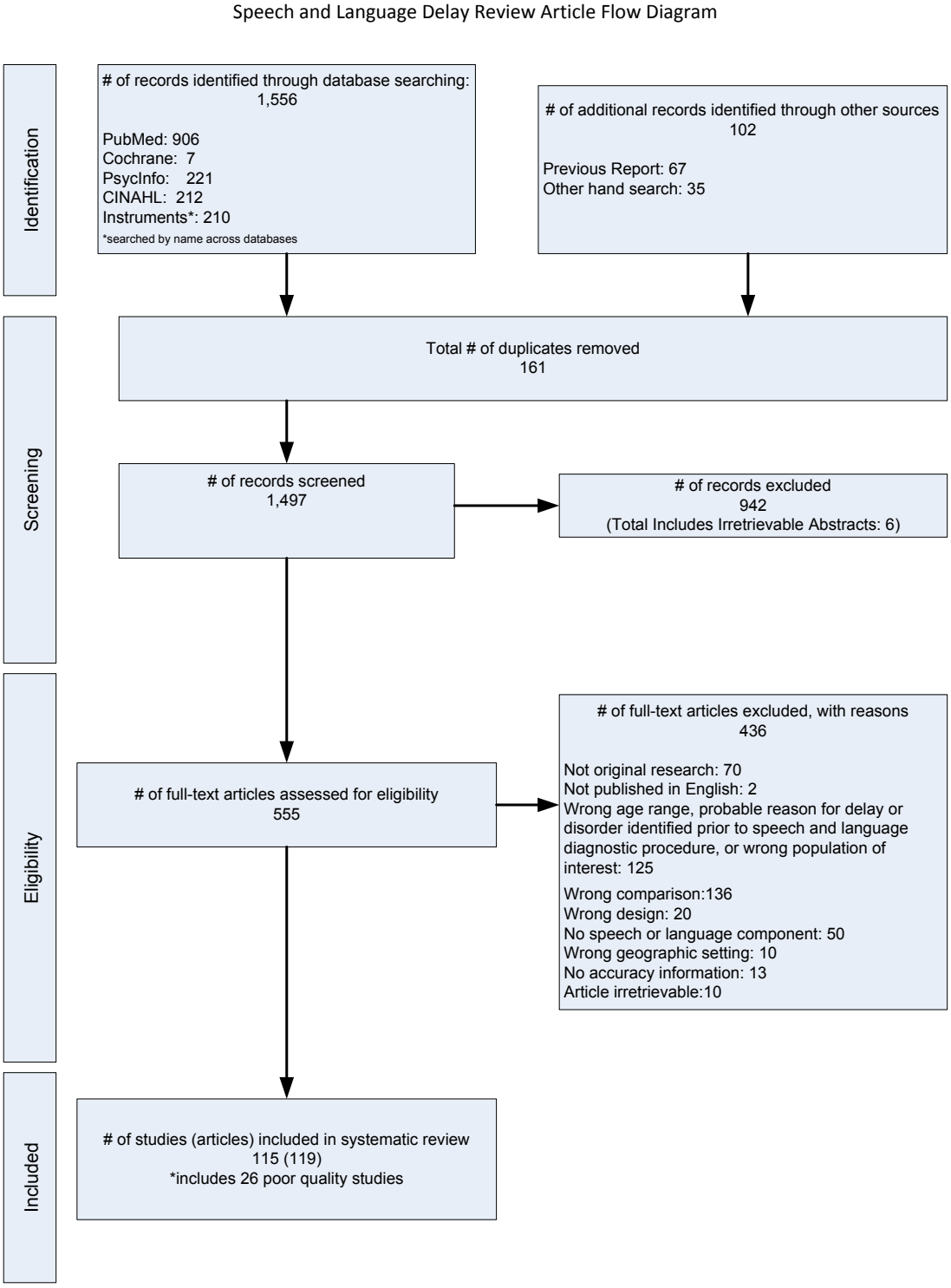


Figure 3a. Parent-Reported Screening Instruments: Sensitivity Values

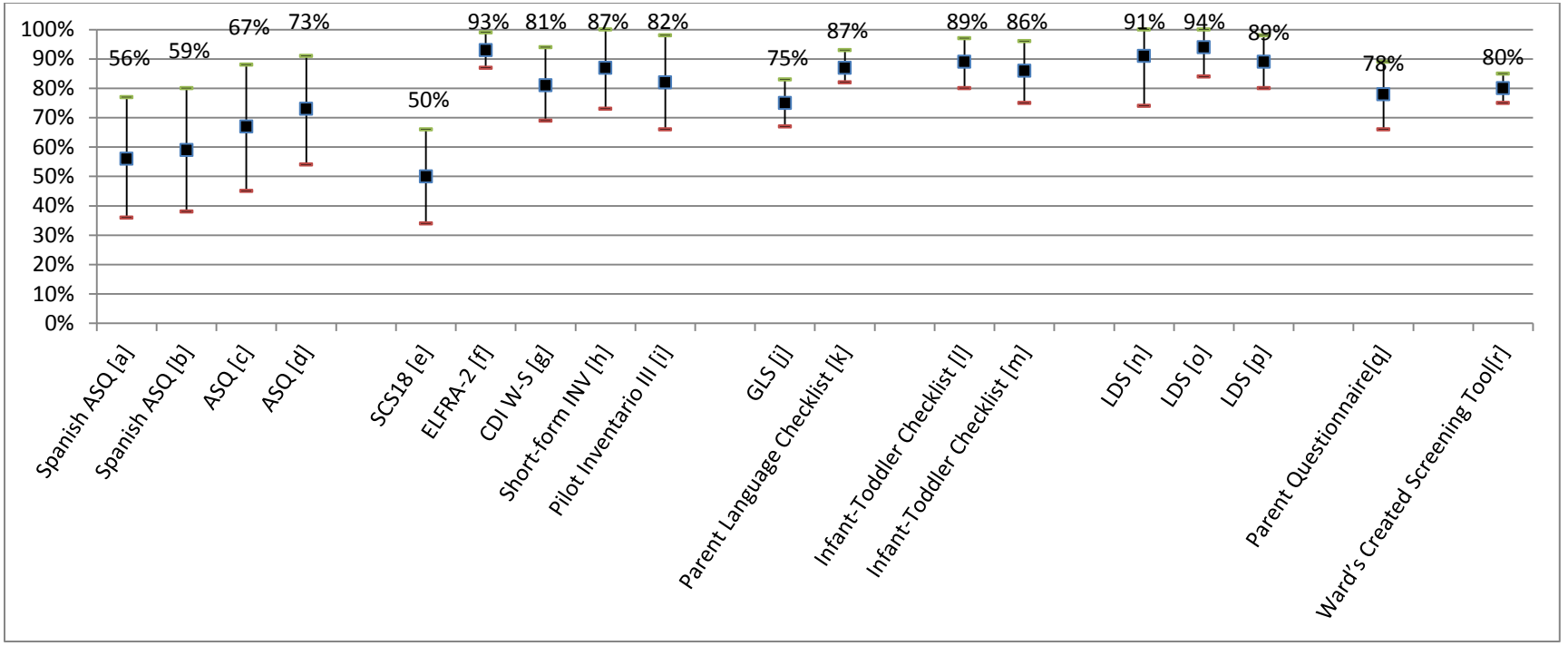


Figure Notes: [a] Guiberson et al, 2011[74]; [b] Guiberson and Rodriguez, 2010[195]; [c] Frisk et al, 2009[72], with reference measure PLS-4, Comprehension; [d] Frisk et al, 2009[72], with reference measure PLS-4, Expression; [e] Swedish CDI Words and Sentences, Westerlund et al, 2006[78]; [f] German CDI Words and Sentences, Sachse and Von Suchodoletz, 2008[76], 2009[77]; [g] CDI Words and Sentences, Heilmann et al, 2005[75]; [h] Spanish CDI Words and Sentences, Guiberson et al, 2011[74]; [i] Spanish CDI III, Guiberson and Rodriguez, 2010[195]; [j] Stott et al, 2002[104]; [k] earlier version of GLS, Burden, 1986[95]; [l] Wetherby et al, 2003[88], ages 12 to 17 months; [m] Wetherby et al, 2003[88], ages 18 to 24 months; [n] Klee et al, 2000[122]; [o] Rescorla and Alley, 2001[102]; [p] Rescorla, 1989[54]; [q] Stokes, 1997[103]; and [r] Ward, 1984[108]. One study (GLS, Stott et al, 2002[104], with reference measure EAT, RDLS, and BPVS) was omitted because lack of data made it impossible to compute a confidence interval.

Abbreviations: ASQ = Ages and Stages Questionnaire; BPVS = British Picture Vocabulary Scale; CDI = Communicative Development Inventory; CI = confidence interval; EAT = Edinburgh Articulation Test; ELFRA = Elternfragebogen fur die fruberkennung von riskokindern; GLS = General Language Screen; INV = Inventario; LDS = Language Development Survey; RDLS = Reynell Developmental Language Scale; PLS = Preschool Language Scale; SCS-18 = Swedish Communication Screening at 18 months of age; W-S = Words and Sentences.

Figure 3b. Parent-Reported Screening Instruments: Specificity Values

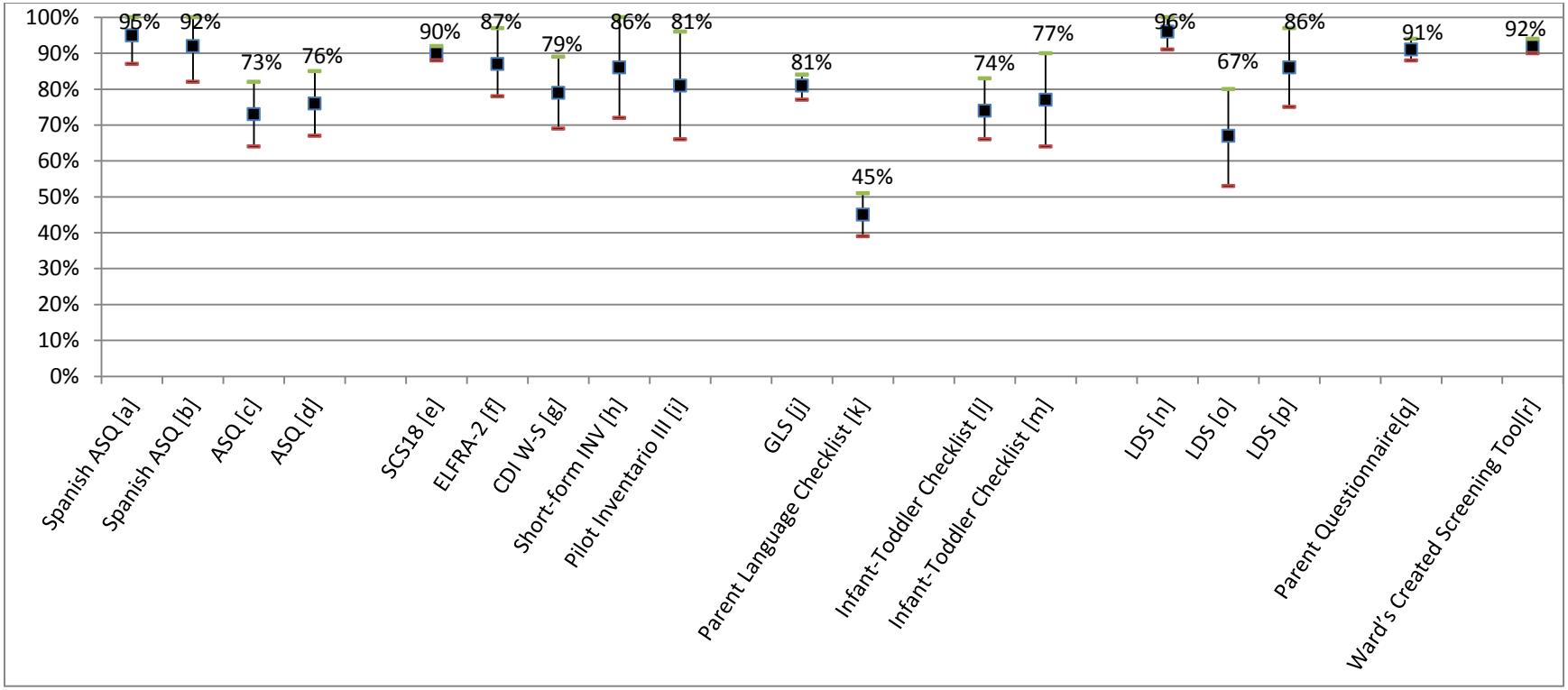


Figure Notes: [a] Guiberson et al, 2011[74]; [b] Guiberson and Rodriguez, 2010[195]; [c] Frisk et al, 2009[72], with reference measure PLS-4, Comprehension; [d] Frisk et al, 2009[72], with reference measure PLS-4, Expression; [e] Swedish CDI Words and Sentences, Westerlund et al, 2006[78]; [f] German CDI Words and Sentences, Sachse and Von Suchodoletz, 2008[76], 2009[77]; [g] CDI Words and Sentences, Heilmann et al, 2005[75]; [h] Spanish CDI Words and Sentences, Guiberson et al, 2011[74]; [i] Spanish CDI III, Guiberson and Rodriguez, 2010[195]; [j] Stott et al, 2002[104]; [k] earlier version of GLS, Burden, 1986[95]; [l] Wetherby et al, 2003[88], ages 12 to 17 months; [m] Wetherby et al, 2003[88], ages 18 to 24 months; [n] Klee et al, 2000[122]; [o] Rescorla and Alley, 2001[102]; [p] Rescorla, 1989[54]; [q] Stokes, 1997[103]; and [r] Ward, 1984[108]. One study (GLS, Stott et al, 2002[104], with reference measure EAT, RDLS, and BPVS) was omitted because lack of data made it impossible to compute a confidence interval.

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Figure 4a. Trained Examiner Screening Instruments: Sensitivity Values

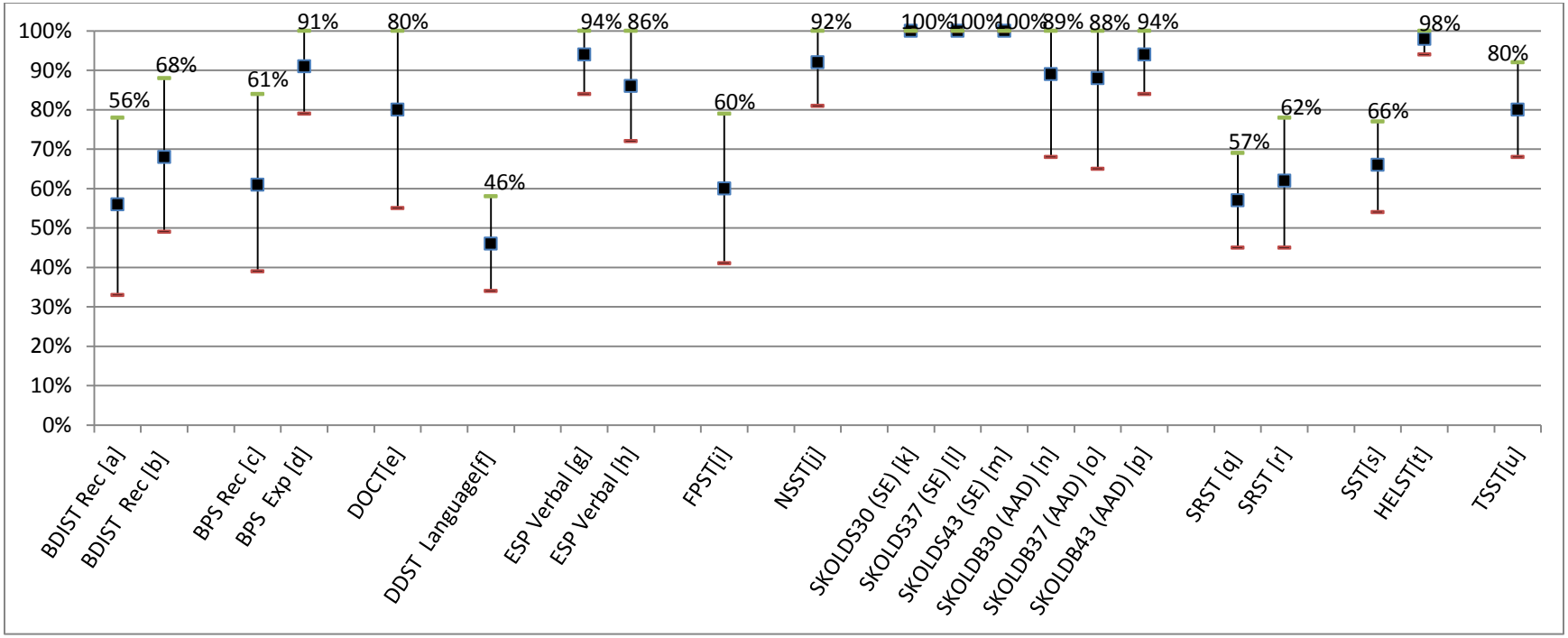

Figure Notes: [a] Frisk et al, 2009[72], with reference measure PLS-4, Comprehension; [b] Frisk et al, 2009[72], with reference measure PLS-4, Expression; [c] Frisk et al, 2009[72], with reference measure PLS-4, Receptive; [d] Frisk et al, 2009[72], with reference measure PLS-4, Expressive; [e] Alberts et al, 1995[91]; [f] Borowitz and Glascoe, 1986[94]; [g] Frisk et al, 2009[72], with reference measure PLS-4, Comprehension; [h] Frisk et al, 2009[72], with reference measure PLS-4, Expression; [i] Allen and Bliss, 1987[92]; [j] Allen and Bliss, 1987[92]; [k] Bliss and Allen, 1984[93], ages 30 to 36 months; [l] Bliss and Allen, 1984[93], ages 37 to 42 months; [m] Bliss and Allen, 1984[93], ages 43 to 48 months; [n] Bliss and Allen, 1984[93], ages 30 to 36 months; [o] Bliss and Allen, 1984[93], ages 37 to 42 months; [p] Bliss and Allen, 1984[93], ages 43 to 48 months; [q] Sturner et al, 1996[106], with reference measure AAPS-R; [r] Sturner et al, 1996[106], with reference measure ITPA, Bankson; [s] Laing et al, 2002[99]; [t] Law, 1994[100]; and [u] Rigby and Chesham, 1981[86]. Several studies (Denver Articulation Screening Test, Drumwright et al, 1973[97]; Developmental Nurse Screen, Stokes, 1997[103]; and Studies 1 and 2, FPSLST Articulation, FPSLST Language, Sturner et al, 1993[106]) were omitted because lack of data made it impossible to compute confidence intervals.

Abbreviations: AAD = African American dialect; BDIST = Battelle Developmental Inventory Screening Test; BPS = Brigance Preschool Screening; CI = confidence interval; DDST = Denver Developmental Screening Test; DOCT = Davis Observation Checklist for Texas; ESP = Early Screening Profile; FPSLST = Fluharty Preschool Speech and Language Screening Test; FPST = Fluharty Preschool Screening Test; HELST = Hackney Early Language Screening Test; ITPA = Illinois Test of Psycholinguistic Abilities; NSST = Northwestern Syntax Screening Test; PLS = Preschool Language Scale; SE= Standard English; SKOLD = Screening Kit of Language Development; SRST = Sentence Repetition Screening Test; SST = Structured Screening Test; TSST = trial speech screening test.

Figure 4b. Professional/Paraprofessional-Reported Screening Instruments: Specificity Values

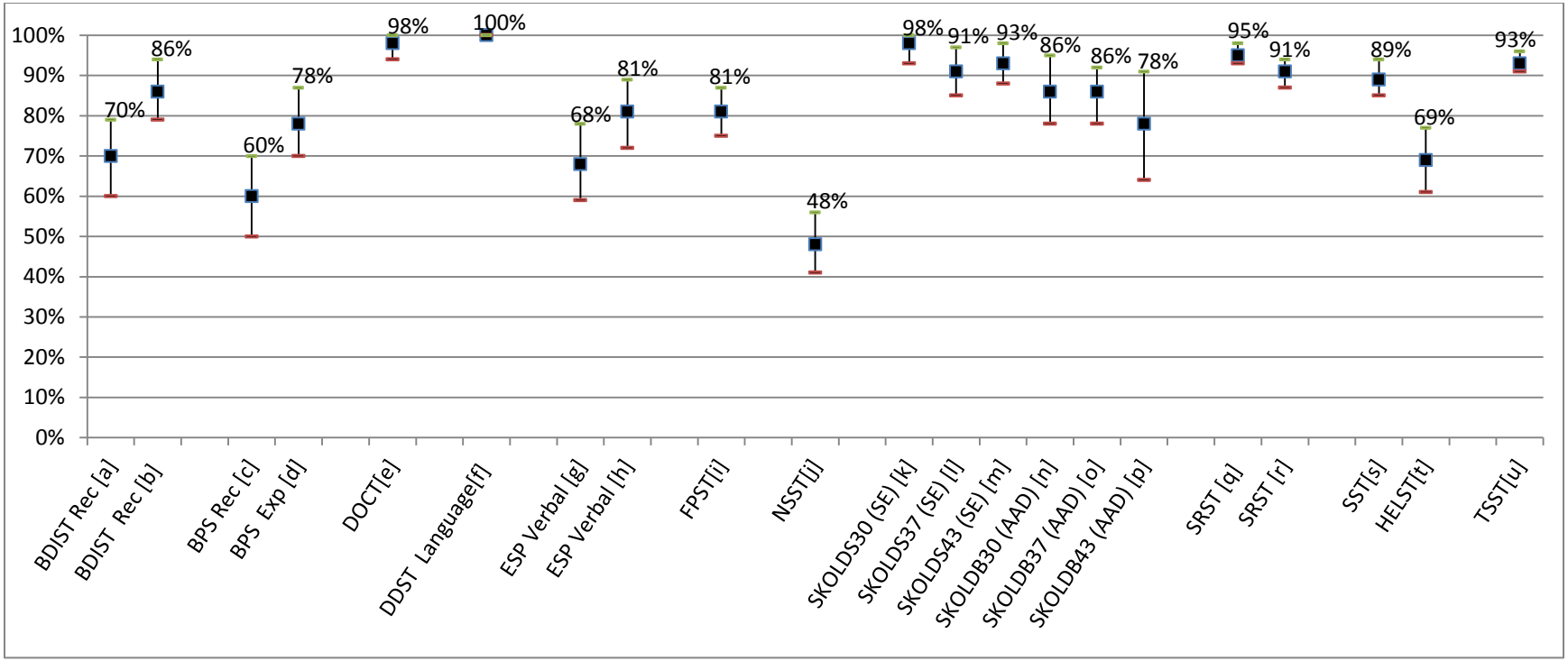

Figure Notes: [a] Frisk et al, 2009[72], with reference measure PLS-4, Comprehension; [b] Frisk et al, 2009[72], with reference measure PLS-4, Expression; [c] Frisk et al, 2009[72], with reference measure PLS-4, Receptive; [d] Frisk et al, 2009[72], with reference measure PLS-4, Expressive; [e] Alberts et al, 1995[91]; [f] Borowitz and Glascoe, 1986[94]; [g] Frisk et al, 2009[72], with reference measure PLS-4, Comprehension; [h] Frisk et al, 2009[72], with reference measure PLS-4, Expression; [i] Allen and Bliss, 1987[92]; [j] Allen and Bliss, 1987[92]; [k] Bliss and Allen, 1984[93], ages 30 to 36 months; [l] Bliss and Allen, 1984[93], ages 37 to 42 months; [m] Bliss and Allen, 1984[93], ages 43 to 48 months; [n] Bliss and Allen, 1984[93], ages 30 to 36 months; [o] Bliss and Allen, 1984[93], ages 37 to 42 months; [p] Bliss and Allen, 1984[93], ages 43 to 48 months; [q] Sturner et al, 1996[106], with reference measure AAPS-R; [r] Sturner et al, 1996[106], with reference measure ITPA, Bankson; [s] Laing et al, 2002[99]; [t] Law, 1994[100]; and [u] Rigby and Chesham, 1981[86]. Several studies (Denver Articulation Screening Test, Drumwright et al, 1973[97]; Developmental Nurse Screen, Stokes, 1997[103]; and Studies 1 and 2, FPSLST Articulation, FPSLST Language, Sturner et al, 1993[106]) were omitted because lack of data made it impossible to compute confidence intervals.

Abbreviations: AAD = African American dialect; BDIST = Battelle Developmental Inventory Screening Test; BPS = Brigance Preschool Screening; CI = confidence interval; DDST = Denver Developmental Screening Test; DOCT = Davis Observation Checklist for Texas; ESP = Early Screening Profile; FPSLST = Fluharty Preschool Speech and Language Screening Test; FPST = Fluharty Preschool Screening Test; HELST = Hackney Early Language Screening Test; ITPA = Illinois Test of Psycholinguistic Abilities; NSST = Northwestern Syntax Screening Test; PLS = Preschool Language Scale; SE= Standard English; SKOLD = Screening Kit of Language Development; SRST = Sentence Repetition Screening Test; SST = Structured Screening Test; TSST = trial speech screening test.

Table 1. Differences in Included Studies in the 2006 Review and Current Review

2006 Review	Current Review
Screening Studies • Screening instruments reviewed could be ≤30 minutes. • Studies included some children older than age 6 years. • Studies included some children with known conditions (e.g., cleft palate). • Acceptable reference standards included other screening instruments or items extracted from measures of cognitive ability. **Treatment Studies** • RCTs included no treatment as well as treatment comparisons, such as usual care.	**Screening Studies** • Screening instruments could be >10 minutes if administered outside primary care office and interpreted only by clinician. • If studies included children older than age 6 years, data needed to be available on the sample who were younger than age 6 years. • Studies were excluded if they included children with known conditions (e.g., cleft palate). • Reference standards had to be instruments used by speech and language practitioners to diagnose speech and language delay or disorders in either research or clinical venues. **Treatment Studies** • Treatment studies were limited to RCTs with treatment comparisons limited to unspecified usual care or care in the community.

Abbreviation: RCT = randomized, controlled trial.

Table 2. Comparison of Studies Meeting Inclusion and Key Question Quality Criteria in Previous and Present USPSTF Reviews

Key Question/Contextual Question	Study	2006	Current
KQ 1. Improved outcomes from screening	NA		
KQ 2. Accuracy of screening instruments	Alberts 1995[91]	X	X
	Allen 1987[92]	X	X
	Blaxley 1983[112]	X	
	Bliss 1984[93]	X	X
	Borowitz 1986[94]	X	X
	Burden 1996[95]	X	X
	Chaffee 1990[113]	X	
	Clark 1995[66]	X	
	Conti-Ramsden 2003[196]	X	
	Coplan 1982[197]	X	
	Dodge 1980[114]	X	
	Drumwright 1973[97]	X	X
	Feeney 1996[119]	X	
	Frisk 2009[72]		X
	German 1982[120]	X	
	Glascoe 1991[115]	X	
	Glascoe 1993[198]	X	
	Guiberson 2010[73]		X
	Guiberson 2011[74]		X
	Heilmann 2005[75]		X
	Klee 1998[98]	X	X
	Klee 2000[122a]	X	X
	Laing 2002[99]	X	X
	Law 1994[100]	X	X
	Law 1998[89] (SR)	X	
	Leppert 1998[199]	X	
	Levett 1983[67]	X	
	Macias 1998[200]	X	
	Nelson 2006[64] (SR)[b]		X
	Nelson 2006[90] (SR)		X
	Rescorla 1989[54]	X	X
	Rescorla 1993[69]	X	
	Rescorla 2001[102]	X	X
	Rigby 1981[86]		X
	Sachse 2008[76]		X
	Sachse 2009[77c]		X
	Scherer 1995[117]	X	
	Sherman 1996[68]	X	
	Stokes 1997[103]	X	X
	Stott 2002[104]	X	X
	Sturner 1993[105]	X	X
	Sturner 1996[106]	X	X
	Ward 1984[108]	X	X
	Westerlund 2006[78]		X
	Wetherby 2003[88]		X
KQ 3. Harms of screening	NA		
KQ 4. Surveillance	NA		

Table 2. Comparison of Studies Meeting Inclusion and Key Question Quality Criteria in Previous and Present USPSTF Reviews

Key Question/Contextual Question	Study	2006	Current
KQ 5. Benefits of treatment	Almost 1998[134]	X	X
	Barratt 1992[142]	X	
	Cole 1986[143]	X	
	Courtright 1979[144]	X	
	Fricke 2013[125]		X
	Gibbard 1994[136]	X	X
	Girolametto 1996[137]	X	X
	Girolametto 1997[138]	X	X
	Glogowska 2000[135]	X	X
	Jones 2005[126]		X
	Law 1998[89] (SR)	X	
	Law 1999[147]	X	
	Law 2003[201] (SR)	X	
	Lewis 2008[127]		X
	Morgan 2009[131] (SR)		X
	Nelson 2006[64] (SR)[b]		X
	Nelson 2006[90] (SR)		X
	Robertson 1997[140]	X	X
	Robertson 1999[139]	X	X
	Rvachew 2001[145]	X	
	Shelton 1978[141]	X	X
	Wake 2011[128]		X
	Wake 2013[130]		X
	Wilcox 1991[146]	X	
	Yoder 2005[129]		X
KQ 6. Nonspeech and language benefits of treatment	Fricke 2013[125]		X
	Girolametto 1996[137]	X	
	Glogowska 2000[135]	X	
	Law 1998[89] (SR)	X	
	Law 1999[147]	X	
	Nelson 2006[64] (SR)[b]		X
	Nelson 2006[90] (SR)		X
	Robertson 1999[139]	X	X
	Rvachew 2001[145]	X	
	Wake 2011[128]		X
	Wake 2013[130]		X
KQ 7. Harms of treatment	Glogowska 2000[135]	X	X
	Robertson 1999[139]	X	X
	Wake 2013[130]		X

Table 2. Comparison of Studies Meeting Inclusion and Key Question Quality Criteria in Previous and Present USPSTF Reviews

Key Question/Contextual Question	Study	2006	Current
CQ 1. Techniques of screening	Alvik 2011[202]		X
	Dionne 2006[203]		X
	Drumwright 1973[97]	X	X
	Fenson 2007[204]		X
	Fluharty 1974[205]	X	X
	Frankenburg 1992[52]	X	X
	Guiberson 2010[73]		X
	Guiberson 2011[74]		X
	Heo 2008[82]		X
	Jackson-Maldonado 2013[206]		X
	Kerstjens 2009[186]		X
	Rescorla 1989[54]	X	X
	Rescorla 2002[121]	X	X
	Rescorla 2005[207]		X
	Sices 2009[84]		X
	Squires 1999[208]		X
	Sturner 1993[164]		X
	Sturner 1994[209]		X
	Vach 2010[210]		X
	van Agt 2007[85]		X
	Westerlund 2004[211]		X
	Wetherby 2002[212]		X

Table 2. Comparison of Studies Meeting Inclusion and Key Question Quality Criteria in Previous and Present USPSTF Reviews

Key Question/Contextual Question	Study	2006	Current
CQ 2. Risk factors	Adams-Chapman 2013[180]		X
	Alston 2005[165]		X
	Brookhouser 1979[213]	X	
	Campbell 2003[173]	X	X
	Cantwell 1985[214]	X	
	Choudhury 2003[175]	X	X
	Desmarais 2008[171]		X
	Everitt 2013[215]		X
	Foster-Cohen 2010[185]		X
	Fox 2002[188]	X	X
	Glascoe 2010[216]		X
	Hammer 2010[174]		X
	Harrison 2010[179]		X
	Henrichs 2011[81]		X
	Kerstjens 2009[186]		X
	Kerstjens 2011[189]		X
	Kerstjens 2012[190]		X
	Klein 1986[217]	X	
	Kloth 1995[218]	X	
	Law 2009[46]		X
	Law 2012[172]		X
	Lyytinen 2001[219]	X	
	Mossabeb 2012[83]		X
	O'Leary 2009[220]		X
	Pena 2011[183]		X
	Peters 1997[221]	X	
	Potijk 2353[191]		X
	Pruitt 2010[166]		X
	Reilly 2007[178]		X
	Reilly 2009[177]		X
	Reilly 2013[181]		X
	Roth 2011[222]		X
	Schjolberg 2011[192]		X
	Singer 2001[184]	X	X
	Tallal 1989[182]	X	X
	Tomblin 1991[167]	X	X
	Tomblin 1997[168]	X	X
	van Batenburg-Eddes 2013[223]		X
	Van Lierde 2009[193]		X
	Weindrich 2000[170]	X	X
	Whitehurst 1991[169]	X	X
	Yliherva 2001[224]	X	X
	Zambrana 2014[187]		X
	Zubrick 2007[176]		X
CQ 3. Role of providers	None		

[a] Companion to Klee 1998.
[b] Companion to Nelson et al, 2006.
[c] Companion to Sachse 2008.

Abbreviations: CQ = contextual question; KQ = key question; SR = systematic review; USPSTF = U.S. Preventive Services Task Force.

Table 3. Screening Accuracy Studies From 2006 Review and New Review

Study, Reference Quality Rating Source	Screening Tool Screening Source	Country Recruitment Setting	Sample Description, Recruitment Method, Inclusion/Exclusion Criteria, Sampling for Reference Measure
Alberts et al, 1995[91] Fair 2006 review	Davis Observation Checklist for Texas Trained examiner	USA Head Start centers in central Texas	Children ages 52–67 months No description of recruitment methods Eligibility included normal hearing and English-language dominance No sampling for reference measure
Allen and Bliss, 1987[92] Fair 2006 review	Fluharty Preschool Screening Test Northwestern Syntax Screening Test Trained examiner	USA Child care centers in suburban Detroit	Preschool-age children ages 36–47 months No description of recruitment methods No inclusion/exclusion criteria provided No sampling for reference measure
Bliss and Allen, 1984[93] Fair 2006 review	Screening Kit of Language Development Trained examiner	USA Child care centers in metropolitan Detroit	Preschool-age children ages 30–48 months No description of recruitment methods No inclusion/exclusion criteria provided No sampling for reference measure
Borowitz and Glascoe, 1986[94] Fair 2006 review	Denver Developmental Screening Test Trained examiner	USA Developmental evaluation center in middle Tennessee	Children ages 18–66 months Children referred by Head Start centers, daycare and preschool centers, public schools, public health agencies, the Department of Human Services, and private physicians Children referred because of their home environment, medical problems, and suspected delays No sampling for reference measure
Burden et al, 1996[95] Good 2006 review	Parent Language Checklist Parent report	UK Community sample within Cambridge Health Authority	Children age 36 months Same sample as described by Stott et al, 2002,[104] but differs in terms of who was followed and analyzed. Families residing within the Cambridge Health Authority with a child born during a 9-month period were invited by mail to complete the screening when the child was age 36 months. 1,936 of 2,590 were returned. Of the 472 net-positive children, 277 proceeded to the screening. From the pool of randomly selected net-negative children, 226 were randomly selected and 148 proceeded to the screening. A total of 425 children were included Children were eligible if they were not a product of a multiple birth, did not have a listed medical condition (not described), did not live in a multilingual home, or were not eliminated on the telephone interview All children who failed and were not excluded and a matched sample of children who passed
Drumwright et al, 1973[97] Fair 2006 review	Denver Articulation Screening Exam Trained examiner	USA Head Start, public and private child care centers, schools, and pediatric clinics in Denver	Children ages 2.5–6 years No description of recruitment methods Children from economically disadvantaged homes No sampling for reference measure

Table 3. Screening Accuracy Studies From 2006 Review and New Review

Study, Reference Quality Rating Source	Screening Tool Screening Source	Country Recruitment Setting	Sample Description, Recruitment Method, Inclusion/Exclusion Criteria, Sampling for Reference Measure
Frisk et al, 2009[72] Fair New	Ages and Stages Questionnaire, Communication domain Parent report Battelle Developmental Inventory Screening Test, communication domain Brigance Preschool Screen Early Screening Profiles Trained examiner	Canada Child Development Programs (programs that provide early intervention services to young children at risk for developmental disabilities) in Ontario	Parents of children age 4.5 years No description of recruitment methods Children were eligible if they were not legally blind, not profoundly hearing impaired, not untestable because of global delay, not diagnosed with autism spectrum disorder, or did not use English as a second language with <19 months daily exposure to English Of the 131 children initially screened, data were available for only 111 children No sampling for reference measure
Guiberson and Rodriguez, 2010[73] Fair New	Spanish Ages and Stages Questionnaire, Communication domain Pilot Inventario-III (Spanish Communicative Development Inventory) Parent report	USA Head Start centers, early childhood program, and medical clinic in 2 western states	Parents of children ages 32–62 months Recruitment included sending flyers home to families with children enrolled in preschool programs, posting flyers in early childhood centers and medical clinics, and attending preschool family nights and Head Start community health fairs Eligible families spoke only or mostly Spanish; eligible children had normal hearing, no known neurological impairment, no severe phonological impairment, and spoke only or mostly Spanish Predetermined that approximately half of sample would have language delays and half without
Guiberson et al, 2011[74] Fair New	Spanish Ages and Stages Questionnaire, Communication domain Short-form Inventarios del desarrollo de habilidades comunicativas: palabras y enunciados (Spanish CDI) Parent report	USA Early Head Start center and early intervention programs in 2 western states	Parents of toddlers ages 24–35 months Study flyers sent to Early Head Start family members and service coordinators; interested parents of children in these programs who met inclusion criteria were invited Eligible families spoke only or mostly Spanish; eligible children had normal hearing, no known neurological impairment, and spoke only or mostly Spanish; children with both typical language development and expressive language delays were included Predetermined that approximately half of sample would have language delays and half without
Heilmann et al, 2005[75] Study 2 Fair New	MacArthur-Bates Communicative Development Inventory: Words and Sentences Parent report	USA University research center	Parents of children who were age 24 months Children were part of a larger longitudinal study of language delay who were recruited via birth registry, newspapers, flyers, posters at health fairs, and referrals from providers (birth to age 3 years) Eligible children were from a monolingual English-speaking home, scored within the normal range on Denver II for general development, had normal hearing, and normal oral and speech motor abilities Included 38 late talkers and 62 children who were part of the larger study who had typical language

Table 3. Screening Accuracy Studies From 2006 Review and New Review

Study, Reference Quality Rating Source	Screening Tool Screening Source	Country Recruitment Setting	Sample Description, Recruitment Method, Inclusion/Exclusion Criteria, Sampling for Reference Measure
Klee et al, 1998[98] Fair 2006 review Klee et al, 2000[122] Fair	Language Development Survey Parent report	USA Community in Wyoming	Parents of children ages 24–26 months of age Families recruited by mail from 2 cities No inclusion/exclusion criteria provided All children who screened positive in an earlier study and a sample of those who screened negative were invited to participate in a comprehensive evaluation Same sample as in Klee et al, 1998[98], with a different analysis
Laing et al, 2002[99] Good 2006 review	Structured Screening Test Trained examiner	UK Health center in section of London	Children age 30 months Health visitors invited all parents who attended their child's 30-month developmental checkup to participate Children were eligible whether or not they had a previously diagnosed developmental disability No sampling for reference measure
Law, 1984[100] Good 2006 review	Hackney Early Language Screening Test Trained examiner	UK Pediatric practice in section of London	Children age 30 months All children attending a routine developmental checkup at age 30 months in a London suburb were screened No description of inclusion/exclusion criteria All children who tested positive and a sample of those who passed were seen for a diagnostic evaluation, provided their first language was English
Rescorla, 1989[54] Study 3 Fair 2006 review	Language Development Survey Parent report	USA University research center	Parents of children ages 23–34 months Parents recruited by a telephone inquiry following a notice in the paper and pediatricians' offices about a study of delayed language (delayed language sample) and through lists of participants in a previous study or those whose pediatrician recommended them (typical language sample) Children recruited for study of language delay and the typical language comparison group
Rescorla and Alley, 2001[102] Study 2 Fair 2006 review	Language Development Survey Parent report	USA University research center	Parents of children ages 23–34 months Sample of parents who were recruited for an epidemiological study of language delay by a letter sent to all families of children age 2 years in 4 townships in a suburban Philadelphia county. The set of children who failed the LDS and a matched group who passed the LDS were invited to participate in Study 2. No inclusion/exclusion criteria described for epidemiological study other than age; for Study 2, sample of typical language children were matched to group with language delays on age, sex, and SES All children who failed the LDS in the epidemiological study and a matched sample who passed the LDS

Table 3. Screening Accuracy Studies From 2006 Review and New Review

Study, Reference Quality Rating Source	Screening Tool Screening Source	Country Recruitment Setting	Sample Description, Recruitment Method, Inclusion/Exclusion Criteria, Sampling for Reference Measure
Rigby and Chesham, 1981[86] Fair New	A Trial Speech Screening Test Trained examiner	UK Primary care practice	Children age 4.5 years Total population of children attending the school entrant medical examination Children were excluded if they were already receiving speech therapy No sampling for reference measure
Sachse and Von Suchodoletz, 2008[76] Sachse and Von Suchodoletz, 2009[77] Good New	ELFRA-2 (German version of MacArthur CDI, Toddler form) Parent report	Germany Community	Parents of children age 2 years Parents recruited via birth announcements in a newspaper in Germany Children were eligible if they were from a monolingual German-speaking home and did not have poor vision, a hearing impairment, an abnormal result on a hearing screening, or missing subtests on the reference standard due to poor cooperation All children classified as late talkers based on the screening and a random sample of children with typical language development
Stokes, 1997[103] Good 2006 review	Developmental Nurse Screen Trained examiner Parent Questionnaire Parent	Australia Child Health Centers in metropolitan Perth	Parents of children ages 34–40 months Letters were sent inviting parents along with a questionnaire Children were eligible if they had no developmental disability and English was their primary language Of the 1,500 parents invited, 409 consented and 398 were included (11 were removed because of a developmental disability or non-English language) No sampling for reference measure
Stott et al, 2002[104] Fair 2006 review	General Language Screen (formerly Parent Language Checklist) Parent report	UK Community within Cambridge Health authority	Children age 36 months Families with a child born during a 9-month period were invited by mail to complete the screening 1,936 of 2,590 were returned, and 75 were excluded based on predefined (but unstated) criteria Selection of both passes and fails: 596 of 636 parents were interviewed at 37 months and 419 of the children were assessed at 39 months; 254 of 279 families who were invited were followed up at 45 months
Sturner et al, 1993[105] Fair 2006 review Study 1	Fluharty Preschool Speech and Language Screening Test (Revision of Fluharty Preschool Screening Test) Trained examiner	USA School in a rural county in North Carolina	Children ages 53–68 months Parents recruited during kindergarten registration to bring their children back for screening; of the 378 who registered, 279 came for screening All kindergarten registrants Stratified samples of children completing the screening invited to return for testing; all positive screens and sample of borderline and negative screens

Table 3. Screening Accuracy Studies From 2006 Review and New Review

Study, Reference Quality Rating Source	Screening Tool Screening Source	Country Recruitment Setting	Sample Description, Recruitment Method, Inclusion/Exclusion Criteria, Sampling for Reference Measure
Sturner et al, 1993[105] Fair 2006 review Study 2	Fluharty Preschool Speech and Language Screening Test (Revision of Fluharty Preschool Screening Test) Trained examiner	USA School in a rural county in North Carolina	Children ages 55–69 months Parents recruited during kindergarten registration to bring their children back for screening; of the 533 who registered, 421 came for screening All kindergarten registrants Stratified samples of children completing the screening invited to return for diagnostic testing; all positive screens and sample of borderline and negative screens
Sturner et al, 1996[106] Fair 2006 review	Sentence Repetition Screening Test Trained examiner	USA School in a rural county in North Carolina	Children ages 54–66 months Parents recruited during kindergarten registration to bring their children back for screening All kindergarten registrants Followup of all positive screens and sample of borderline and negative screens
Ward, 1984[108] Fair 2006 review	Ward screening tool (author-created) Trained examiner	UK Community in one district in Manchester	Children ages 7–23 months All parents in district were invited to a local clinic for a hearing test between the ages of 7 and 9 months (screening occurred between 7 and 23 months) Children were ineligible if their caregivers had limited English No sampling for reference measure
Westerlund et al, 2006[78] Fair 2006 review	Swedish Communication Screening-18 (derived from Swedish MacArthur-Bates CDI) Parent report	Sweden Community sample invited to all child health centers in one county	Parents of children age 18 months All parents of 18-month-old children invited to child health care centers based on the national population register of the region All had Swedish as their primary language No sampling for reference measure
Wetherby et al, 2003[88] Fair New	Infant-Toddler Checklist from the Communication and Symbolic Behavior Scales Parent report	USA Research sample recruited from the community for a longitudinal study	Parents of children ages 6–24 months Parents recruited from public announcements, community family events, health care providers, child care providers, and public agency that provides services to infants and toddlers under part C of the Individuals With Disabilities Education Act Sample was drawn from 2,434 parents who completed the Infant-Toddler Checklist and the subset of 392 children ages 12 to 24 months whose parents also completed a Behavior Sample Inclusion criteria included completion of Behavior Sample within 2 months of the Infant-Toddler Checklist All children who failed the screen and samples of those who scored between the mean and 1 SD below the mean and those who scored at or above the mean

Abbreviations: LDS = Language Development Survey; SD = standard deviation; UK = United Kingdom; USA = United States of America.

Table 4. Screening Instruments for Speech and Language Delays and Disorders in Children Age 5 Years and Younger

Screening Instrument	Domain(s) or Skills Screened	Summary Scores	Number of Items Time to Complete	Appropriate Ages	Reliability	Screening Source
Ages and Stages Questionnaire Communication domain, 2nd edition[72,208]	Broad communication skills	• Communication	6 (at each of 19 age levels) NR	4–60 months	Coefficient alpha = 0.63–0.75	Parent report
Spanish version of Ages and Stages Questionnaire Communication domain[73]	Broad communication skills in Spanish	• Communication	6 (at each of 19 age levels) NR	4–60 months	NR	Parent report
Battelle Developmental Inventory Screening Test Communication domain[72]	Receptive and expressive language skills	• Receptive • Expressive	9 9 NR	12–96 months	NR	Trained examiner
Brigance Preschool Screen[72]	Receptive and expressive language skills	• Understanding reading (receptive language) • Expressive language	2 4 NR	45–56 months	NR	Trained examiner
Davis Observation Checklist for Texas[91]	Speaking, understanding, speech fluency, voice, and hearing	• Communication	2 to 5 behaviors (in each of 6 areas) NR	4–5 years	NR	Trained examiner
Denver Articulation Screening Exam[97]	Articulation	• Articulation	34 sound elements NR	2.5–7 years	Test-retest = 0.95	Trained examiner
Denver Developmental Screening Test Language Sector[94]	Broad language skills	• Global language	NR NR	1 month to 6 years	NR	Trained examiner
Developmental Nurse Screen[103]	Broad language	• Global language	1 NR	34–40 months	NR	Trained examiner
Early Screening Profiles[72]	Word comprehension and production	• Verbal concepts	25 NR	2.0–6.11 years	NR	Trained examiner
Fluharty Preschool Screening Test/Fluharty Preschool Speech and Language Screening Test[105,209]	Articulation, expressive and receptive language skills	• Articulation • Language	35 6–10 minutes	2–6 years	Test-retest = 0.96 to 0.98	Trained examiner
General Language Screen (GLS)/Parent Language Checklist[95,104]	Comprehension, expression, articulation, pragmatics	• Global language	11 NR	36 months	Coefficient alpha = 0.74	Parent report
Infant-Toddler Checklist[88]	Emotion and use of eye gaze, communication, gestures, sound use, word use, word understanding, object use	• Social composite • Speech composite • Symbolic composite • Total score	24 5–10 minutes (entire screening)	6–24 months	Test-retest Total = 0.86 Social = 0.70 Speech = 0.73 Symbolic = 0.79	Parent report

Table 4. Screening Instruments for Speech and Language Delays and Disorders in Children Age 5 Years and Younger

Screening Instrument	Domain(s) or Skills Screened	Summary Scores	Number of Items Time to Complete	Appropriate Ages	Reliability	Screening Source
Language Development Survey[54,102]	Expressive vocabulary and word combinations	• Expressive language	310 words, word combinations NR	18–35 months	Coefficient alpha = 0.99 Test-retest = 0.86 to 0.99 for categories	Parent report
MacArthur-Bates Communicative Development Inventory (CDI): Words and Sentences(W-S)[75,204]	Expressive vocabulary, morphology, and grammar	• Productive vocabulary	798 words, morphological markers, and sentences 20–40 minutes	16–30 months	Test-retest Complexity = 0.96 Vocabulary = 0.95	Parent report
ELFRA-2 German version of MacArthur CDI–Toddler (now CDI Words and Sentences)[76]	German expressive vocabulary, morphology, and grammar	• Global language (using all components)	260 vocabulary 25 syntax 11 morphology NR	16–30 months	NR	Parent report
Pilot Inventario-III (Spanish version of CDI-III)[73]	Expressive vocabulary, grammar, usage	• Expressive language	100 vocabulary 12 sentence usage 12 language use NR	30–37 months	Coefficient alpha Vocabulary = 0.92 Sentences = 0.95 Usage = 0.94	Parent report
Short Form of Inventarios del desarrolo de habilidades comunicativas: palabras y enuciados: Spanish version of CDI–WS[74,206]	Spanish expressive vocabulary, morphology, and grammar	• Expressive language	100 words, word combinations 15 minutes	16–30 months	NR	Parent report
Swedish Communication Screening (SCS-18) (derived from Swedish CDI)[78]	Swedish expressive and receptive vocabulary, morphology, grammar	• Word production	90 words 13 gestures NR	18 months	Coefficient alpha Word production = 0.97 Word comprehension = 0.96 Test-retest Word production = 0.97 Word comprehension = 0.89	Parent report
Northwestern Syntax Screening Test[92]	Expressive and receptive knowledge of syntactic forms	• Syntactic expression • Syntactic comprehension	40–20 expressive and 20 receptive NR	3–8 years	NR	Trained examiner
Parent Questionnaire[103]	Sentence use, comprehension, articulation, problems	• Global language	4 2 minutes	34–40 months	NR	Parent report

Table 4. Screening Instruments for Speech and Language Delays and Disorders in Children Age 5 Years and Younger

Screening Instrument	Domain(s) or Skills Screened	Summary Scores	Number of Items Time to Complete	Appropriate Ages	Reliability	Screening Source
Screening Kit of Language Development[93]	Vocabulary comprehension, story completion, sentence completion, paired sentence repetition, individual sentence repetition with and without pictures, comprehension of commands	• Global language	38–50 items per subtest 10 minutes	30–60 months	NR	Trained examiner
Sentence Repetition Screening Test[106,164]	Expressive morphology and articulation	• Global language • Articulation	15 NR	54–66 months	Coefficient alpha Language = 0.83 Articulation = 0.88	Trained examiner
Trial Speech Screening Test[86]	Articulation, grammar	• Language	12 NR	54 months	NR	Trained examiner
Ward screening tool (author created)[108]	Attention to auditory and language stimuli, prelanguage expression	• Prelinguistic behaviors	10 NR	7–9 months	NR	Parent report

Abbreviation: NR = not reported.

Table 5. Accuracy of Parent-Rated Screening Instruments for Speech and Language Delays and Disorders

Instrument and Version (Decision Cutoff Point)	Author, Year, USPSTF Quality	Age	N	Reference Instrument	Sensitivity (95% CI)[a]	Specificity (95% CI)[a]	Prevalence[a]	PPV[a,b] NPV[a,b]	PLR[a] NLR[a]
Ages and Stages Questionnaire, 2nd ed ("recommended cutoff")	Frisk et al, 2009[72] Fair	4.5 years	110	PLS-4 Comprehension PLS-4 Expression	67% (45–88) 73% (54–91)	73% (64–82) 76% (67–85)	16% 20%	32% 92% 43% 92%	2.4 0.46 3.0 0.36
Ages and Stages Questionnaire, Spanish version (NR)	Guiberson et al, 2011[74] Fair	24–35 months	45	PLS-4 Expression, Spanish edition	56% (36–77)	95% (87–100)	51%	92%[c] 67%[c]	12.4 0.46
Ages and Stage Questionnaire, Spanish version (NR)	Guiberson and Rodriguez, 2010[73] Fair	32–36 months	48	PLS-4 Expression, Spanish edition	59% (38–80)	92% (82–100)	46%	87% 73%	7.7 0.44[c]
SCS-18: Swedish CDI Words and Sentences (<8 words)	Westerlund et al, 2006[78] Fair	18 months	891	Language Observation, 3 years	50% (34–66)	90% (88–92)	4%	18%[c] 89%[c]	4.8[c] 0.56
Communicative Development Inventory (CDI): Words and Sentences (<19th percentile)	Heilmann et al, 2005[75] Fair	24 months	100	PLS-3 Expression	81% (69–94)	79% (69–89)	38%	70%[c] 89%[c]	3.9 0.23
ELFRA-2: German CDI Words and Sentences (<50 words or 50–80 words and grammatical scores below cutoff)	Sachse and Von Suchodoletz, 2008, 2009[76,77] Good	24–26 months	117	SETK-2	93% (87–99)	87% (78–97)	59%	91%[c] 89%[c]	7.3 0.08
Short Form Inventarios de Desarrollo de Habilidades Comunicativas: Spanish CDI Words and Sentences (NR)	Guiberson et al, 2011[74] Fair	24–35 months	45	PLS-4 Expression, Spanish edition	87% (73–100)	86% (72–100)	51%	87%[c] 86%[c]	6.4 0.15
Pilot Inventario–III: Spanish CDI III (NR)	Guiberson and Rodriguez, 2010[73] Fair	32–36 months	48	PLS-4 Expression, Spanish edition	82% (66–98)	81% (66–96)	46%	78% 84%	4.2[c] 0.22[c]
General Language Screen (≥2 of 11 items endorsed)	Stott et al, 2002[104] Fair	36 months	596	DPII (37 months) EAT, RDLS, BPVS (45 months)	75% (67–83) 67%[d]	81% (77–84) 68%[d]	8%[c] 4%[c]	47% 94% 31% 91%	3.9[c] 0.31[c] ---[d] ---[d]

Table 5. Accuracy of Parent-Rated Screening Instruments for Speech and Language Delays and Disorders

Instrument and Version (Decision Cutoff Point)	Author, Year, USPSTF Quality	Age	N	Reference Instrument	Sensitivity (95% CI)[a]	Specificity (95% CI)[a]	Prevalence[a]	PPV[a,b] NPV[a,b]	PLR[a] NLR[a]
Parent Language Checklist: previous version of the General Language Screen (1 failed item)	Burden et al, 1996[95] Good	36 months	425	Renfrew Action Picture Test, Bus Story, study-derived tests of phonology and comprehension	87% (82–93)	45% (39–51)	32%	42% 89%	1.6 0.28
Infant-Toddler Checklist (NR)	Wetherby et al, 2003[88] Fair	12–17 months 18–24 months	151 81	CSBS Behavior Sample	89% (80–97) 86% (75–96)	74% (66–83) 77% (64–90)	35% 52%	65%[c] 92%[c] 80%[c] 83%[c]	3.5 0.15 3.7 0.19
Language Development Survey (<50 words or no word combinations) (≥28 screening score)	Klee et al, 1998[98] Fair Klee et al, 2000[122e] Fair	24–26 months 24–26 months	64 64	Clinical judgment on infant MSEL language scales, MLU	91% (74–100) 91% (74–100)	87% (78–96) 96% (91–100)	17% 17%	59% 98% 83% 98%	6.9 0.10 24.1 0.09
Language Development Survey Study 2 (<50 words or no word combinations)	Rescorla and Alley, 2001[102] Fair	25.4 months	66	RLDS Expressive	94% (84–100)	67% (53–80)	27%	52%[c] 97%[c]	2.8 0.08
Language Development Survey Study 3 (<50 words or no word combinations)	Rescorla, 1989[54] Fair	24–34 months	81	RLDS Expressive	89% (80–98)	86% (75–97)	56%	89% 86%	6.4 0.13
Parent Questionnaire (NR)	Stokes, 1997[103] Fair	34–40 months	381	SLP rating using language sample, RDLS Comprehension	78% (66–89)	91% (88–94)	13%	56%[c] 96%[c]	8.3 0.24
Ward's Created Screening Tool (≥1 item)	Ward, 1984[108] Fair	7–23 months	1,070	REEL	80% (75–85)	92% (90–94)	24%[c]	75% 94%	9.6 0.22

[a] Calculated by EPC authors unless otherwise noted that study investigators provided data. Prevalence values were not estimated or weighted to reflect sampling.
[b] Predictive values may be questionable for studies in which prevalence exceeded 10%; the problem arises when investigators choose a random sample of children with negative screens to complete the reference measures.
[c] Study investigators provided data.
[d] Could not calculate because of lack of data.
[e] Same data using a different decision rule for screening postitive.

Abbreviations: BPVS = British Picture Vocabulary Scales; CDI = Communicative Development Inventory; CDI WS = Communicative Development Inventory, Words And Sentences; CSBS = Communication and Symbolic Behavior Scale; DPII = Developmental Profile II; EAT = Edinburgh Articulation Test; ELFRA = Elternfragebogen fur die Fruberkennung von Riskokindern; MLU = mean length of utterance; MSEL = Mullen Scale of Early Learning; N = number; NR = not reported; NLR = negative likelihood ratio; NPV = negative predictive value; PLS = Preschool Language Scale; PLR = positive likelihood ratio; PPV = positive predictive value; REEL = Receptive Expressive Emergence of Language; RDLS = Reynell Developmental Language Scale; SCS-18 = Swedish communication screening at 18 months of age; SETK-2 = Sprachentwicklungstest fur sweijahrige slindes; SETK-3/5 = Sprachentwicklungstest fur dreibis funfjahrige Kinder; SICD = Sequenced Inventory of Communication Development; SLP = speech-language pathologist, USPSTF = U.S Preventive Services Task Force.

Table 6. Accuracy of Professional/Paraprofessional-Administered Screening Instruments for Speech and Language Delays and Disorders

Instrument and Component (Decision Cutoff Point)	Author, Year, USPSTF Quality	Age	N	Reference Instrument	Sensitivity (95% CI)[a]	Specificity (95% CI)[a]	Prevalence[a]	PPV[a,b] NPV[a,b]	PLR[a] NLR[a]
Battelle Developmental Inventory Screening Test–Receptive (<1 SD)	Frisk et al, 2009[72] Fair	4.5 years	110	PLS-4 Comprehension PLS-4 Expression	56% (33–78) 68% (49–88)	70% (60–79) 86% (79–94)	16% 20%	26% 89% 56% 92%	1.8 0.89 5.0 0.37
Brigance Preschool Screen–Receptive (<1 SD) –Expressive (<1 SD)	Frisk et al, 2009[72] Fair Frisk et al, 2009[72] Fair	4.5 years 4.5 years	110 110	PLS-4 Comprehension PLS-4 Expression	61% (39–84) 91% (79–100)	60% (50–70) 78% (70–87)	16% 20%	23% 89% 51% 97%	4.2 1.5 0.12 0.65
Davis Observation Checklist for Texas (NR)	Alberts et al, 1995[91] Fair	52–67 months	59	MSCA, GFTA, informal language sample	80% (55–100)	98% (94–100)	17%	89% 96%	39.2 0.20
Denver Articulation Screening Test (<15th percentile)	Drumwright et al, 1973[97] Fair	30–72 months	150	Henja Articulation Test	92%[d]	97%[d]	----[d]	----[d]	----[d]
Denver Developmental Screening Test Language Sector (NR)	Borowitz and Glascoe, 1986[94] Fair	18–66 months	71	PLS	46% (34–58)	100% (100–100)	92%	100% 15%	---[e] 0.53
Developmental Nurse Screen	Stokes, 1997[103] Fair	34–40 months	378	SLP rating using language sample, RDLS Comprehension	76%[d]	96%[d]	----[d]	80% 96%	----[d] ----[d]
Early Screening Profile Verbal Concepts (<1 SD)	Frisk et al, 2009[72] Fair	4.5 years	110	PLS-4 Comprehension PLS-4 Expression	94% (84–100) 86% (72–100)	68% (59–78) 81% (72–89)	16% 20%	40% 98% 53% 96%	3.0 0.08 4.5 0.17
Fluharty Preschool Screening Test (Failure ≥1 subtests)	Allen and Bliss, 1987[92] Fair	36–47 months	182	SICD	60% (41–79)	81% (75–87)	14%	33% 93%	3.1 0.49
Fluharty Preschool Speech and Language Screening Test (FPSLST) Articulation (NR)	Sturner et al, 1993[105] Study 1 Fair	53–68 months	51	AAPS-R	74%[d]	96%[d]	4%[c]	50% ----[d]	----[d] ----[d]

Table 6. Accuracy of Professional/Paraprofessional-Administered Screening Instruments for Speech and Language Delays and Disorders

Instrument and Component (Decision Cutoff Point)	Author, Year, USPSTF Quality	Age	N	Reference Instrument	Sensitivity (95% CI)[a]	Specificity (95% CI)[a]	Prevalence[a]	PPV[a,b] NPV[a,b]	PLR[a] NLR[a]
FPSLST Language (NR)	Sturner et al, 1993[105] Study 1 Fair	53-68 months	51	TACL-R	38%[d]	85%[d]	17%[c]	42% ----[d]	----[d] ----[d]
FPSLST Articulation (NR)	Sturner et al, 1993[105] Study 2 Fair	55–69 months	147	TD	43%[d]	93%[d]	5%[c]	26% ----[c]	----[d] ----[d]
FPSLST Language (NR)	Sturner et al, 1993[105] Study 2 Fair	55–69 months	147	TOLD-P	17%[d]	97%[d]	22%[c]	50% ---[d]	----[d] ----[d]
Northwestern Syntax Screening Test (Failure ≥1 subtests)	Allen and Bliss, 1987[92] Fair	36–47 months	182	SICD	92% (81–100)	48% (41–56)	14%	22% 97%	1.8 0.16
Screening Kit of Language Development (SKOLD) SKOLDS-30 (<11) SKOLDS-37 (<10) SKOLDS-43 (<19) SKOLDB-30 (<9) SKOLDB-37 (<14) SKOLDB-43 (<19)	Bliss and Allen, 1984[93] Fair	30–36 months 37–42 months 43–48 months 30–36 months 37–42 months 43–48 months	47 93 100 75 91 54	SICD SICD SICD SICD SICD SICD	Standard English 100% (100–100) 100% (100–100) 100% (100–100) AA Dialect 89% (68–100) 88% (65–100) 94% (84–100)	98% (93–100) 91% (85–97) 93% (88–98) 86% (78–95) 86% (78–92) 78% (64–91)	6% 11% 9% 12% 9% 33%	75% 100% 33% 100% 60% 100% 47% 98% 37% 99% 68% 97%	44.0 0 11.1 0 15.2 0 6.5 0.13 6.0 0.15 4.2 0,07
Sentence Repetition Screening Test (<20th percentile)	Sturner et al, 1996[106] Fair	54–66 months	323	AAPS-R ITPA, Bankson	57% (45–69) 62% (45–78)	95% (93–98) 91% (87–94)	19%[c] 11%[c]	12.5 6.6	0.45 0.42

Table 6. Accuracy of Professional/Paraprofessional-Administered Screening Instruments for Speech and Language Delays and Disorders

Instrument and Component (Decision Cutoff Point)	Author, Year, USPSTF Quality	Age	N	Reference Instrument	Sensitivity (95% CI)[a]	Specificity (95% CI)[a]	Prevalence[a]	PPV[a,b] NPV[a,b]	PLR[a] NLR[a]
Structured Screening Test (<10)	Laing et al, 2002[99] Good	30 months	282	RDLS	66% (54–77)	89% (85–94)	23%	65% 90%	6.2[c] 0.38[c]
Hackney Early Language Screening Test, earlier version (≤10)	Law, 1994[100] Good	30 months	189	RDLS	98% (94–100)	69% (61–77)	26%	53% 99%	3.17 0.03
Trial Speech Screening Test (<12 elements)	Rigby and Chesham, 1981[86] Fair	54 months	438	SLP evaluation of Renfrew, RDLS, Edinburgh Articulation	80% (68–92)	93% (91–96)	10%	58% 98%	12.1 0.21

[a] Calculated by EPC authors unless otherwise noted that study investigators provided data. Prevalence values were not estimated or weighted to reflect sampling.
[b] Predictive values may be questionable for studies in which prevalence exceeded 10%; the problem arises when investigators choose a random sample of children with negative screens to complete the reference measures.
[c] Study investigators provided data.
[d] Could not calculate because of lack of data.
[e] Calculated as infinity.

Abbreviations: AAPS-R = Arizona Articulation Proficiency Scale–Revised; AA = African American; GFTA = Goldman-Fristoe Test of Articulation; ITPA = Illinois Test of Psycholinguistic Abilities; MSCA = McCarthy Scale of Children's Abilities; NR = not reported; PLS = Preschool Language Scale; RLDS = Reynell Developmental Language Scale; SICD = Sequenced Inventory of Communication Development; SLP = speech-language pathologist; TACL-R = Test for Auditory Comprehension of Language–Revised; TD = Templin-Darley Test of Articulation, Consonant Singles Subtest; TOLD-P = Test of Language Development–Primary; USPSTF = U.S. Preventive Services Task Force.

Table 7. Characteristics of Randomized, Controlled Trials of Speech and Language Interventions

Study, Country, Risk of Bias	Speech and Language Domains	Intervention	Length of Intervention, Timing of Outcome Assessment	Inclusion/Exclusion Criteria	Child's Age at Baseline (Months)	N Patients Randomized
Almost et al, 1998[134] Canada Fair	Speech sounds (phonology) Language (expressive)	G1: Clinician-directed individualized therapy G2: Delayed tx	Two 30-min sessions per week for 4 mo (1,040 minutes total). Outcome assessment at 4 mo.	Inclusion: severe phonological disorder, normal receptive language, hearing, oral structures and function, and sufficient attention span	G1: 42.5 (range, 33–61) G2: 42.5 (range, 33–55)	Overall: 26 G1: 13 G2: 13
Fricke et al, 2013[125] United Kingdom Fair	Language (expressive and receptive) Speech sounds (phonological awareness)	G1: Oral language group intervention to teach skills related to vocabulary, expressive vocabulary, and grammatical competence and to encourage active listening and build confidence in independent speaking G2: Usual nursery/primary school activities	Three 15-min group sessions per wk for 10 wk, increasing to 5 sessions per wk (three 30-min group sessions plus two 15-min individual sessions) for 20 wk (2,850 min total). Outcome assessment at end of tx (30 wk) and at 6 mo followup.	Inclusion: 12 children in each of 15 nursery schools with the lowest mean verbal composite scores	G1: 48 G2: 48 (Screening occurred at 48 months)	Overall: 180 G1: 90 G2: 90
Gibbard, 1994[136] United Kingdom Fair	Language (expressive and receptive)	G1: Parent group S&L training, mix of approaches focusing on activities for parent to use with children, many from the Derbyshire Language Scheme G2: Wait list	60–75 min every other wk for 6 mo (780–975 min total). Outcome assessment at 6 mo.	Inclusion: Age 27–39 mo; little or no expressive language; no general developmental delay, medical condition indicative of a language delay, or previous S&L therapy	G1: 35 (range, 29–39) G2: 32 (range: 27–39)	Overall: 36 G1: 18 G2: 18
Girolametto et al, 1996[137] Companion: Girolametto et al, 1997[138] Canada Fair	Language (expressive) Speech sounds (phonology)	G1: Hanen Program for Parents training program modified to be consistent with a focused stimulation of children's language G2: Wait list	Eight 150-min parent group sessions (1,200 min total) and three home visits over 11 wk. Outcome assessment 3 wk following end of tx.	Inclusion: Expressive language delay, single-word stage of language development, only English spoken in home Exclusion: Major sensory impairment, oral motor problems, neurological problems, ASD	G1: 28.7 (range, 25–35) G2: 28.6 (range, 23–34)	Overall: 25 G1: 12 G2: 13
Glogowska et al, 2000[135] United Kingdom Good	Language (expressive and receptive) Speech sounds (phonology)	G1: Individually tailored "routine" S&L therapy by a therapist G2: Wait list "watchful waiting"	Average of 6.2 hr of therapy over 12 mo (372 min total). Outcome assessment at 12 mo.	Inclusion: Preschoolers in S&L therapy based on general or expressive language group scores on Preschool Language Scale or phonology group scores	G1: 34.2 (range, 18–42) G2: 34.2 (range, 24–42)	Overall: 159 G1: 71 G2: 88 (18 crossed over before study end)

Table 7. Characteristics of Randomized, Controlled Trials of Speech and Language Interventions

Study, Country, Risk of Bias	Speech and Language Domains	Intervention	Length of Intervention, Timing of Outcome Assessment	Inclusion/Exclusion Criteria	Child's Age at Baseline (Months)	N Patients Randomized
Jones et al, 2005[126] New Zealand Fair	Fluency	G1: Lidcombe Program of Early Stuttering according to the manual G2: Delayed tx	Conducted in two stages. During stage 1, parent conducted program each day and speech pathologist once per wk. Outcome assessment at 9 mo.	Inclusion: Age 3–6 years, diagnosed stuttering with ≥2% of syllables stuttered, English-speaking Exclusion: Stuttering, tx in previous 12 mo, onset in 6 mo before recruitment	G1: 56.4 G2: 46.8 (range, 36–72)	Overall: 54 G1: 29 G2: 25
Lewis et al, 2008[127] Australia Fair	Fluency	G1: Lidcombe Program of Early Stuttering, a manualized intervention delivered through telehealth (phone, video, and audio recordings) G2: Delayed tx	Typically at least 1 weekly phone consultation; video demonstrations, phone and mail support. Outcome assessment at 9 mo.	Inclusion: Stuttering for >6 mo, no current or previous tx, all other development normal, parent and child English-speaking	Mean: NR (range, 36–54)	Overall: 22 G1: 9 G2: 13
Morgan and Vogel, 2009[131] Australia Systematic review Fair	Childhood apraxia of speech	RCT tx studies of interventions delivered by S&L therapists	No studies met inclusion criteria.	Include: Age 3–16 yrs	NA	NA
Robertson et al, 1997[140] United States Fair	Language (expressive and receptive)	G1: Unstructured play sessions in "house" area with normal peers G2: No play sessions with normal peers	At least four 15- to 20-min sessions over 3 wk (minimum of 60 min). Outcome assessment 3 wk following end of tx.	Inclusion: Language impairment and placement in language-based early childhood classroom; WISC-R score of ≥85; poor receptive and expressive language; no motor, emotional, or physical handicaps; no hearing or vision problems; monolingual English	G1: 49.8 G2: 49.6 (overall range, 44–61)	Overall: 20 G1: 10 G2: 10
Robertson et al, 1999[139] United States Fair	Language (expressive and receptive) Speech sounds (intelligibility)	G1: Speech-language pathologist directed small group therapy of no more than four children G2: Wait list	150 min per wk for 12 wk (1,800 min total). Outcome assessment at end of tx.	Include: Normal hearing, oral and speech motor abilities, no frank neurological impairment, monolingual English-speaking homes, CDI vocabulary scores <10th percentile, no other delays, no prior S&L therapy	G1: 25.6 (range, 21–30) G2: 24.6 (range, 21–28)	Overall: 21 G1: 11 G2: 10

Table 7. Characteristics of Randomized, Controlled Trials of Speech and Language Interventions

Study, Country, Risk of Bias	Speech and Language Domains	Intervention	Length of Intervention, Timing of Outcome Assessment	Inclusion/Exclusion Criteria	Child's Age at Baseline (Months)	N Patients Randomized
Shelton et al, 1978[141] United States Fair	Speech sounds (phonology, articulation) Language (expressive and receptive)	G1: Parent-directed speech sound listening/discrimination activities (listening group) G2: Parent-child storybook interaction (reading and talking group) G3: Control group	G1: 5 min per day, 5 days per wk for 57 days (1,425 min total) G2: 15 min per day, 5 days per wk for 57 days (4,275 min total). Outcome assessment at end of tx.	Inclusion: Below cut-off score on Templin-Darley Articulation Screening Test, pass audiometric screening	G1: 47 G2: 49 G3: 39 (overall range, 27–55)	Overall: 45 G1: 15 G2: 15 G3: 15
Wake et al, 2011[128] Clustered randomized trial Australia Good	Language (expressive and receptive)	G1: Modified "You Make the Difference" (Hanen parent training program): low-intensity version of parent-delivered toddler language promotion program for toddlers identified as slow to talk on universal screening G2: Usual care (not defined)	120 min per wk for 6 wk (720 min total). Outcome assessment at child age 2 yr (12–14 wk following program completion) and 3 yr.	Inclusion: ≤20th percentile in expressive vocabulary at 18 mo Exclusion: Cognitive delay, major medical conditions, or suspected ASD; parents with insufficient English	G1: 18.1 (SD, 0.7) G2: 18.1 (SD, 0.8)	Overall: 301 G1: 158 G2: 143
Wake et al, 2013[130] Australia Fair	Language (expressive and receptive) Speech sounds (phonological awareness)	G1: 18 1-hr home-based therapy sessions conducted by a "language assistant" G2: No intervention control; "free to participate in community-based tx"	18 in-home 1-hr targeted sessions in 3 blocks of weekly sessions for 6 wk starting every 3 mo.	Inclusion: Expressive and/or receptive language scores >1.25 SD below normal Exclusion: Intellectual disability, major medical conditions, hearing loss >40 dB in the better ear, ASD, parents with insufficient English	G1: 50 G2: 49 (recruited at 48 mo)	Overall: 200 G1: 99 G2: 101
Yoder et al, 2005[129] United States Fair	Language (expressive) Speech sounds (intelligibility)	G1: Broad target recasts intervention G2: No intervention control; "free to participate in community-based tx"	Three 30-min tx sessions per wk for 6 mo (2,340 min total). Outcome assessment at end of tx and at followup (8 mo later).	Inclusion: Specific language and speech accuracy impairments; nonverbal IQ >80; no hearing impairment; monolingual English; no oral motor disorders	G1: 44.3 (SD, 7.6) G2: 43.2 (SD, 9.6)	Overall: 52 G1: 26 G2: 26

Abbreviations: ASD = autism spectrum disorder; CDI = MacArthur-Bates Communicative Development Inventory; G = group; min = minute; mo = month; N = number; NR = not reported; RCT = randomized, controlled trial; SD = standard deviation; tx = treatment; WISC-R = Wechsler Intelligence Scale for Children; wk = week; yr = year.

Table 8. Outcomes of Randomized, Controlled Trials of Speech and Language Interventions

Study, Country, Risk of Bias	Speech and Language Domains	Speech and Language Outcomes (KQ 5) Nonspeech and Language Outcomes (KQ 6)	Summary of Findings
Almost et al, 1998[134] Canada Fair	Speech sounds (phonology) Language (expressive)	Difference measured through ANCOVA to adjust for baseline, tx, and time[a] **Speech and Language (KQ 5)** Phonological processes (APP-R): F=8.64, d=1.15 (p=0.007) Articulation (GFTA): F=8.92, d=1.17 (p=0.007) Consonants correct (PCC): F=8.06, d=1.11 (p=0.009) Mean length of utterances: F=0.23, d=0.18 (p=0.638) **Nonspeech and Language (KQ 6)** None reported	S&L: More improvement in 3 of 4 measures of phonology Non-S&L: No measures reported
Fricke et al, 2013[125] United Kingdom Fair	Language (expressive and receptive) Speech sounds (phoneme awareness)	Difference measured through structural equation modeling to allow for missing data and clustering of children within schools **Speech and Language (KQ 5)** Language at end of tx: d=0.80 (p<0.01); followup: d=0.83 (p<0.001) Narrative at end of tx: d=0.39 (p=0.003); followup: d=0.30 (p=0.041) Phoneme awareness at end of tx: d=0.49 (p<0.031); followup: d=0.49 (p=0.01) **Nonspeech and Language (KQ 6)** Literacy at end of tx: d=0.31 (p=0.07); followup: d=0.14 (p=0.354) Letter knowledge at end of tx: d=0.41 (p<0.001) Difference in reading comprehension at followup: 0.97 (95% CI, 0.40 to 1.54), d=0.52 (p=0.001)	S&L: Better performance on language, narrative, and phoneme awareness at posttest and 6-mo followup Non-S&L: Better reading comprehension but no difference in reading accuracy at 6-mo followup
Gibbard, 1994 [136] Study 1 United Kingdom Fair	Language (expressive and receptive)	All differences measured through ANCOVA to adjust for baseline, tx, and time[a] **Speech and Language (KQ 5)** Reynell Expressive: F=64.89, d=2.69 (p<0.001) Reynell Comprehension: F=34.11, d=1.95 (p<0.001) Derbyshire One Word Score: F=34.24, d=1.95 (p<0.001) Derbyshire Total Score: F=31.94, d=1.88 (p<0.001) Renfrew Grammatical Ability: F=20.36, d=1.50 (p<0.001) Renfrew Information: F=32.0, d=1.89 (p<0.001) Mean length of utterances: F=24.44, d=1.65 (p<0.001) **Nonspeech and Language (KQ 6)** None reported	S&L: More improved in all measures of S&L Non-S&L: No measures

Table 8. Outcomes of Randomized, Controlled Trials of Speech and Language Interventions

Study, Country, Risk of Bias	Speech and Language Domains	Speech and Language Outcomes (KQ 5) Nonspeech and Language Outcomes (KQ 6)	Summary of Findings
Girolametto et al, 1996[137] Companion: Girolametto et al, 1997[138] Canada Fair	Language (expressive) Speech sounds (phonology)	Difference measured through MANCOVA to adjust for baseline, tx, and time[a] **Speech and Language (KQ 5)** Expressive vocabulary: Size: F=4.90, d=0.88 (p<0.01) Number of different words in interaction: F=7.96, d=1.13 (p<0.02) Number of learned control words: F=17.25, d=1.67 (p<0.01) Talkativeness: F=2.38, d=0.62 (p<0.06) Parent report on structural complexity: F=2.85, d=0.68 (p<0.04) Consonant inventory: F=4.34 (p<0.01) Early consonants, d=1.0; middle consonants, d=1.1; late consonants, d= 0.6 Percent of consonants correct: d=−0.3 (p=NS) Number of vocalizations: p=NS Syllable structure level (level 3 vocalizations): F=6.74, d=0.9 (p<0.01) **Nonspeech and Language (KQ 6)** None reported	S&L: More improved in measures of vocabulary size, use of more different words, more structurally complete and complex utterances, more multiword utterances, and larger inventory of consonants. No difference in number of vocalizations or rate of words per minute Non-S&L: No measures
Glogowska et al, 2000[135] United Kingdom Good	Language (expressive and receptive) Speech sounds (phonology)	All differences measured through ANCOVA to adjust for baseline, tx, and time (95% CI)[a] **Speech and Language (KQ 5)** Auditory comprehension, average of difference at 6 & 12 mo: 4.1 (0.5 to 7.6), d=~0.3 (p=0.025) Expressive language, average of difference at 6 & 12 mo: 1.4 (−2.1 to 4.8) (p =0.44) Phonology error rate, average of difference at 6 & 12 mo: −4.4 (−12.0 to 3.3) (p=0.26) Bristol Language Development Scale, average of difference at 6 & 12 mo: 0.1 (−0.4 to 0.6) (p=0.73) Improvement by 12 mo on clinical criteria used for study entry: OR=1.3 (0.67 to 2.4) (p=0.46) **Nonspeech and Language (KQ 6)** Well-being, average of difference at 6 & 12 mo: 0.04 (−0.2 to 0.3) Attention level, average of difference at 6 & 12 mo: 0.02 (−0.3 to 0.3) (p=0.91) Play level, average of difference at 6 & 12 mo: 0.04 (−0.2 to 0.2) Vineland Socialization Scale, average of difference at 6 & 12 mo: 0.6 (−3.1 to 4.2)	S&L: More improved auditory comprehension, no difference in expressive language, phonology error rate, and language development Non-S&L: No difference in well-being, attention, play level, or socialization skills
Jones et al, 2005[126] New Zealand Fair	Fluency	Percent syllables stuttered: adjusted mean difference (95% CI)[a] **Speech and Language (KQ 5)** 2.3 (0.8 to 3.9) (p=0.003) Difference measured through logistic regression to adjust for baseline Odds of <1% of syllables stuttered: OR=0.13 (0.03 to 0.63) (p=0.011) **Nonspeech and Language (KQ 6)** None reported	S&L: Greater reduction in percent of syllables stuttered and greater odds of stuttering <1% of syllables Non-S&L: No measures

Table 8. Outcomes of Randomized, Controlled Trials of Speech and Language Interventions

Study, Country, Risk of Bias	Speech and Language Domains	Speech and Language Outcomes (KQ 5) Nonspeech and Language Outcomes (KQ 6)	Summary of Findings
Lewis et al, 2008[127] Australia Fair	Fluency	Difference measured through ANCOVA to adjust for baseline, tx, and time (95% CI) **Speech and Language (KQ 5)** Stuttering frequency at 9 mo: 69% (13% to 89%) (p=0.04) Adjusting for patient characteristics: 73% (25% to 90%) (p=0.02) **Nonspeech and Language (KQ 6)** None reported	S&L: Greater reduction in perecnt of syllables stuttered during speech sample; more "responders" (i.e., decrease of >80% in stuttered syllables) Non-S&L: No measures
Robertson et al, 1999[139] United States Fair	Language (expressive and receptive) Speech sounds (intelligibility)	Difference measured through ANCOVA to adjust for baseline, tx, and time[a] **Speech and Language (KQ 5)** Mean length of utterances: F=10.33, d=1.40 (p<0.003) Total number of words: F=46.83, d=2.99 (p<0.001) Number of different words: F=41.05, d=2.80 (p<0.001) Number of different words, controlling for number of words: F=24.03, d=2.14 (p<0.001) Lexical repertoire: F=46.86, d=2.99 (p<0.001) Percentage of intelligible utterances: F=24.44, d=2.16 (p<0.001) **Nonspeech and Language (KQ 6)** Vineland Socialization Scale: F=12.15, d=1.52 (p=0.003) Parental stress (child domain of the PSI): F=53.32, d=3.19 (p<0.001)	S&L: More improvement in Mean length of utterances, number of words, vocabulary size, lexical diversity, and percent of intelligible utterances Non-S&L: More improvement in socialization skills, greater reduction in parental stress
Robertson et al, 1997[140] United States Fair	Language (expressive and receptive)	Difference measured through ANCOVA to adjust for baseline, tx, and time[a] **Speech and Language (KQ 5)** Number of words: F=70.72 (p<0.01) Number of different words: F=73.79 (p<0.01) Play theme–related acts: F=99.80 (p<0.01) Linguistic markers: F=73.51 (p<0.01) **Nonspeech and Language (KQ 6)** None reported	S&L: More words used; greater verbal productivity; more lexical diversity, reported play acts, and linguistic markers Non-S&L: No measures

Table 8. Outcomes of Randomized, Controlled Trials of Speech and Language Interventions

Study, Country, Risk of Bias	Speech and Language Domains	Speech and Language Outcomes (KQ 5) Nonspeech and Language Outcomes (KQ 6)	Summary of Findings
Shelton et al, 1978[141] Study 1 United States Fair	Speech sounds (phonology, articulation) Language (expressive and receptive)	Difference between the 3 groups measured through ANCOVA to adjust for baseline, tx, and time,[a] results always compared with control **Speech and Language (KQ 5)** Test of Auditory Discrimination (quiet), Listening: d= 0.17; Reading & Talking: d=−0.05 (p=0.90) Test of Auditory Discrimination (noise), Listening: d=−0.41; Reading & Talking: d=0.91; (p=0.03) (greatest improvement in controls) Northwestern Syntax Screening Test, Listening: d=−0.17; Reading & Talking: d=0.10 (p=0.72) Auditory Association Subtest of ITPA, Listening: d=0.50; Reading & Talking: d=0.51 (p=0.25) Discrimination Task, Listening: d=0; Reading & Talking: d=−0.05 (p=1.00) Error Recognition, Listening: d=0.17; Reading & Talking: d=0.40 (p=0.26) Templin-Darley Articulation Screening Test, Listening: d=0.65; Reading & Talking: d=0.02 (p=0.07) McDonald Screening Deep Test of Articulation, Listening: d=0.06; Reading & Talking: d=−0.38 (p=0.51) **Nonspeech and Language (KQ 6)** None reported	S&L: No difference in improvement between intervention and control groups in relation to articulation, auditory discrimination, or auditory association Non-S&L: No measures
Wake et al, 2011[128] Australia Good	Language (expressive and receptive)	All differences measured through random-effects regression to adjust for clustering, potential confounders, and baseline measures (95% CI)[a] **Speech and Language (KQ 5)** MCDI vocabulary raw score At 2 yr: 2.1 (−3.0 to 7.2), d=0.004 (p=0.42) At 3 yr: 4.1 (−2.3 to 10.6), d=0.08 (p=0.21) PLS expressive communication standard score At 2 yr: 1.2 (−1.6 to 4.0), d=0.02 (p=0.41) EVT expressive vocabulary standard score At 3 yr: −0.5 (−4.4 to 3.4), d=−0.08 (p=0.80) PLS auditory comprehension standard score At 2 yr: 1.4 (−2.2 to 5.0), d=−0.01 (p=0.44) At 3 yr: −0.3 (−4.2 to 3.7), d=−0.06 (p=0.90) **Nonspeech and Language (KQ 6)** CBCL externalizing behavior raw score At 2 yr: −0.3 (−1.6 to 1.1), d=−0.04 (p=0.71) At 3 yr: −0.1 (−1.6 to 1.4), d=−0.01 (p=0.86) CBCL internalizing behavior raw score At 2 yr: 0.1 (−0.9 to 1.1), d=−0.06 (p=0.78) At 3 yr: −0.1 (−1.3 to 1.2), d=−0.06 (p=0.92)	S&L: No difference in expressive or receptive language outcomes at age 2 or 3 years Non-S&L: No difference in internalizing or externalizing problem behaviors at age 2 or 3 years

Table 8. Outcomes of Randomized, Controlled Trials of Speech and Language Interventions

Study, Country, Risk of Bias	Speech and Language Domains	Speech and Language Outcomes (KQ 5) Nonspeech and Language Outcomes (KQ 6)	Summary of Findings
Wake et al, 2013[130] Australia Fair	Language (expressive and receptive) Speech sounds (phonological awareness)	Mean difference (95% CI) measured at age 5, adjusting for sex, mother's education, recruitment from Let's Read or Let's Learn Language, baseline expressive and receptive language scores, and baseline measure of the outcome being considered, when available **Speech and Language (KQ 5)** Expressive language: 2.0 (−0.5 to 4.4), d=0.2 (p=0.12) Receptive language: 0.6 (−2.5 to 3.8), d=0.05 (p=0.69) Pragmatic language: −1.0 (−3.7 to 1.6), d=−0.1 (p=0.45) Phonological awareness: 5.0 (2.2 to 7.8), d=0.6 (p<0.001) **Nonspeech and Language (KQ 6)** Letter knowledge: 2.4 (0.3 to 4.5), d=0.3 (p=0.03) Number of behavior problems: −0.5 (−1.7 to 0.7), d=−0.1 (p=0.43) Health-related quality of life: −0.8 (−5.2 to 3.5), d=−0.05 (p=0.71)	S&L: No difference in expressive or receptive language outcomes; better phonological awareness Non-S&L: Better letter knowledge; no difference in behavior problems or health-related quality of life
Yoder et al, 2005[129] US Fair	Language (expressive) Speech sounds (intelligibility)	Difference measured through ANCOVA to adjust for baseline, tx, and time **Speech and Language (KQ 5)** At end of tx: p=NS 8 mo following end of tx: p=NS Among children who began tx with lowest articulation scores, difference in mean length of utterances at end of tx (p=0.01) and at 8 mo followup (p=0.03) **Nonspeech and Language (KQ 6)** None reported	S&L: No difference between groups in change over time Non-S&L: No measures

[a] Cohen's d calculated by the review authors.

Abbreviations: ANOVA = analysis of variance; APP-R: Assessment of Phonological Processes-Revised; CBCL = Child Behavior Checklist; CI = confidence interval; d = Cohen's d; EVT = Expressive Vocabulary Test; GFTA = Goldman-Fristoe Test of Articulation; ITPA = Illinois Test of Psycholinguistic Ability; MCDI = MacArthur-Bates Communicative Development Inventory; MANCOVA = multivariate analysis of variance; mo = month; NA = not applicable; NS = not significant; OR = odds ratio; PCC = percentage consonants correct; PLS = Preschool Language Scale; PSI = Parental Stress Index; S&L = speech and language; tx = treatment; VABS = Vineland Adaptive Behavior Scale; yr = year.

Table 9. Summary of Evidence

Intervention/ Screening	Trials, k Observations, n	Major Limitations	Consistency	Applicability	Quality Ratings	Summary of Findings
Key Question 1 (effect of screening on speech and language and other outcomes)						
NA	k=0	NA	NA	NA	NA	No studies addressed the overarching key question.
Key Question 2 (accuracy of screening)						
Parent-rated speech and language screening	k=13; n=3,994	Different reference measures, some studies had small sample sizes	Mixed	Many studies included children with language delays or disabilities and typical language development rather than unselected samples; some studies were in countries with different health care structures	2: Good 11: Fair	CDI and LDS have the highest sensitivity (median, 82% and 91%); specificity is comparable across the CDI, LDS, and ASQ (87%, 86%, and 87%). Sensitivity and specificity are generally comparable across the toddler and preschool years; prediction over 1 year indicates some reduction in accuracy for the CDI and LDS.
Professional/ paraprofessonal-administered speech and language screening	k=12[a]; n=2,911	Few studies examined the same screening instrument, different reference measures used, criteria for failure not always explicit	Mixed	Not clear how many of the instruments would actually be used today in the United States; would require some training of staff to administer to children	2: Good 9: Fair	Great variability in sensitivity and specificity; sensitivity ranged between 17% and 100% (median, 74%), specificity ranged between 31% and 100% (median, 91%).
Key Question 3 (adverse effects of screening)						
NA	k=0	NA	NA	NA	NA	No studies addressed this question.
Key Question 4 (role of surveillance in identifying children)						
NA	k=0	NA	NA	NA	NA	No studies addressed this question.
Key Question 5 (speech and language benefits of treatment)						
Language	k=9; n=839	Small sample sizes, limited replication of positive treatment approaches, limited use of manualized approaches, lack of consistency in outcome measurement	Inconsistent	4 of 9 trials conducted in United States but all in English; 2 manualized programs evaluated, 1 of which is relatively expensive	2: Good 7: Fair	5 of 9 trials reported significant positive results.
Speech sounds	k=5; n=307	Limited replication of positive treatment approaches, limited use of manualized approaches	Inconsistent	Only 1 of the trials was conducted in the United States but all in English; 2 were delivered by parents, 1 individualized	1: Good 4: Fair	2 of 5 trials reported significant positive results.

Table 9. Summary of Evidence

Intervention/ Screening	Trials, k Observations, n	Major Limitations	Consistency	Applicability	Quality Ratings	Summary of Findings
Fluency	k=2; n=76	Only 1 approach evaluated in 1 fluency disorder (stuttering)	Consistent	2 trials of the same manualized treatment for stuttering, both conducted in English but outside the United States	2: Fair	The Lidcombe Program of Early Stuttering can reduce stuttering in children.
Key Question 6 (other benefits of treatment than speech and language)						
NA	k=4; n=661	Outcomes and comparisons vary across studies	Inconsistent	All outcomes measured are relevant to U.S. population, all studies conducted in English, 1 study in the United States	2: Good 2: Fair	A limited number of disparate outcomes were measured across a minority of studies.
Key Question 7 (harms of treatment)						
NA	k=2; n=180	Harms of treatment generally not measured in studies	Inconsistent	Only parent stress and child well-being measured	1: Good 1: Fair	Studies generally did not report on harms.

[a] Two studies included both parent-rated and professional/paraprofessional-administered screening instruments.

Abbreviations: ASQ = Ages and Stages Questionnaire; CDI = Communicative Development Inventory; LDS = Language Development Survey; NA = not applicable.

Table 10. Risk Factors: Earlier Speech and Language Concerns Through Parental Education

Author, Year Analysis Approach[a]	Speech and Language Outcome	Population (N)	Age	Earlier Speech and Language Concerns	Family History of Language Disorders	Male	SES	Maternal Age	Parental Education
Adams-Chapman et al, 2013[180] Multivariate	Language delay composite measure (expressive and receptive)	Preterm infants born ≤26 weeks included in U.S. Neonatal Research Network Follow-Up Study (N=1,477)	18–22 months	NR	NR	↑	NR	NR	Mom <high school: ↑
Alston and St. James-Roberts, 2005[165] Univariate	Language and communication difficulty	Infants who completed the WILSTAAR early language and communication screening assessment (N=60)	Mean age: Not at-risk: 9.4 months At-risk: 10.0 months	NR	NR	0	0	Dad age: ↑	NR
Campbell, 2003[173] Multivariate	Speech delay	Cohort of children being followed to study otitis media, Pittsburgh (N=639)	36 months	NR	↑	↑	NR	NR	Low Mom: ↑
Choudhury and Benasich, 2003[175] Case control: univariate	Low language as measured by PLS-3: expressive, receptive, and total score; Stanford-Binet: verbal vocabulary, verbal comprehension; CELF-P: word structure, sentence structure	Cohort with family history of specific language impairment and matched controls, New York City area (N=92)	36 months	NR	All measures except CELF-P sentence structure: ↑	↑	NR	NR	NR
Desmarais et al, 2008[171] Analysis approach varies by study	Late talking	Review of 25 publications	18–39 months	NR	↑	NR	↑	NR	0
Everitt et al, 2013[215] Case control	Persistent expressive language delay vs. typical language development among children with specific expressive language delay 1 year earlier	Nursery school children in Scotland (N=94)	4–5 years	Specific expressive language delay: 0 Received S&L therapy: 0 Poorer performance on PLS-3 AC, PLS-3 EC, and Recalling Sentences subtest 1 year earlier	0	0	NR	NR	Mother: 0 Father: 0

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Author, Year Analysis Approach[a]	Speech and Language Outcome	Population (N)	Age	Earlier Speech and Language Concerns	Family History of Language Disorders	Male	SES	Maternal Age	Parental Education
Foster-Cohen et al, 2010[185] Multivariate	Poorer receptive and expressive language ability	Very preterm cohort compared with full-term born in New Zealand (N=204)	4 years	NR	NR	NR	NR	NR	NR
Fox et al, 2002[188] Multivariate	Functional speech disorders	German cohort (N=113)	32–86 months	NR	↑	NR	NR	NR	NR
Glascoe and Leew, 2010[216] Multivariate	Delay in communication (expressive and receptive language)	U.S. nationally representative sample included in Brigance Infant and Toddler Screen study (N=382)	2 weeks to 24 months	NR	NR	NR	Employment: 0	NR	0
Hammer, 2010[174] Multivariate	Parent-reported speech-language impairment	Head Start Family and Child Experiences Survey cohort (N=1,015)	3–4 years (mean, 50 months)	NR	NR	↑	NR	NR	0
Harrison and McLeod, 2010[179] Multivariate	Expressive speech and language concern, receptive speech and language concern, low receptive vocabulary	Growing Up in Australia–The Longitudinal Study of Australian Children cohort (N=4,980)	51–67 months, 80% were 54–60 months	NR	NR	All 3 outcomes: ↑	Household income: Expressive and receptive: 0 Vocabulary: ↓ Financial hardship, all outcomes: 0	Expressive and receptive: 0 Vocabulary: ↓	Mom: Expressive and receptive: 0 Vocabulary: ↓ Dad, all outcomes: 0
Henrichs et al, 2011[81] Multivariate	Expressive vocabulary delay (late bloomers, late onset, or persistent delay)	Generation R Study cohort, The Netherlands (N=3,759)	Mean, 31.6 months	Receptive delay at 18 months: ↑	NR	NR	0	Late bloomer: ↑ Late onset: ↓	Late onset: ↓ Persistent: ↓
Kerstjens et al, 2011[189] Multivariate	Ages and Stages Communication domain delays	Community-based and preterm cohorts in The Netherlands (N=1,983)	43–49 months (4-year-old assess-ment)	NR	NR	Included in model but NR	NR	NR	In model but NR
Kerstjens et al, 2009[186] Multivariate	Ages and Stages Communication domain delays	Community-based and preterm cohorts in The Netherlands (N=1,893)	43–49 months (4-year-old assess-ment)	NR	NR	↑	Low: ↑	NR	0

Table 10. Risk Factors: Earlier Speech and Language Concerns Through Parental Education

Author, Year Analysis Approach[a]	Speech and Language Outcome	Population (N)	Age	Earlier Speech and Language Concerns	Family History of Language Disorders	Male	SES	Maternal Age	Parental Education
Kerstjens et al, 2012[190] Multivariate	Ages and Stages Communication domain delays	Community-based and preterm cohorts in The Netherlands (N=1,983)	43–49 months (4-year-old assess-ment)	NR	NR	Included in model but NR	NR	NR	In model but NR
Law et al, 2009[46] Multivariate	Specific language impairment (SLI); nonspecific language impairment (N-SLI)	British Cohort Study cohort (N=9,132)	5 years (60 months)	Ever seen speech and language therapist: SLI ↑, N-SLI ↑	NR	SLI: ↓ N-SLI: ↓	Overcrowding SLI: ↑ N-SLI: ↑	NR	Mom: SLI: 0 N-SLI: ↓ Parent poor reader: SLI: ↑ N-SLI: ↑
Law et al, 2012[172] Multivariate	Nonspecific language impairment (N-SLI)	U.K. nationwide birth cohort (N=11,383)	60 months	Vocabulary at age 3 years	NR	NR	NR	NR	Mom: ↓
Mossabeb et al, 2012[83] Multivariate	Language delay measured through number of words	Born at <34 weeks in Pennsylvania hospital (N=178)	26 months	NR	NR	↑	NR	NR	NR
O'Leary, 2009[220] Multivariate	Ages and Stages Communication domain delays	Randomly Ascertained Sample of Children born to moms in Western Australia Survey of Health (RASCAL) cohort (N=1,692)	24-month survey	NR	NR	NR	0	Young maternal age during pregnancy: ↑	0
Pena et al, 2011[183] Multivariate	Risk for language impairment	Latino bilingual pre-kindergarten in central Texas and northern Utah (N= 1,029)	58–68 months Older age: ↓	NR	NR	NR	NR	NR	Mom: ↓
Potijk et al, 2013[191] Multivariate	Delay communication domain score on Ages and Stages Questionnaire	Community-based sample of preterm- and term-born children (Longitudinal Preterm Outcome Project), The Netherlands (N=1,470)	4 years	NR	NR	In model but NR	Lower SES: ↑	In model but NR	NR
Pruitt, 2010[166] Univariate	Specific language impairment	African American children in Louisiana (N=161)	25–100 months	NR	↑	NR	NR	NR	Mom: 0

Table 10. Risk Factors: Earlier Speech and Language Concerns Through Parental Education

Author, Year Analysis Approach[a]	Speech and Language Outcome	Population (N)	Age	Earlier Speech and Language Concerns	Family History of Language Disorders	Male	SES	Maternal Age	Parental Education
Reilly et al, 2007[178] Multivariate	Poorer expressive language as measured by the Communication and Symbolic Behavior Scales (CSBS) and MacArthur-Bates Communication Development Inventory (CDI)	Early Language in Victoria Study cohort, Australia (N=1,720)	24 months	NR	CSBS and CDI: ↑	CSBS and CDI: ↑	CSBS and CDI: 0	CSBS: ↑ CDI: 0	Mom, CSBS and CDI: 0
Reilly, 2009[177] Multivariate	Stuttering onset by age 3 years	Prospective community-ascertained cohort (Early Language in Victoria Study), Melbourne, Australia (N=1,619)	24–36 months	Higher communication and symbolic behavior scales scores at age 2 years: 0 Higher Communication Development Inventory raw vocabulary score at age 2 years: ↑	0	↑	0	NR	Mom: ↑
Reilly et al, 2013[181] Multivariate	Stuttering onset by age 4 years	Prospective community-ascertained cohort (Early Language in Victoria Study), Melbourne, Australia (N=1,619)	4 years	Higher communication and symbolic behavior scales scores at age 2 years: ↑	0	↑	0	NR	Mom higher: ↑
Roth, 2011[222] Multivariate	Severe or moderate language based on parent report	Norwegian mother and child cohort (N=35,135 or 36,136 depending on the analysis)	36-month followup	NR	NR	NR	NR	NR	Included in model but NR
Schjolberg, 2011[192] Multivariate	Slow language development	Norwegian mother and child cohort (N=42,107)	18 months	NR	NR	↑	Income: ↓	0	Mom: ↓ Dad: 0
Singer et al, 2001[184] Multivariate	Speech-language development delay	Very low birth weight cohort, with and without bronchopulmonary dysplasia, and controls, Cleveland, OH (N=246)	36 months	NR	NR	NR	↓	NR	NR

Table 10. Risk Factors: Earlier Speech and Language Concerns Through Parental Education

Author, Year Analysis Approach[a]	Speech and Language Outcome	Population (N)	Age	Earlier Speech and Language Concerns	Family History of Language Disorders	Male	SES	Maternal Age	Parental Education
Tallal et al, 1989[182] Univariate	Specific language impairment	Cases and control from San Diego, CA, longitudinal study (N=130)	48–59 months	NR	Mom: ↑ Dad: ↑ Siblings: ↑	NR	NR	NR	Mom held back and history of learning problems: ↑ Dad held back: ↑

[a] In each study identified as reporting multivariate results, the statistical significance of each risk factor is presented controlling for all of the other identified risk factors. Unless otherwise stated, risk factors reported as NR were not included in the model.

Abbreviations: ↓ = statistically significant decreased risk; ↑ = statistically significant increased risk; 0 = no statistically significant association; AC = auditory comprehension; CSBS = Communication and Symbolic Behavior Scale; ED = expressive communication; CELF-P = Clinical Evaluation of Language Fundamentals-Preschool; EC = expressive communication; ELBW = extremely low birth weight; G = group; N = number; N-SLI = nonspecific language impairment; NR = not reported; SES = socioeconomic status; SLI = specific language impairment; PLS-3 = Preschool Language Scale; RASCAL = Randomly Ascertained Sample of Children born to moms in western AustraLia; WILSTAAR = Ward Infant Language Screening Test Assessment Acceleration Remediation.

Table 11. Risk Factors: Low Birth Weight Through Other Associations

Author, Year	Low Birth Weight	Birth Order	Prematurity	Other Perinatal Factors	Parent Stress	Parenting Practices	Child Medical Conditions	Other Associations
Adams-Chapman et al, 2013[180]	ELBW: 0	NR	NA: Whole cohort is premature	1 month mechanical ventilation: ↑ Multiple birth: ↑	NR	NR	Cerebral palsy: ↑ Severe intraventricular hemorrhage: 0 Necrotizing enterocolitis: 0 Hearing impairment: ↑	Dysfunctional feeding:↑ Non-English speaking: ↑ Steroid exposure: 0 Black race: ↑ Private insurance: ↓
Alston, 2005[165]	NR	0	NR	NR	NR	Mother-infant time interacting: ↓ Spontaneous maternal interaction: ↓	NR	Total television: ↓ Infant babbling: ↓
Campbell, 2003[173]	NR	NR	NR	NR	NR	NR	NR	Medicaid health insurance: 0 African American race: 0
Choudhury and Benasich, 2003[175]	NR	NR	NR	NR	NR	NR	Autoimmune disease: ↑ Asthma: 0	NR
Desmarais et al, 2008[171]	NR	NR	NR	NR	↑	History of otitis media: 0	Behavior: 0 Language stimulation: 0 Lexical acquisition: 0 Communicative intent: 0 Phonetic and phonological skills: 0	NR
Everitt et al, 2013[215]	NR	0	NR	Mild problems: 0	0	NR	Hearing concerns: 0 Ear infection: 0	Mother's occupation: 0 Father's occupation: 0
Foster-Cohen et al, 2010[185]	NR	NR	Very preterm Receptive: ↑ Expressive: ↑	Severity of neonatal white matter abnormality: 0	NR	Parent-child synchrony: ↓	NR	Social risk index: 0 Cognitive ability: ↓ Parent-child synchrony: ↓
Fox et al, 2002[188]	NR	NR	NR	Birth difficulties: ↑	NR	NR	Ear problems: 0	Sucking habits: ↑
Glascoe and Leew, 2010[216]	NR	NR	NR	NR	Elevated scores on depression screen: ↑ Anxiety: 0	Not talking to child in a special way: ↑ Not helping child learn by showing child things: ↑	NR	>3 siblings in home ↑ ≥2 household moves in the past year: ↑ Limited English facility: ↑ Ethnicity: 0
Hammer, 2010[174]	NR	NR	NR	NR	NR	NR	NR	Child age: 0 2-parent household: 0 Race/ethnicity: 0

Table 11. Risk Factors: Low Birth Weight Through Other Associations

Author, Year	Low Birth Weight	Birth Order	Prematurity	Other Perinatal Factors	Parent Stress	Parenting Practices	Child Medical Conditions	Other Associations
Harrison, 2010[179]	All outcomes: 0	Older siblings: Expressive: ↑ Receptive: ↓ Vocabulary: 0	All outcomes: 0	Neonatal intensive care: 0 Breastfed >9 months, all outcomes: 0	Mom distress/ well-being, all outcomes: ↓	Support for children learning at home: Expressive and receptive: 0 Vocabulary: ↓ TV watching, all outcomes: 0	Asthma, all outcomes: 0 Bronchiolitis, all outcomes: 0 Ear infections: Expressive: ↑ Receptive and vocabulary: 0 Ongoing hearing problems: Expressive and receptive: ↑ Vocabulary: 0 Social temperament: Expressive and receptive: 0 Vocabulary: ↓ Persistence temperament, all outcomes: ↓ Reactivity temperament, all outcomes: ↑	Parents' language other than English status: Expressive: ↓ Receptive: 0 Vocabulary: ↑ Parents' indigenous status, all outcomes: 0 Number of children in household: Expressive and receptive: 0 Vocabulary: ↑ Smoking in household: Expressive and receptive: 0 Vocabulary: ↑ Neighborhood disadvantaged, all outcomes: 0
Henrichs et al, 2011[81]	0	NR	Late bloomers: ↑		Late onset: ↑	NR	NR	Marital status: 0 Ethnicity non-Western: Late bloomers: ↓ Late onset: ↑ Single motherhood and late bloomers: ↓
Kerstjens, 2011[189]	Included in model but NR	NR	Early preterm: ↑ Moderate preterm: 0	Multiple birth included in model but NR	NR	NR	NR	Non-Dutch birth included in model but NR
Kerstjens, 2009[186]	NR	NR	↑	NR	NR	NR	NR	1-parent family: ↓
Kerstjens, 2012[190]	Included in model but NR	NR	↑	Multiple birth included in model but NR	NR	NR	NR	Non-Dutch birth included in model but NR
Law, 2009[46]	SLI: 0 N-SLI: ↑	NR	NR	Mom smoked during pregnancy: SLI: 0 N-SLI: 0	NR	No reading to child: SLI: 0 N-SLI: ↑	Neurotic behaviors: SLI: 0 N-SLI: ↑ Antisocial behaviors: SLI: 0 N-SLI: ↑	No preschool: SLI ↑ Some preschool: N-SLI ↑ Mom single parent: SLI: 0 N-SLI: ↑

Table 11. Risk Factors: Low Birth Weight Through Other Associations

Author, Year	Low Birth Weight	Birth Order	Prematurity	Other Perinatal Factors	Parent Stress	Parenting Practices	Child Medical Conditions	Other Associations
Law, 2012[172]	NR	NR	NR	Small for gestational age: 0	NR	NR	NR	Pattern Construction: ↑ Behavior: ↓ Language concerns: ↓
Mossabeb et al, 2012[83]	NR	Singleton: 0	NA	NR	NR	NR	NR	Public health insurance: ↑ Singleton gestation: 0 Small for gestational age: 0 Days on ventilator: 0 PDS ligation: 0 Culture + sepsis: 0 IVH grade 1–2: 0 IVH grade 3–4: 0
O'Leary, 2009[220]	NR	Parity: 0	NR	Binge drinking: Prepregnancy: 0 Trimester 1: 0 Trimester 2: ↑ Trimester 3: ↑	Maternal (mild): ↑	Poor parenting: ↑	NR	Marital status: 0 Parent smoking: 0 Parent drug use: 0
Pena et al, 2011[183]	NR	NR	NR	NR	NR	NR	NR	Bilingual: 0 Later first English exposure: ↑
Potijk et al, 2013[191]	NR	NR	Decreasing gestational age: ↑	NR	NR	NR	NR	Multiplicative effect of SES and gestational age decreased the individual additive effect of the 2 associations; number of siblings in model but NR
Pruitt, 2010[166]	NR	NR	NR	NR	NR	NR	NR	NR
Reilly, 2007[178]	CSBS and CDI: 0	CSBS and CDI: 0	CSBS and CDI: 0	Twin: CSBS and CDI: 0	Mom mental health score: CSBS and CDI: 0	NR	NR	CSBS score at 12 months: ↓ Non-English speaking background: CSBS: 0 CDI: ↑ Maternal vocabulary score: ↑
Reilly, 2009[177]	0	0	0	Twin: ↑	Mom mental health score: 0	NR	NR	Temperament: 0
Reilly et al, 2013[181]	0	Older siblings: 0	<36 weeks: 0	Twin birth: ↑	Mom mental health score: 0	NR	NR	Temperament: 0

Table 11. Risk Factors: Low Birth Weight Through Other Associations

Author, Year	Low Birth Weight	Birth Order	Prematurity	Other Perinatal Factors	Parent Stress	Parenting Practices	Child Medical Conditions	Other Associations
Roth, 2011[222]	NR	NR	NR	Maternal use of folic acid supplements: Severe language delay: ↓ Moderate language delay: 0	NR	NR	NR	Maternal body mass index and marital status included in models but NR
Schjolberg et al, 2011[192]	↑	NR	↑	Apgar score: ↑ Multiple birth: ↑	↑		NR	Siblings: ↑ Fussy: 0 Gestational diabetes: 0 Smoking during pregnancy: 0 Alcohol consumption 1st trimester: ↑ Alcohol consumption 3rd trimester: 0 Language other than Norwegian: ↑ Daycare before age 18 months: 0
Singer et al, 2001[184]	0	NR	0	Multiple birth: 0	NR	NR	Higher neurologic risk: ↑ Patent ductus arteriosis: ↑ Necrotizing enterocolitis: 0 Septicemia: 0 Peak bilirubin: 0 Retinopathy of prematurity: 0	Minority race: ↑
Tallal et al, 1989[182]	NR	NR	NR	NR	NR	NR	NR	NR
Tomblin et al, 1991[167]	0	Later: ↑	NR	NR	NR	NR	NR	At-risk determination at birth (parental background, maternal health during pregnancy, birth characteristics, and health as infant): ↑
Tomblin et al, 1997[168]	0	NR	NR	Cesarean delivery: 0 Duration of breast feeding: ↓	NR	NR	NR	Parent exposure to diseases, tobacco, alcohol, and drugs: 0 Maternal occupational exposure: 0

Table 11. Risk Factors: Low Birth Weight Through Other Associations

Author, Year	Low Birth Weight	Birth Order	Prematurity	Other Perinatal Factors	Parent Stress	Parenting Practices	Child Medical Conditions	Other Associations
van Batenburg-Eddes, 2013[223]	In model but NR	NR	Gestational age in model but NR	NR	NR	NR	NR	Neuromotor development: Receptive delay at 1.5 years: ↑ Expressive delay at 1.5 years: 0 Expressive delay at 2.5 years: ↑ Expressive delay across ages: ↑ Ethnicity in model but NR Marital status in model but NR
Van Lierde, 2009[193]	ELBW associated with poorer receptive language, expressive language (vocabulary, semantics, and morpho-syntaxis), and total score	NR	NR	NR	NR	NR	NR	NR
Weindrich et al, 2000[170]	NR	NR	NR	Composite measure of organic risk: ↑	NR	NR	NR	Composite measure of psychosocial risk: ↑
Whitehurst, 1991[169]	NR	NR	NR	NR	NR	NR	NR	NR
Yliherva et al, 2001[224]	Speech: ↑ if low, not very low Concepts: ↑ if very low	Production: 0 Perceptions and concepts: ↑	NR	Composite measure of risk: 0	NR	NR	Hearing impaired (all analyses): ↑	Reconstructed family: Perception and concepts: ↑ Urban residence (all analyses): 0

Table 11. Risk Factors: Low Birth Weight Through Other Associations

Author, Year	Low Birth Weight	Birth Order	Prematurity	Other Perinatal Factors	Parent Stress	Parenting Practices	Child Medical Conditions	Other Associations
Zambrana et al, 2014[187] Multivariate	NR	Older siblings: Analysis 1: 0 Analysis 2 (2+): ↑ Analysis 3: 0	NR	Multiple birth (all analyses): 0	NR	NR	NR	Parents with other mother tongue (all analyses): 0 Spoken to in another language (all analyses): 0 Mom partnership status (all analyses): 0
Zubrick, 2007[176]	↑	≥2 children in family: ↑	↑	Cigarette use during pregnancy: 0	Depression anxiety stress scale: 0	Parenting scale: 0 Family function: 0	NR	Paid employment: 0 Family type: 0 In daycare: 0 Other ASQ scales abnormal: Gross motor: ↑ Fine motor: ↑ Adaptive score: ↑ Personal-social: ↑ Child Behavior Checklist: 0 Dimension of Temperament scale: 0

Abbreviations: ↓ = decreased; ↑ = increased; ASQ = Ages and Stages Questionnaire; CDI = MacArthur-Bates Communication Development Inventory; ELBW = extremely low birth weight; IVH = intraventricular hemorrhage; N = number; NA = not applicable; NR = not reported in univariate analyses or included in a reported multivariate analysis; N-SLI = nonspecific language impairment; PDS = polydioxanone; SES = socioeconomic status; SLI = specific language impairment; TV = television.

Appendix A. Search Strategy

Speech Language Evidence 2004 Forward Searches

	Search String	Results
#1	Search (“Communication Disorders/classification”[Mesh] OR “Communication Disorders/diagnosis”[Mesh])	15523
#5	Search (“Communication Disorders/classification”[Mesh] OR “Communication Disorders/diagnosis”[Mesh]) Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	1246
	OVERARCHING EVIDENCE	
#6	Search (“Communication Disorders/classification”[Mesh] OR “Communication Disorders/diagnosis”[Mesh]) Filters: Review; Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	95
#16	Search (“Communication Disorders/classification”[Mesh] OR “Communication Disorders/diagnosis”[Mesh]) Filters: Controlled Clinical Trial; Guideline; Practice Guideline; Meta-Analysis; Multicenter Study; Randomized Controlled Trial; Publication date from 2004/01/01; English; Preschool Child: 2-5 years; Infant: birth-23 months	55
#23	Search ”Epidemiologic Studies”[Mesh] Filters: Publication date from 2004/01/01; English; Preschool Child: 2-5 years; Infant: birth-23 months	92332
#24	Search (#16 AND #23) Filters: Publication date from 2004/01/01; English; Preschool Child: 2-5 years; Infant: birth-23 months	24
	SCREENING	
#25	Search ((“Psychological Tests”[Mesh]) OR “Diagnostic Techniques and Procedures”[Mesh]) OR “Mass Screening”[Mesh] Filters: Publication date from 2004/01/01; English; Preschool Child: 2-5 years; Infant: birth-23 months	106030
#26	Search (#1 AND #25) Filters: Publication date from 2004/01/01; English; Preschool Child: 2-5 years; Infant: birth-23 months	797
#27	Search (#1 AND #25) Filters: Review; Publication date from 2004/01/01; English; Preschool Child: 2-5 years; Infant: birth-23 months	34
#28	Search (#1 AND #25) Filters: Review; Publication date from 2004/01/01; English; Infant: birth-23 months	18
#30	Search (#1 AND #25) Filters: Review; Publication date from 2004/01/01; English; Preschool Child: 2-5 years	31
#32	Search ”Risk”[Mesh] Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	37645
#33	Search (#5 AND #32) Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	165
#34	Search ((((“Primary Health Care”[Mesh]) OR “Physicians, Family”[Mesh]) OR “Pediatrics”[Mesh] OR primary care OR family physicians OR pediatrician) OR “Child Health Services”[Mesh]) OR “Preventive Health Services”[Mesh]Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	29572
#35	Search (#5 AND #34) Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	206
#39	Search ((“Sensitivity and Specificity”[Mesh]) OR “Diagnostic Errors”[Mesh]) OR “Diagnosis, Differential”[Mesh] Filters: English; Infant: birth-23 months; Preschool Child: 2-5 years	55512
#40	Search (#5 AND #39) Filters: English; Infant: birth-23 months; Preschool Child: 2-5 years	180
	ADVERSE EFFECTS	
#45	Search ”Communication Disorders”[Mesh] Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	2828
#50	Search (((((“Diagnostic Errors”[Mesh]) OR “Stress, Physiological”[Mesh]) OR “Life Change Events”[Mesh]) OR “Prejudice”[Mesh]) OR “Stereotyping”[Mesh]) OR “Self Concept”[Mesh] OR adverse effect OR harm OR stigma	529148
#55	Search (#45 AND #50) Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	115
#56	Search (#45 AND #50) Filters: Review; Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	8
#62	Search (#45 AND #50) Filters: Controlled Clinical Trial; Meta-Analysis; Multicenter Study; Randomized Controlled Trial; Guideline; Practice Guideline; Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	5
#63	Search (#56 OR #62) Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	12

#65	Search (#23 AND #51) Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	41
	INTERVENTIONS/OUTCOMES	
#68	Search ("Communication Disorders/drug therapy"[Mesh] OR "Communication Disorders/nursing"[Mesh] OR "Communication Disorders/prevention and control"[Mesh] OR "Communication Disorders/rehabilitation"[Mesh] OR "Communication Disorders/surgery"[Mesh] OR "Communication Disorders/therapy"[Mesh]) Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	718
#69	Search (((((((("Cost of Illness"[Mesh]) OR "Quality of Life"[Mesh]) OR "Employment"[Mesh]) OR "Psychology, Industrial"[Mesh]) OR "Family Relations"[Mesh]) OR "Family"[Mesh]) OR "Interpersonal Relations"[Mesh]) OR ("Educational Status"[Mesh] OR "Educational Measurement"[Mesh])) OR "Motivation"[Mesh] Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	29636
#70	Search (#68 AND #69) Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	207
#71	Search (("Outcome and Process Assessment (Health Care)"[Mesh]) OR "Comparative Study" [Publication Type]) OR ("Evaluation Studies" [Publication Type] OR "Evaluation Studies as Topic"[Mesh])) OR "Epidemiologic Studies"[Mesh] Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	132829
#72	Search (#68 AND #71) Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	399
#79	Search (#70 OR #72) Filters: Controlled Clinical Trial; Guideline; Meta-Analysis; Multicenter Study; Practice Guideline; Randomized Controlled Trial; Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	99
#85	Search (#70 OR #72) Filters: Review; Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	43
	COSTS	
#86	Search (("Costs and Cost Analysis"[Mesh] OR "Economics"[Mesh])) Filters:Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	6647
#98	Search (#69 OR #86) Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	34506
#99	Search (#68 AND #98) Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	215
#105	Search (#68 AND #98) Filters: Controlled Clinical Trial; Guideline; Meta-Analysis; Multicenter Study; Practice Guideline; Randomized Controlled Trial; Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	35
#106	Search (#68 AND #98) Filters: Review; Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	24
#107	Search (#99 AND #23) Filters: Publication date from 2004/01/01; English; Infant: birth-23 months; Preschool Child: 2-5 years	69

Total Unduplicated PubMed = 740

Cochrane = 6 = 6 new
PsycInfo = 182 = 173 new
CINAHL = 142 = 136 new
Instruments = 147 = 137 new

Total Unduplicated Database = 1074

Search – July 20, 2013

	Search String	Results
#1	Search ((((((Ages and Stages Questionnaire[Title/Abstract])) OR Battelle Developmental Inventory Screening Test[Title/Abstract]) OR Clinical Adaptive Test[Title/Abstract]) OR (Clinical Linguistic and Auditory Milestone Scale[Title/Abstract])) OR Denver Developmental Screening Test[Title/Abstract]) OR Early Language Milestone Scale[Title/Abstract]	314

Appendix A. Search Strategy

	Search String	Results
#2	Search ((((((Ages and Stages Questionnaire[Title/Abstract])) OR Battelle Developmental Inventory Screening Test[Title/Abstract]) OR Clinical Adaptive Test[Title/Abstract]) OR (Clinical Linguistic and Auditory Milestone Scale[Title/Abstract])) OR Denver Developmental Screening Test[Title/Abstract]) OR Early Language Milestone Scale[Title/Abstract] Filters: Publication date from 2013/03/01	11
#3	Search ((((((Ages and Stages Questionnaire[Title/Abstract])) OR Battelle Developmental Inventory Screening Test[Title/Abstract]) OR Clinical Adaptive Test[Title/Abstract]) OR (Clinical Linguistic and Auditory Milestone Scale[Title/Abstract])) OR Denver Developmental Screening Test[Title/Abstract]) OR Early Language Milestone Scale[Title/Abstract] Filters: Publication date from 2013/04/01	10
#4	Search ((((Fluharty Preschool Speech[Title/Abstract]) OR Infant-Toddler Checklist[Title/Abstract]) OR Language Development Survey[Title/Abstract]) OR McArthur-Bates Communicative Development Inventory[Title/Abstract]) OR WILSTAAR[Title/Abstract] Filters: Publication date from 2013/04/01	4
#5	Search (“Communication Disorders/classification”[Mesh] OR “Communication Disorders/diagnosis”[Mesh]) Filters: Publication date from 2013/04/01	10
#6	Search (“Communication Disorders/classification”[Mesh] OR “Communication Disorders/diagnosis”[Mesh]) Filters: Publication date from 2013/04/01; Infant: 1-23 months	2
#7	Search (“Communication Disorders/classification”[Mesh] OR “Communication Disorders/diagnosis”[Mesh]) Filters: Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	3
#8	Search (“Communication Disorders/classification”[Mesh] OR “Communication Disorders/diagnosis”[Mesh]) Filters: Review; Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	1
#9	Search ((“Psychological Tests”[Mesh]) OR “Diagnostic Techniques and Procedures”[Mesh]) OR “Mass Screening”[Mesh] Filters: Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	227
#10	Search (#7 AND #9) Filters: Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	2
#11	Search ”Risk”[Mesh] Filters: Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	116
#12	Search (#7 AND #11) Filters: Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	0
#13	Search (#7 AND #11) Schema: all Filters: Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	0
#14	Search ((((“Primary Health Care”[Mesh]) OR “Physicians, Family”[Mesh]) OR “Pediatrics”[Mesh] OR primary care OR family physicians OR pediatrician) OR “Child Health Services”[Mesh]) OR “Preventive Health Services”[Mesh] Filters:Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	87
#15	Search (#7 AND #14) Filters: Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	0
#16	Search (#7 AND #14) Schema: all Filters: Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	0
#17	Search ((“Sensitivity and Specificity”[Mesh]) OR “Diagnostic Errors”[Mesh]) OR “Diagnosis, Differential”[Mesh] Filters: Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	46
#18	Search (#7 AND #17) Filters: Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	0
#19	Search (#7 AND #17) Schema: all Filters: Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	0
#20	Search ”Communication Disorders”[Mesh] Filters: Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	7
#21	Search ”Communication Disorders”[Mesh] Filters: Review; Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	1
#22	Search (“Communication Disorders/drug therapy”[Mesh] OR “Communication Disorders/nursing”[Mesh] OR “Communication Disorders/prevention and control”[Mesh] OR “Communication Disorders/rehabilitation”[Mesh] OR “Communication Disorders/surgery”[Mesh] OR “Communication Disorders/therapy”[Mesh]) Filters:Publication date from 2013/04/01; Infant: 1-23 months; Preschool Child: 2-5 years	3

Appendix A. Search Strategy

	Search String	Results
#23	Search (“Communication Disorders/drug therapy”[Mesh] OR “Communication Disorders/nursing”[Mesh] OR “Communication Disorders/prevention and control”[Mesh] OR “Communication Disorders/rehabilitation”[Mesh] OR “Communication Disorders/surgery”[Mesh] OR “Communication Disorders/therapy”[Mesh]) Filters:Publication date from 2013/04/01; English; Infant: 1-23 months; Preschool Child: 2-5 years	3
#24	Search ((“Costs and Cost Analysis”[Mesh] OR “Economics”[Mesh])) Filters:Publication date from 2013/04/01; English; Infant: 1-23 months; Preschool Child: 2-5 years	19
#25	Search (#23 AND #24) Filters: Publication date from 2013/04/01; English; Infant: 1-23 months; Preschool Child: 2-5 years	0
#26	Search (#23 AND #24) Schema: all Filters: Publication date from 2013/04/01; English; Infant: 1-23 months; Preschool Child: 2-5 years	0

PubMed Total Citations = 19 = 11 new

Cochrane = 0
PsycInfo = 10 = 4 new
CINAHL = 11 = 1 new
Instruments = 9

Total NEW Database = 14

Instruments that were searched by name across databases:

- Ages and Stages Questionnaire—3rd Edition,
- Battelle Developmental Inventory Screening Test—2nd edition,
- Clinical Adaptive Test/Clinical Linguistic and Auditory Milestone Scale,
- Denver Developmental Screening Test II,
- Early Language Milestone Scale,
- Fluharty Preschool Speech and Language Screening Test,
- Infant-Toddler Checklist,
- The Language Development Survey,
- McArthur-Bates Communicative Development Inventory, and
- Ward Infant Language Screening Test, Assessment, Acceleration, and Remediation (WILSTAAR).

Search – July 2014

	Search String	Results
#1	Search ((((((Ages and Stages Questionnaire[Title/Abstract])) OR Battelle Developmental Inventory Screening Test[Title/Abstract]) OR Clinical Adaptive Test[Title/Abstract]) OR (Clinical Linguistic and Auditory Milestone Scale[Title/Abstract])) OR Denver Developmental Screening Test[Title/Abstract]) OR Early Language Milestone Scale[Title/Abstract]	345
#2	Search (((((Fluharty Preschool Speech[Title/Abstract]) OR Infant-Toddler Checklist[Title/Abstract]) OR Language Development Survey[Title/Abstract]) OR McArthur-Bates Communicative Development Inventory[Title/Abstract]) OR WILSTAAR[Title/Abstract]	53
#3	Search (#1 OR #2)	398
#4	Search (#1 OR #2) Filters: Publication date from 2013/04/01	53
#5	Search ("Communication Disorders/classification"[Mesh] OR "Communication Disorders/diagnosis"[Mesh]) Filters: Publication date from 2013/04/01	421

Appendix A. Search Strategy

	Search String	Results
#6	Search ("Communication Disorders/classification"[Mesh] OR "Communication Disorders/diagnosis"[Mesh])	16177
#7	Search ("Communication Disorders/classification"[Mesh] OR "Communication Disorders/diagnosis"[Mesh]) Filters: Publication date from 2013/04/01; Infant: 1-23 months	35
#8	Search ("Communication Disorders/classification"[Mesh] OR "Communication Disorders/diagnosis"[Mesh]) Filters: Publication date from 2013/04/01; Infant: 1-23 months; Newborn: birth-1 month	39
#9	Search ("Communication Disorders/classification"[Mesh] OR "Communication Disorders/diagnosis"[Mesh]) Filters: Publication date from 2013/04/01; Infant: 1-23 months; Newborn: birth-1 month; Infant: birth-23 months	39
#10	Search ("Communication Disorders/classification"[Mesh] OR "Communication Disorders/diagnosis"[Mesh]) Filters: Publication date from 2013/04/01; Infant: 1-23 months; Newborn: birth-1 month; Infant: birth-23 months; Preschool Child: 2-5 years	102
#12	Search ((“Psychological Tests”[Mesh]) OR “Diagnostic Techniques and Procedures”[Mesh]) OR “Mass Screening”[Mesh]	5667363
#13	Search (#10 AND #12) Filters: Publication date from 2013/04/01; Infant: 1-23 months; Newborn: birth-1 month; Infant: birth-23 months; Preschool Child: 2-5 years	64
#14	Search (#10 AND #12)	64
#15	Search ("Communication Disorders/classification"[Mesh] OR "Communication Disorders/diagnosis"[Mesh]) Filters: Review; Publication date from 2013/04/01; Infant: 1-23 months; Newborn: birth-1 month; Infant: birth-23 months; Preschool Child: 2-5 years	9
#16	Search “Risk”[Mesh] Filters: Review; Publication date from 2013/04/01; Infant: 1-23 months; Newborn: birth-1 month; Infant: birth-23 months; Preschool Child: 2-5 years	375
#17	Search “Risk”[Mesh]	820783
#18	Search (#10 AND #17) Filters: Review; Publication date from 2013/04/01; Infant: 1-23 months; Newborn: birth-1 month; Infant: birth-23 months; Preschool Child: 2-5 years	1
#19	Search (#10 AND #17)	16
#20	Search ((((“Primary Health Care”[Mesh]) OR “Physicians, Family”[Mesh]) OR “Pediatrics”[Mesh] OR primary care OR family physicians OR pediatrician) OR “Child Health Services”[Mesh]) OR “Preventive Health Services”[Mesh] Filters: Review; Publication date from 2013/04/01; Infant: 1-23 months; Newborn: birth-1 month; Infant: birth-23 months; Preschool Child: 2-5 years	419
#21	Search ((((“Primary Health Care”[Mesh]) OR “Physicians, Family”[Mesh]) OR “Pediatrics”[Mesh] OR primary care OR family physicians OR pediatrician) OR “Child Health Services”[Mesh]) OR “Preventive Health Services”[Mesh]	703870
#22	Search (#10 AND #21) Filters: Review; Publication date from 2013/04/01; Infant: 1-23 months; Newborn: birth-1 month; Infant: birth-23 months; Preschool Child: 2-5 years	0
#23	Search (#10 AND #21) Schema: all Filters: Review; Publication date from 2013/04/01; Infant: 1-23 months; Newborn: birth-1 month; Infant: birth-23 months; Preschool Child: 2-5 years	0
#24	Search (#10 AND #21)	14
#25	Search (((“Sensitivity and Specificity”[Mesh]) OR “Diagnostic Errors”[Mesh]) OR “Diagnosis, Differential”[Mesh])	837185
#26	Search (#10 AND #25)	23
#27	Search "Communication Disorders"[Mesh]	52319
#28	Search "Communication Disorders"[Mesh] Filters: Newborn: birth-1 month	1383
#29	Search "Communication Disorders"[Mesh] Filters: Newborn: birth-1 month; Infant: birth-23 months	3861
#30	Search "Communication Disorders"[Mesh] Filters: Newborn: birth-1 month; Infant: birth-23 months; Infant: 1-23 months	3861
#31	Search "Communication Disorders"[Mesh] Filters: Newborn: birth-1 month; Infant:	10964

Appendix A. Search Strategy

	Search String	Results
	birth-23 months; Infant: 1-23 months; Preschool Child: 2-5 years	
#32	Search "Communication Disorders"[Mesh] Filters: Publication date from 2013/04/01; Newborn: birth-1 month; Infant: birth-23 months; Infant: 1-23 months; Preschool Child: 2-5 years	263
#33	Search "Communication Disorders"[Mesh] Filters: Review; Publication date from 2013/04/01; Newborn: birth-1 month; Infant: birth-23 months; Infant: 1-23 months; Preschool Child: 2-5 years	18
#35	Search ("Communication Disorders/drug therapy"[Mesh] OR "Communication Disorders/nursing"[Mesh] OR "Communication Disorders/prevention and control"[Mesh] OR "Communication Disorders/rehabilitation"[Mesh] OR "Communication Disorders/surgery"[Mesh] OR "Communication Disorders/therapy"[Mesh])	13469
#36	Search (("Costs and Cost Analysis"[Mesh] OR "Economics"[Mesh])) Filters:Review; Publication date from 2013/04/01; Newborn: birth-1 month; Infant: birth-23 months; Infant: 1-23 months; Preschool Child: 2-5 years	54
#37	Search (("Costs and Cost Analysis"[Mesh] OR "Economics"[Mesh]))	487743
#38	Search (("Costs and Cost Analysis"[Mesh] OR "Economics"[Mesh])) Filters:Publication date from 2013/04/01; Newborn: birth-1 month; Infant: birth-23 months; Infant: 1-23 months; Preschool Child: 2-5 years	773
#39	Search (#35 AND #38) Filters: Publication date from 2013/04/01; Newborn: birth-1 month; Infant: birth-23 months; Infant: 1-23 months; Preschool Child: 2-5 years	0
#40	Search (#35 AND #38) Schema: all Filters: Publication date from 2013/04/01; Newborn: birth-1 month; Infant: birth-23 months; Infant: 1-23 months; Preschool Child: 2-5 years	0
#41	Search (#35 AND #38)	0

PubMed Total Citations = 147 = 135 New

Cochrane = 1
PsycInfo = 29= 23
CINAHL = 59 = 20 New
Instruments = 54 = 11 New

Total NEW Database = 190

Instruments that were searched by name across databases:

- Ages and Stages Questionnaire—3rd Edition,
- Battelle Developmental Inventory Screening Test—2nd edition,
- Clinical Adaptive Test/Clinical Linguistic and Auditory Milestone Scale,
- Denver Developmental Screening Test II,
- Early Language Milestone Scale,
- Fluharty Preschool Speech and Language Screening Test,
- Infant-Toddler Checklist,
- The Language Development Survey,
- McArthur-Bates Communicative Development Inventory, and
- Ward Infant Language Screening Test, Assessment, Acceleration, and Remediation (WILSTAAR).

Grey Literature Searches

4/30/2013 ClinicalTrials.Gov
(communication OR language) AND (therapy OR development) | “communication disorders” | Child (76 records)

Communicative development inventory = 32
- Ages and Stages Questionnaire—3rd Edition = 0
- Battelle Developmental Inventory Screening Test—2nd edition = 0
- Clinical Adaptive Test/Clinical Linguistic and Auditory Milestone Scale = 0
- Denver Developmental Screening Test II = 3
- Early Language Milestone Scale = 0
- Fluharty Preschool Speech and Language Screening Test = 0
- Infant-Toddler Checklist = 0
- The Language Development Survey = 1
- McArthur-Bates Communicative Development Inventory = 0
- Ward Infant Language Screening Test, Assessment, Acceleration, and Remediation (WILSTAAR) = 0

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(communication OR language) AND (therapy OR development) | "communication disorders" | Child (34 records)

Communicative development inventory = 10
- Ages and Stages Questionnaire—3rd Edition = 0
- Battelle Developmental Inventory Screening Test—2nd edition = 0
- Clinical Adaptive Test/Clinical Linguistic and Auditory Milestone Scale = 0
- Denver Developmental Screening Test II = 0
- Early Language Milestone Scale = 0
- Fluharty Preschool Speech and Language Screening Test = 0
- Infant-Toddler Checklist = 0
- The Language Development Survey = 0
- McArthur-Bates Communicative Development Inventory = 0
- Ward Infant Language Screening Test, Assessment, Acceleration, and Remediation (WILSTAAR) = 0

Appendix A Table 1. Inclusion/Exclusion Criteria

	Included	Excluded
Populations	**KQs 1–4:** Children age 5 years or younger who are representative of a population seen in a primary care setting **KQs 5–7:** Children age 6 years or younger who are representative of a population seen in a primary care or similar setting identified with speech or language delay or disorder. Treatment studies must focus on treatment of children who were screened and/or diagnosed according to the specified age criteria.	• Screening for or treatment of children with comorbid developmental disorder (e.g., hearing impairment, developmental or neurological/neurogenetic impairment) identified prior to speech and language diagnostic procedure
Interventions: Screening	All instruments and procedures that are applicable for use in children age 5 years or younger: • ≤10 minutes to administer by a primary care provider or to be interpreted in a primary care setting • >10 minutes if completed by a parent or trained examiner and interpreted by the clinician • Instruments specifically for speech and language • General developmental instruments with a separate component for speech and/or language skills	• Instruments not designed for use in children age 5 years or younger • Tools that take >10 minutes to administer by a primary care provider • Tools that require a professional to administer, score, or interpret • General developmental screening instruments that do not have a separate component for speech and/or language skills
Interventions: Treatment	• All therapeutic interventions designed to improve speech or language in children delivered at any age, as long as diagnosis occurs when child is age 6 years or younger. o Therapists may be speech-language pathologists or other clinicians, parents, or teachers • Therapeutic settings include group and individual sessions offered in a clinical locale, school, or home	Therapeutic interventions delivered to children who are diagnosed after age 6 years
Comparisons	**KQs 1, 3:** Screened vs. unscreened **KQ 2: D**ifferent subpopulations (e.g., by age, risk factors) **KQ 4:** Screening vs. surveillance; surveillance vs. no activity **KQs 5–7:** Intervention vs. no intervention	• Single group design with no comparator (KQs 1, 3, 5–7) • Treatment or screening comparisons

Appendix B. Excluded Studies

X1	Not original research (nonsystematic review articles, commentaries, opinions, commentaries, editorials/letters to the editor and other publications with no primary data)
X2	Wrong language (study not published in English)
X3	Wrong age range, probable reason for delay or disorder identified prior to speech and language diagnostic procedure, or wrong population of interest (i.e., wrong condition).
X4	Wrong comparator (Comparison of screening or diagnostic instruments; treatment comparisons; single group designs with no comparator)
X5	Wrong study design based on key questions (e.g., case study, case series, cross-sectional study)
X6	Screening or diagnosis does not focus on speech and language or the instrument does not include a speech and language component
X7	Wrong geographic setting (countries without a high human development index)
X8	No accuracy information provided
X9	Full text article irretrievable

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2. Narrative Ability of Children With Speech Sound Disorders and the Prediction of Later Literacy Skills. Lang Speech Hear Ser Schools. 2011;42(4):561-79. PMID: 21969531 Exclusion Code: X4.
3. Real-Word and Nonword Repetition in Italian-Speaking Children With Specific Language Impairment: A Study of Diagnostic Accuracy. J Speech Lang Hear Res. 2013;56(1):323-36. Exclusion Code: X4.
4. Tense Marking and Spontaneous Speech Measures in Spanish Specific Language Impairment: A Discriminant Function Analysis. J Speech Lang Hear Res. 2013;56(1):352-63. Exclusion Code: X4.
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Appendix C Table 1. Quality Ratings of Studies of Screening Outcomes for Speech and Language Delays in Children Age 5 Years and Younger (KQ 1)

Author, Year	Screening or Treatment Interventions and Comparators	Study Design	Selection Criteria Clearly Described?	Inclusion/Exclusion Criteria Measured Using Valid and Reliable Measures, Implemented Across All Study Participants?	Subject's Status Determined Using Valid and Reliable Methods?	Method of Randomization Adequate?	Allocation Concealment Adequate?
Van Agt et al, 2007[71]	G1: Screening G2: No screening (usual care)	RCT cluster	Yes	Yes	Sometimes	Yes	NA

Author, Year	Recruitment Strategy Differ Across Study Groups?	Baseline Characteristics Similar Between Groups?	Outcome Assessors Blind to Intervention Status of Participants?	Intervention Fidelity Adequate?	Study Protocol Variation Compromise Conclusions of the Study?	Overall Attrition?	High Attrition Raise Concern for Bias?	Intention-to-Treat Analysis?	Cross-Overs or Contamination Raise Concern for Bias?
Van Agt et al, 2007[71]	No	Not among those reported	Yes	No	No	Approximately 50% or more based on outcome	Yes	Yes, but attrition was very high and approach was not described	No

Author, Year	Outcomes Prespecified/Defined and Adequately Described?	Outcome Measures Valid and Reliable?	Duration of Followup Adequate to Assess the Outcome?	Appropriate Method Used to Handle Missing Data?	Acceptable Statistical Methods Used ?	Quality Rating	Comments
Van Agt et al, 2007[71]	Yes	Some	Yes	Unknown, but believe not	Yes	Poor	This study had a very high attrition rate, so we could not be confident that the results were comparing a comparable group of children screened to those not screened

Appendix C Table 2. Quality Ratings of Studies of Screening Accuracy for Speech and Language Delays in Children Age 5 Years and Younger (KQ 2a)[a]

Author, Year	Screening Test Adequately Described?	Selection Criteria Clearly Described?	Credible Reference Standard Used?	Time Period Between Screening Test and the Comparator Short Enough?	Whole or a Random Selection of the Sample Received Screening Test?
Alberts et al, 1995[91]	Yes	Yes	Yes	NR	Yes
Allen and Bliss, 1987[92]	Yes	No	Yes	Yes	Yes
Bliss and Allen, 1984[93]	Yes	No	Yes	NR	Yes
Borowitz and Glascoe, 1986[94]	Yes	Yes	Yes	Yes	Yes
Burden et al, 1996[95]	Yes	Yes	Yes	Yes	Yes
Clark et al, 1995[66]	Yes	No	Yes	Yes	Yes
Coulter and Gallagher, 2001[87]	Yes	Yes	Unclear	Unclear	Yes
Dixon et al, 1988[96]	Yes	No	Yes	Yes	Yes
Drumwright et al, 1973[97]	Yes	No	Yes	Yes	Yes
Elbaum et al, 2010[79]	Yes	Yes	Yes	Yes	Yes
Frisk et al, 2009[72]	Yes	Yes	Yes	Yes	Yes
Guiberson and Rodriguez, 2010[73]	Yes	Yes	Yes	Yes	Yes
Guiberson et al, 2011[74]	Yes	Yes	Yes	Yes	Yes
Heilmann et al, 2005[75]	Yes	Yes	Yes	Yes	Yes
Henrichs et al, 2011[81]	Yes	Yes	No	No	Yes
Heo et al, 2008[82]	Yes	Yes	No	Yes	Yes
Klee et al, 1998[98]	Yes	No	Yes	Yes	Yes
Klee et al, 2000[122]	Yes	No	Yes	Yes	Yes
Laing et al, 2002[99]	Yes	Yes	Yes	Yes	Yes
Law, 1994[100]	Yes	Yes	Yes	Yes	Yes
Levett and Muir, 1983[67]	Yes	Yes	Yes	Yes	Yes
McGinty, 2000[101]	No	Yes	Yes	Yes	Yes
Mossabeb et al, 2012[83]	Yes	Yes	No	Unclear	Unclear
Rescorla, 1989[54]	Yes	Unclear	Yes	Yes	Yes
Rescorla et al, 1993[69]	Yes	Yes	No	Yes	Yes
Rescorla and Alley, 2001[102]					
Study 1	Yes	No	No	Yes	Yes
Study 2	Yes	No	Yes	Yes	Yes
Rigby and Chesham, 1981[86]	Yes	Yes	Yes	Unclear	Yes
Sachse and Von Suchodoletz, 2008[76] Sachse and Von Suchodoletz, 2009[77]	Yes	Yes	Yes	Yes	Yes
Sherman et al, 1995[65]	Yes	Yes	Yes	Yes	Yes
Sices et al, 2009[84]	Yes	Yes	No	Yes	Yes
Skarakis-Doyle and Campbell, 2009[80]	Yes	Yes	No	No	Yes
Stokes, 1997[103]	Yes	Yes	Yes	Yes	Yes
Stott et al, 2002[104]	Yes	No	Yes	Yes	Yes
Sturner et al, 1993[105]					
Study 1	Yes	No	Yes	Yes	Yes
Study 2	Yes	No	Yes	Yes	Yes
Sturner et al, 1996[106]	Yes	No	Yes	Yes	Yes

Appendix C Table 2. Quality Ratings of Studies of Screening Accuracy for Speech and Language Delays in Children Age 5 Years and Younger (KQ 2a)[a]

Author, Year	Screening Test Adequately Described?	Selection Criteria Clearly Described?	Credible Reference Standard Used?	Time Period Between Screening Test and the Comparator Short Enough?	Whole or a Random Selection of the Sample Received Screening Test?
Van Agt et al, 2007[71]	Yes	Yes	No	Unclear	Yes
Walker et al, 1989[107]	Yes	Yes	Yes	Yes	Yes
Ward, 1984[108]	Yes	Yes	Yes	Yes	Yes
Westerlund et al, 2006[78]	Yes	Yes	Yes	No	Yes
Wetherby et al, 2003[88]	Yes	Yes	Yes	Yes	Yes

Author, Year	Patients Receive the Same Reference Test Regardless of Results?	Reference Standard Independent of Screening Test?	Sample Size Adequate?	Quality Rating	Comments
Alberts et al, 1995[91]	Yes	Yes	Yes 59	Fair	Sample size is adequate but not good. Reference test is a combination of measures, including a cognitive measure. No information about the length of time between the two tests.
Allen and Bliss, 1987[92]	Yes	Unclear	Yes 182	Fair	No description of eligibility or exclusionary criteria other than the children were in Head Start. It was not explicitly stated that the reference test and screening test were independently administered.
Bliss and Allen, 1984[93]	Yes	Yes	Yes 602	Fair	No description of eligibility or exclusionary criteria other than the children were in Head Start. No indication of the the length of time between screening and reference standard.
Borowitz and Glascoe, 1986[94]	Yes	Yes	Yes 71	Fair	Sample size is adequate but not good.
Burden et al, 1996[95]	Yes	Yes	Yes 425	Good	This is a large epidemiological sample that is well described. All criteria for a good rating were met.
Clark et al, 1995[66]	Yes	Unclear	Yes 99	Poor	Eligibility and exclusionary criteria not described other than age. May not be independent assessment and screening.
Coulter and Gallagher, 2001[87]	Unclear	Unclear	Yes 1,174	Poor	No information is provided on the reference standard, nor is there any information about the screening instrument, though there are references.
Dixon, 1988[96]	Yes	Yes	No 40	Poor	It is unclear what the eligibility criteria were. Two separate samples were combined, and the sample size is small.
Drumwright et al, 1983[97]	Yes	Yes	Yes 150	Fair	Little information regarding the sample other than age and that participants were economically disadvantaged.
Elbaum et al, 2010[79]	Yes	No	Yes 100	Poor	Screening test, which is a subset of the full instrument, was validated against the full instrument; that is, the subset of items was extracted from the larger data set from the whole test—no separate administration.
Frisk et al, 2009[72]	Yes	Yes	Yes 112	Fair	Somewhat restricted sample; 41% of sample were cognitively below average and 8% had global cognitive delay. Also, screening tests were not administered as separate instruments but were intermingled.

Appendix C Table 2. Quality Ratings of Studies of Screening Accuracy for Speech and Language Delays in Children Age 5 Years and Younger (KQ 2a)[a]

Author, Year	Patients Receive the Same Reference Test Regardless of Results?	Reference Standard Independent of Screening Test?	Sample Size Adequate?	Quality Rating	Comments
Guiberson and Rodriguez, 2010[73]	Yes	Yes	No 48	Fair	Meets all criteria except sample size.
Guiberson et al, 2011[74]	Yes	Yes	No 45	Fair	Meets all criteria except sample size.
Heilmann et al, 2005[75] Study 2	Yes	Yes	Yes 100	Fair	Meets all criteria: uses appropriate diagnostic procedure, interprets diagnosis separate from screening procedure, sample is 100 late talking toddlers and typical language toddlers.
Henrichs et al, 2011[81]	Yes	Yes	Yes 3,759	Poor	Uses another screening instrument as a reference test. The length of time between the screening test and the reference test is 1 year, which is too long for children this age.
Heo et al, 2008[82]	No	Yes	Yes 404 (in validity analysis)	Poor	Reference test is screening instrument, not diagnostic assessment.
Klee et al, 1998[98] Klee et al, 2000[122]	Yes	Yes	Yes 64	Fair	Sample size is adequate but not good.
Laing et al, 2002[99]	Yes	Yes	Yes 458	Good	This is a large epidemiological sample that is well described. All criteria for a good rating were met.
Law, 1994[100]	Yes	Yes	Yes 189	Good	This is a large epidemiological sample that is well described. All criteria for a good rating were met.
Levett and Muir, 1983[67]	Yes	Yes	No 14	Poor	Sample size for sensitivity and specificity evaluation is too small.
McGinty, 2000[101]	Yes	Yes	Yes 200	Poor	Limited information is given about screening test.
Mossabeb et al, 2012[83]	Yes	Yes	Yes 178	Poor	It is not clear when the children were screened in relation to receiving the reference test. Reference test is a measure of cognitive development and not a reasonable reference measure.
Rescorla, 1989[54]	Yes	Yes	Yes 81	Fair	Little information regarding exclusionary criteria. Sample size is adequate but not good.
Rescorla et al, 1993[69]	Yes	Yes	Yes 108 and 92	Poor	The reference test is insufficient to determine language delay.
Rescorla and Alley, 2001[102] Study 1	Yes	Unclear	Yes 422	Poor	Reference test is individual items from two measures of cognitive development. No information was provided about eligibility or exclusionary criteria other than age.
Rescorla and Alley, 2001[102] Study 2	Yes	Unclear	Yes 66	Fair	Unlike Study 1, a credible reference standard is used. No information was provided about eligibility or exclusionary criteria other than the sample was comprised of 2-year-olds who screened positive in study 1 or screened negative and were matched with an at-risk child.

Appendix C Table 2. Quality Ratings of Studies of Screening Accuracy for Speech and Language Delays in Children Age 5 Years and Younger (KQ 2a)[a]

Author, Year	Patients Receive the Same Reference Test Regardless of Results?	Reference Standard Independent of Screening Test?	Sample Size Adequate?	Quality Rating	Comments
Rigby and Chesham, 1981[86]	Yes	No	Yes 438	Fair	This is a large epidemiological sample that is generally well carried out with some limitations. No indication of the time span between the screening and diagnostic test. All children received two of the diagnostic instruments; the third, an articulation test, was only given if SLP felt it was necessary.
Sachse and Von Suchodoletz, 2008[76] Sachse and Von Suchodoletz, 2009[77]	Yes	Yes	Yes 117	Good	All criteria for a good rating are met.
Sherman et al, 1996[65]	Yes	No	Yes 173	Poor	The reference standard was not independent of the screening test because the same individual administered both during the same session.
Sices et al, 2009[84]	Yes	No	Yes 60	Poor	The reference standard is only the provider's rating of a concern, not a diagnostic assessment, and the providers were present when the screening test was completed.
Skarakis-Doyle and Campbell, 2009[80]	No	No	Yes 58	Poor	No independent reference test is provided, only classification status as LI/TLD prior to screening.
Stokes, 1997[103]	Yes	Yes	Yes 398	Fair	This is a large epidemiological sample that is well described. All criteria for a good rating were met.
Stott et al, 2002[104]	Yes	Yes	Yes 254	Fair	The sample is only described in terms of age and how they were recruited, no exclusionary criteria provided.
Sturner et al, 1993[105] Study 1	Yes	Yes	Yes 51	Fair	The sample is only described in terms of age and how they were recruited, no exclusionary criteria provided. The sample size is adequate but not large.
Sturner et al, 1993[105] Study 2	Yes	Yes	Yes 147	Fair	The sample is only described in terms of age and how they were recruited, no exclusionary criteria provided.
Sturner et al, 1996[106]	Yes	Yes	Yes 76	Fair	The sample is only described in terms of age and how they were recruited, no exclusionary criteria provided. The sample size is adequate but not large.
van Agt et al, 2007[71]	No	No	Yes 317	Poor	Inappropriate reference test: two procedures used for validation used for positive and negative screens—a parent response to a question or a specialist report for children who were seen for suspected language problems. The reference test was not independent of the screening test. Also, there isno information regarding the timing between the screening and the reference test.
Walker et al, 1989[107]	Yes	No	Yes 77	Poor	The same individuals who administered the screening instrument administered the reference standard.

Appendix C Table 2. Quality Ratings of Studies of Screening Accuracy for Speech and Language Delays in Children Age 5 Years and Younger (KQ 2a)[a]

Author, Year	Patients Receive the Same Reference Test Regardless of Results?	Reference Standard Independent of Screening Test?	Sample Size Adequate?	Quality Rating	Comments
Ward, 1984[108]	Yes	Unclear	Yes 1,070	Fair	The report indicates that the author visited those who screened positive and 10% of those who screened negative. The report does not say that they were blinded as to group membership.
Westerlund et al, 2006[78]	Yes	Yes	Yes 891	Fair	18 months between screening and reference test is long for an initial evaluation of the sensitivity and specificity of the instrument because of changes in development, but the authors state that no children received speech and language services.
Wetherby et al, 2003[88]	Yes	Unclear	Yes 232	Fair	Not specified whether the two procedures were completely independent; a random selection of those who were screened had the behavior sampling, but the sample size was sufficient.

[a] All studies in previous review and newly found studies were rated for quality.

Abbreviations: KQ = key question; LI/TLD = language impaired/typical language development; NR = not reported; SL = speech language; SLP = speech-language pathologist.

Appendix C Table 3. Quality Ratings of Included Randomized, Controlled Trials Examining Interventions for Speech and Language Delays or Disorders

Author, Year	Screening or Treatment Interventions and Comparators	Study Design	Eligibility Criteria Described Clearly?	Inclusion/Exclusion Criteria Measured Using Valid and Reliable Measures, Implemented Across All Study Participants?	Subject's Status Determined Using Valid and Reliable Methods?	Method of Randomization Adequate?	Allocation Concealment Adequate?
Denne et al, 2005[132]	G1: Phonological awareness therapy G2: No treatment	RCT	Yes	Yes	Yes	NR	NR
Fricke et al, 2013[125]	G1: Oral language skills, phonological awareness, literacy skill intervention G2: Wait-list control group	RCT cluster	Yes	Yes	Yes	NR	NR
Grogan-Johnson et al, 2010[133]	G1: Teletherapy G2: Conventional therapy	RCT cross-over	Yes	No	Yes	NR	NR
Jones et al, 2005[126]	G1: Lidcombe program for stuttering G2: No treatment	Dynamically balanced randomization with stratification	Yes	Yes	Yes	Yes	Yes
Lewis et al, 2008[127]	G1: Telehealth of Lidcombe stuttering intervention G2: No Treatment	RCT	Yes	NR	Yes	NR	Yes
Wake et al, 2011[128]	G1: Parent-based languge program G2: Usual care	Block randomization	Yes	Yes	Yes	Yes	Yes
Wake et al, 2013[130]	G1: 18 in-home sessions by language assistant over 1 year G2: Parents contacted and given information on local speech-pathology services	RCT	Yes	NR	Yes	Yes	Yes
Yoder et al, 2005[129]	G1: Broad target recasts	Two-arm RCT	Yes	Yes	Yes	Yes	No

Appendix C Table 3. Quality Ratings of Included Randomized, Controlled Trials Examining Interventions for Speech and Language Delays or Disorders

Author, Year	Recruitment Strategy Differ Across Study Groups?	Baseline Characteristics Similar Between Groups?	Outcome Assessors Blind to Intervention Status of Participants?	Intervention Fidelity Adequate?	Study Protocol Variation Compromise Study Conclusions?	Overall Attrition?	High Attrition Raise Concern for Bias?	Intention-to-Treat Analysis?	Cross-Overs or Contamination Raise Concern for Bias?	Outcomes Prespecified /Defined and Adequately Described?
Denne et al, 2005[132]	No	Yes, but no demographic information was included, only pretest information	NR	Yes	No	0.05	No	No	No	Yes
Fricke et al, 2013[125]	No	Yes	NR	Yes	No	0.09	No	NR	No	Yes
Grogan-Johnson et al, 2010[133]	No	Not reported	NR	Yes	No	0.16	NR	NR	No	Yes
Jones et al, 2005[126]	No	Yes	Yes	Yes	No	0.13	No	Yes	No	Yes
Lewis et al, 2008[127]	No	No/Yes for baseline stuttering	NR	Yes	No	0.18	No	Yes	No	Yes
Wake et al, 2011[128]	No	Yes	Yes	Yes	No	5% at 2 years; 11% at 3 years	No	Yes	No	Yes
Wake et al, 2013[130]	No	Yes	Yes	NR	NR	8% for intervention; 13% for control	No	Yes	NR	Yes
Yoder et al, 2005[129]	No	Yes	Yes	Yes	No	0	No	NR	No	Yes

Author, Year	Outcome Measures Valid and Reliable?	Duration of Followup Adequate to Assess Outcome?	Appropriate Method Used to Handle Missing Data?	Acceptable Statistical Methods Used?	Quality Rating	Comments
Denne et al, 2005[132]	Yes	Yes: End of treatment	NR	Yes	Poor	No discussion of how the group was randomized or whether they used any procedures for missing data. No baseline data other than pretest scores were presented. Intention-to-treat is not addressed other than to say one intervention participant had to be excluded because s/he was unable to attend several therapy sessions.
Fricke et al, 2013[125]	Yes	Yes: 6 months	Yes	Yes	Fair	No discussion of how groups were randomized or whether analysis was conducted on an intention-to-treat basis. However, they did use appropriate techniques for missing data.

Appendix C Table 3. Quality Ratings of Included Randomized, Controlled Trials Examining Interventions for Speech and Language Delays or Disorders

Author, Year	Outcome Measures Valid and Reliable?	Duration of Followup Adequate to Assess Outcome?	Appropriate Method Used to Handle Missing Data?	Acceptable Statistical Methods Used?	Quality Rating	Comments
Grogan-Johnson et al, 2010[133]	Yes	Yes: Every 3 months	NR	No	Poor	There is no mention of how the children were assigned. No baseline characteristics provided. Data for many variables are combined across conditions. Therapists who provided treatment rated children's progress; no independent measure of outcome.
Jones et al, 2005[126]	Yes	Yes: 9 months post-randomization	Yes	Yes	Fair	Differential attrition (13%) is close to the limit, with somewhat more in the control group. No data were available after randomization for these participants. Five protocol violations occurred: four children in the control group received some Lidcombe treatment and one child in treatment group had only 3 weeks of treatment.
Lewis et al, 2008[127]	Yes	Yes: 9 months post-randomization and 12 months after stage 1 (treatment group) and 18 months after randomization (control group)	NR	Yes	Fair	No information on how missing data was handled. Atrittion is at the lower end of acceptable. Some differences in baseline characteristics.
Wake et al, 2011[128]	Yes	Yes: 3 and 15 months post-program	Yes	Yes	Good	Meets all criteria.
Wake et al, 2013[130]	Yes	Yes: 1 year	NR	NR	Fair	Intention-to-treat principles were used (outcomes were compared based on randomization without regard for adherence to protocol), but no information was provided about how missing outcome data were handled. No information was provided about handling missing data in general. Although there was training and ongoing consultation to help maintain fidelity of implementation, no fidelity measures were reported. No information is given on whether children in the experimental groups received other therapy, or what kind of therapy children in the control group may have received. These factors represent potential confounders that were not addressed in the analyses.
Yoder et al, 2005[129]	Yes	Yes; 6 and 14 months	NR	Yes	Fair	This study does not appear to have any fatal flaws. However, the extent to which there was any loss through attrition is unclear, and if it occurred, how it was handled.

Abbreviations: G = group; NR = not reported; RCT = randomized, controlled trial.

Appendix C Table 4. Quality Ratings of Randomized, Controlled Trials From the 2006 USPSTF Review Examining Interventions for Speech and Language Delays or Disorders

Study	Randomization	Blinding of Assessors	Similarities at Baseline	Explanation of Withdrawals	Discounting in Analysis of Missing Values	Degree of Attrition	Intention-to-Treat Analysis	Power	Description of Eligibility Criteria	USPSTF Quality Rating
Almost et al, 1998[134]	A	A	A	A	A (last known scores used)	C (0.15)	A (intention-to-treat)	A	A	Fair
Fey et al, 1993[225]	B	A	C (mother's education)	A	C	A (0.03)	B	B	A	Poor
Fey et al, 1994[226]	B	C	A	A	A (none)	A (none)	B	B	A	Poor
Fey et al, 1997[227]	B	A	A	A	C	A (0.06)	B	B	A	Poor
Gibbard, 1994[136] Study 2	B	B	A	A (none)	A (none)	A (none)	B	B	A	Poor
Gibbard, 1994[136] Study 1	B	B	A	A (none)	A (none)	A (none)	B	B	A	Fair
Girolametto et al, 1996[137]	B	A	A	A (none)	A (none)	A (none)	B	B	A	Fair
Girolametto et al, 1996[228]	B	A	C (behavior)	A (none)	A (none)	A (none)	B	B	A	Poor
Girolametto et al, 1997[138]	B	A	A	A (none)	A (none)	A (none)	B	B	A	Fair
Glogowska et al, 2000[135]	A	A	A	A	C	A (0.03)	A (intention-to-treat)	C	A	Good
Glogowska et al, 2002[229]	A	B	B	C	B	B	B	B	C	Poor
Mulac and Tomlinson, 1977[230]	B	A	B	B	B	B	B	B	B	Poor
Robertson and Ellis Weismer, 1997[140]	A	B	A	A	B	A (none)	B	B	A	Fair
Robertson and Ellis Weismer, 1999[139]	B	B	A	A	C	C (0.13)	B	B	A	Fair
Rvachew and Nowak, 1994[145]	B	A	A	B	C	C (0.13)	B	B	A	Poor
Schwartz et al, 1985[231]	B	C	B	B	B	B	B	B	A	Poor
Shelton et al, 1978[141]	B	B	A	A	C	A (0.08)	B	B	A	Fair

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening Instrument	Goal of Screening/ Intervention	Inclusion Criteria	Exclusion Criteria	Study Design	Study Design Description	Study Duration or Length
Frisk et al, 2009[72]	Screen: ASQ communication domain; Battelle Developmental Inventory Screening Test; Brigance Preschool Screen; Early Screening Profile	To determine how well four extensively used American-normed screening tests identify Ontario preschoolers with language delays	Children in infant and child care development programs who did not meet exclusion criteria	Legally blind; profoundly hearing impaired; severe global developmental delay; ESL with <19 months daily exposure to English; autism spectrum disorder diagnosis	Other	Prospective f/u of screened group	Mean length, 9.9 months
Guiberson and Rodriguez, 2010[73]	Screen: Spanish ASQ communication domain; translated pilot version of the CDI-III (Pilot Inventario-III)	To determine the relationship between Spanish ASQ, Pilot INV-III, and PLS-4 and the accuracy of the Spanish ASQ communication domain and Pilot INV-III for detecting expressive language delays	Families speaking only or mostly Spanish; normal hearing; no known neurological impairment; children spoke only or mostly Spanish; lack of severe phonological impairment	NR	Other	Prospective f/u of screened group	7–10 days
Guiberson et al, 2011[74]	Screen: Spanish ASQ communication domain; Spanish adapatation of CDI Words and Sentences Short-form (Inventarios del desarrolo de habilidades comunicativas: palabras y enuciados [INV-II]); mean of 3 longest reported utterances (M3L); demographic and developmental questionnaire Test: SPLS	To determine if toddler-age Spanish-speaking children with expressive language delays can be accurately detected with parent-reported screening tools	Families speaking only or mostly Spanish; normal hearing; no known neurological impairment; children spoke only or mostly Spanish; either typical development or ELD	NR	Other	Cohort f/u	7–10 days
Heilmann et al, 2005[75]	CDI-WS	To determine the validity of the CDI-WS in characterizing language skills of 30-month-olds who were initially identified as late talkers at 24 months	Study 1 and 2: Monolingual English-speaking home; score of general development within normal range on Denver II; exhibit normal hearing; demonstrate normal oral and speech motor abilities	NR	Other	2 studies: prospective f/up	6 months

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening Instrument	Goal of Screening/ Intervention	Inclusion Criteria	Exclusion Criteria	Study Design	Study Design Description	Study Duration or Length
Rigby and Chesham, 1981[86]	Screen: Picture cards and spontaneous sentence Test: Renfrew and Reynell Test, Edinburgh Articulation Test	To analyze usefulness of screening for speech and language capabilities	Children attending school entry medical examinations	Already attending a speech therapist	Other	Group screened then tested	NA
Sachse and Von Suchodoletz, 2008[76] Sachse and Von Suchodoletz, 2009[77]	German version of the CDI toddler version (ELFRA-2)	To compare accuracy and diagnostic power of parent-reported measure of language delay with that of direct assessment of language abilities; both concurrent and predictive validity assessed	Monolingual German-speaking home; no evidence of autism or any general medical disorders	Poor vision, hearing impairment, abnormal result on hearing screening, missing subtests	Other	Prospective f/u of screened group	Assessment immediately following screening and 1 year later
Westerlund et al, 2006[78]	G1: SCS-18 (derived from CDI) G2: Traditional 18-month assessment (child's use of at least 8 words and understanding of more)	To evaluate SCS-18 (a parent-reported measure based on the CDI) in accuracy of prediction of children's later performance at 3 years, as well as in comparison with traditional 18-month method	Children invited to come to Child Health Care centers based on the national population register of the region; all had Swedish as their primary language	NR	RCT cluster	Two groups of practices, one in which the new screening instrument is used	18 months
Wetherby et al, 2003[88]	Infant-Toddler Checklist (from the CSBS)	To screen for prelinguistic delays	Children in a longitudinal study who were recruited from announcements, health care providers, and childcare providers; 3% were served under IDEA part C. Demographically diverse and representative of the community.	NR	Other	Diagnostic validity	NA

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Funding Source	Diagnosis or Objective of Screening	Overall Age	% Female	% Race/Ethnicity	Comments
Frisk et al, 2009[72]	Central West Region Ministry for Children and Youth; Infant and Child Development Services, Durham	Language delays	Mean age at screening (SD): 54 months (SD, 0.6) Mean age at reference test (SD): 63.9 months (SD, 2.8)	32.10%	NR	NA
Guiberson and Rodriguez, 2010[73]	American Speech-Language-Hearing Association; University of Northern Colorado	Expressive language delay	Total: 29.42 months (SD, 3.70) G1: 23 months G2: 22 months	Total: 50% G1: 45.4% G2: 53.8%	All identified as Hispanic and Mexican	NA
Guiberson et al, 2011[74]	NR	Expressive language delay	Total: 29.42 months (SD, 3.70) G1: 29 months (3.61) G2: 29.86 months (3.83)	G1: 39.1% G2: 63.6%	All identified as Hispanic and Mexican	
Heilmann et al, 2005[75]	National Institute of Child Health and Human Development; National Institute on Deafness and Other Communication Disorders	Screening for late talkers	24 months at baseline; 30 months at f/u	Study 1: 32% Study 2: NR	Study 1: White: 94.7% African American: 2.6% Biracial: 2.6% Study 2: White: 93% African American: 2% Asian: 1% Biracial: 4%	NA
Rigby and Chesham, 1981[86]	NR	Usefulness of screening instrument	Mean age not reported, but ~4.5 years	NR	NR	NR
Sachse and Von Suchodoletz, 2008[76] Sachse and Von Suchodoletz, 2009[77]	NR	Screening study for late talking (language delay)	24 months (n=3) 25 months (n=95) 26 months (n=19)	Total: 33% G1: 26% G2: 43%	NR	Mean developmental age about 1 month lower in late talker group
Westerlund et al, 2006[78]	Origin of Man, Language and Languages Eurocores; Anna Ahlstrom and Ellen Terserus Foundation; Gillbergska Foundation; University of Gavle	Screening for children who will be "severely language disabled"	18 months at baseline; 3 years at f/u	Total: 47.8% G1: 49% G2: 46.9%	NR	NA
Wetherby et al, 2003[88]	U.S. Department of Education Office of Special Education and Rehabilitation and Institute of Education Sciences	To screen for prelinguistic delays	Ages 12 to 24 months, divided into a younger group (n=151) of 12 to 17 months (14.0 [SD, 1.8]) and older group (n=81) of 18 to 24 months (20.4 [SD, 1.8])	NR	66% Caucasian; 28% African American; 5% Hispanic; 4% other	NA

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening and Comparators	Intervention Between Screening and Diagnosis	Detailed Description of Interventions/Screening	Fidelity or Adherence to Treatment	Modifying Effects of Any Demographic or Other Patient Characteristics?	Country	Recruitment Setting
Frisk et al, 2009[72]	Screen: ASQ; BDIST; BPS; ESP	NA	**Screening Test:** ASQ: Set of parent-report questionnaires for children ages 2 to 60 months. Communication domain, assessing expressive language skills: sentence length, child's ability to express knowledge in sentences; production of appropriate grammar; 6 questions at each of the age levels. BDIST: Communication scale: 18 items, separate scores for receptive and expressive language. Receptive: child's ability to follow instructions; comprehension of specific aspects of grammar. Expressive: sentence length and production of specific grammatical structures. BPS: Children ages 3 years 9 months to 4 years 8 months. Understanding Reading Composite: 2 items, child's ability to point to different colors and body parts. Expressive Language Composite: 4 items, child's expressive vocabulary, short-term verbatim memory for sentences, production of specific aspects of grammar, expression of knowledge. ESP: Language scale, Verbal Concept: 25 vocabulary items. **Reference Tests:** PLS-4: gold standard. 130 items: Auditory Comprehension, Expressive Comprehension. BBCS-R: gold standard measure of verbal concept knowledge for children ages 2 years 6 months to 7 years 11 months. 11 scales assessing 308 concept words.	NA	No	Canada	5 Infant and Child Development Programs

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening and Comparators	Intervention Between Screening and Diagnosis	Detailed Description of Interventions/Screening	Fidelity or Adherence to Treatment	Modifying Effects of Any Demographic or Other Patient Characteristics?	Country	Recruitment Setting
Guiberson and Rodriguez, 2010[73]	Spanish ASQ Communication Domain; Spanish CDI-III (Pilot Inventario-III)		**Screening Test:** Spanish translation of ASQ communication subscale: parent survey to screen 6 questions. Spanish translation of CDI-III (Pilot INV-III): vocabulary checklist of 100 items, 12 questions on sentence usage, 12 yes/no questions about language usage; completed by parent. Cronbach's alpha: vocabulary: 0.92; sentences: 0.95; usage: 0.94 **Diagnostic Test:** PLS-4 Spanish-language: direct assessment measuring receptive and expressive language skills (expressive used to test classification accuracy) Split-half internal consistency ranged from 0.80 to 0.90 (n=575) Test-retest reliability ranged from 0.77 to 0.86	NA		United States	Two Head Start programs, a regional early childhood program, and a medical clinic in the western United States

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening and Comparators	Intervention Between Screening and Diagnosis	Detailed Description of Interventions/Screening	Fidelity or Adherence to Treatment	Modifying Effects of Any Demographic or Other Patient Characteristics?	Country	Recruitment Setting
Guiberson et al, 2011[74]	Screen: Spanish ASQ; Spanish translation of CDI Short-form (Inventarios del desarrolo de habilidades comunicativas: palabras y enuciados [INV-II]); mean of 3 longest reported utterances (M3L) Test: SPLS-4	NA	**Screening Test:** Spanish ASQ communication subscale: parent survey to screen development of communication, 6 questions. Internal consistency on ASQ entire scale (not subscale): Interrater reliability: 0.94 Test-retest: 0.94 Short-form INV-II (Spanish version of CDI Words and Sentences): 100 productive vocabulary checklist and a question about combining words M3L-W: asks parents to write down 3 longest sentences that they heard their child say. Correlation with parents' report of vocabulary: r=0.63 **Diagnostic Test:** SPLS-4 (Spanish edition of PLS-4): comprehensive language test of receptive and expressive language skills; part of criteria that identified children with ELDs. Administered by bilingual SLP. Test-retest: 0.73 to 0.97 Split-half internal consistency correlations: 0.83 to 0.87	NA	No	United States	A regional Early Head Start program and 2 Early Intervention programs for infants and toddlers with disabilities
Heilmann et al, 2005[75]	CDI	NA	Study 1 and 2: **Screening Test:** CDI-WS: parent-completed assessment of child's vocabulary around age 24 months and again at 30 months **Diagnostic Test**: Two 1-hour sessions in laboratory; direct assessment of children at age 30 months: hearing screening, Bayley Scale of Infant Development II; Arizona Articulation Proficiency Scale III; oral motor examination; parent-child language sample; Denver II; Preschool Language Scale III; examiner-child language sample	NR	No	United States	University research center

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening and Comparators	Intervention Between Screening and Diagnosis	Detailed Description of Interventions/Screening	Fidelity or Adherence to Treatment	Modifying Effects of Any Demographic or Other Patient Characteristics?	Country	Recruitment Setting
Rigby and Chesham, 1981[86]	Screen: picture cards and spontaneous sentence Test: Renfrew and Reynell Test, Edinburgh Articulation Test		**Screening Test:** Children asked to state the names of familiar objects on picture cards. Second part of screening analyzes the child's spontaneous sentence for 2 verbs, comprehensibility, and articulation errors. Screened by doctor. Screening designed for the trial. **Diagnostic Test:** Renfrew and Reynell Test and Edinburgh Articulation Test. Not described. Administered by speech pathologist.	NR	Parental concern	England(?)	Clinic(?)
Sachse and Von Suchodoletz, 2008[76] Sachse and Von Suchodoletz, 2009[77]	ELFRA-2	Two moms of LT group received parent-focused language intervention program to learn language-facilitating behavior	**Screening Test:** German version of the CDI toddler version (ELFRA-2); parent questionnaire for 2-year-olds: language and communication 3 scales: Productive Vocabulary (total number of words), Syntax, Morphology (word combinations of differing complexity). Screening-defined cutoff: LT=productive vocabulary <50 words or productive vocabualry of 50–80 words and grammatical score <cutoff (syntax <7 and morphology score <2). Time to score (done by parent prior to visit): NR Reliability: NR **Diagnostic Test:** SETK-2 of productive and receptive language: 4 subtests including word production, sentence production, word comprehension, and sentence comprehension. Standardized for 2 groups (ages 24–29 and 30–36 months). Delay if score below normal on 1 of 4 subtests. SETK-3/5 (1 year later): test for ages 3–5 years. 3 of 4 subtests (picture description, marking of plurals, sentence comprehension), delay if score below normal on any.	NA	Mother's education	Germany	Sample recruited via birth announcements in a newspaper (all reported unless parent objects); screening sent to parents to complete

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening and Comparators	Intervention Between Screening and Diagnosis	Detailed Description of Interventions/Screening	Fidelity or Adherence to Treatment	Modifying Effects of Any Demographic or Other Patient Characteristics?	Country	Recruitment Setting
Westerlund et al, 2006[78]	G1: Swedish Communication Screening at age 18 months (SCS-18); derived from CDI G2: Traditional 18-month assessment: child's use of at least 8 words and understanding of more	NA	**Screening Test:** Swedish Communication Screening at age 18 months (SCS-18); developed to discriminate between low-performing and medium- and high-performing children at age 18 months. 90 common words checklist for production and understanding Subscale of 13 communicative gestures for parents to check if their child uses Time to administer: NR Internal consistency: word production: α=0.97; word comprehension: α=0.96 Test-retest reliability: word production r=0.97; word comprehension r=0.89 Correlation to longer form SECDI: r=0.91 Internal consistency gesture scale: α=0.56; test-retest reliability: r=0.89 Correlation to longer form SECDI: r=0.74 **Standard Screening:** One question to parent about number of words used and understood **Diagnostic Test:** Language observation at age 3 years (LO-3): based on nurse's direct and formalized observation of expressive and receptive language in children age 3 years ± 2 months. Failures identified as inability of children to express themselves in 3-word sentences or show comprehension of 3/5 standardized questions that can be answered by talking/pointing at photos Time to administer: NR 95.5% identified as severely language disabled were verified by clinical examination.	NA	No	Sweden	Community health centers

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening and Comparators	Intervention Between Screening and Diagnosis	Detailed Description of Interventions/Screening	Fidelity or Adherence to Treatment	Modifying Effects of Any Demographic or Other Patient Characteristics?	Country	Recruitment Setting
Wetherby et al, 2003[88]	Infant-Toddler Checklist (from the CSBS)	NA	Parent checklist; 5 to 10 minutes	NA	NA	United States	Public advertisments, health care providers, childcare, IDEA providers

Author, Year	Screening/Diagnostic Testing Setting	Method of Patient Recruitment	N Eligible	N Randomized or Enrolled	N Completers	N Analyzed	Comments
Frisk et al, 2009[72]	NR	NR	NR	131	112	112	NA
Guiberson and Rodriguez, 2010[73]	Health center and preschool center	Sending flyers home to families with children enrolled in preschool programs, posting flyers in early childhood centers and medical clinic, participating in preschool family nights, and Head Start community health fairs	NR	Total: 48 G1: 22 G2: 26	Total: 48 G1: 22 G2: 26	Total: 48 G1: 22 G2: 26	
Guiberson et al, 2011[74]	Early Head Start center or preschool rooms at the Early Intervention programs	Invitation from research team at mentioned centers	NR	Total: 45 G1: 23 G2: 22	Total: 45 G1: 23 G2: 22	Total: 45 G1: 23 G2: 22	
Heilmann et al, 2005[75]	Home, laboratory	Birth registry, newspapers, flyers, posters at health fairs, and referrals from providers	NR; all participants for both studies were part of a larger longitudinal project of language delay	Study 1: G1: 38 Study 2: G1: 38 G2: 62	Study 1: G1: 38 Study 2: G1: 38 G2: 62	Study 1: G1: 38 Study 2: G1: 38 G2: 62	First study consists of all late talkers and examines concurrent validity with other measures. Second study is same group of late talkers plus other normal talkers; study examined sensitivity and specificity.
Rigby and Chesham, 1981[86]	Clinic(?)	Total population attending clinic for school entry medical examinations	NR	438	438	438	NA

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening/Diagnostic Testing Setting	Method of Patient Recruitment	N Eligible	N Randomized or Enrolled	N Completers	N Analyzed	Comments
Sachse and Von Suchodoletz, 2008[76] Sachse and Von Suchodoletz, 2009[77]	Screening: mailed to parents; self report Diagnostic test: quiet room in outpatient department of hospital during two 1-hour sessions, following screening and at 1 year later.	Birth announcement in a newspaper that prints these unless parent objects	Screening sent to 1,490; return rate 71%; n=1,056 Included: n=932 who were monolingual Based on screening eligibility: G1: LT: 154 G2: TLD: 109 (random selection)	N=117 G1: LT: 70 G2: TLD: 47	N=117 G1: LT: 70 G2: TLD: 47 1 year later: N=102 G1: LT: 59 G2: TLD: 43	Age 2 (post screening): 117 Age 3 (1 year later): 102	Other: Nonverbal measure of cognitive functioning and hearing screening measured at age 2 years
Westerlund et al, 2006[78]	Child health care centers	Cluster sampling: half of clinics in county were selected for screening, other half for traditional screening	NR	G1: 1,145 G2: 1,519	18 months: G1: 1,021 G2: 1,312 3 years: G1: 891 G2: 1,189	G1: 891 G2: 1,189	
Wetherby et al, 2003[88]	Research laboratory	Advertisements for a longitudindal study of child language	392 children completed a checklist and some were asked to return for a behavior sample: all who were <1 SD below mean, a comparable number of randomly selected children between 16th and 50th percentile, and another comparable number of randomly selected children between 50th and 99th percentile. 80% of those invited came in. Study comprised of 232 children whose parents completed both the checklist and the behavior sample within 2 months.	Ages 12–17 months: 151 Ages 18–24 months: 81	Ages 12–17 months: 151 Ages 18–24 months: 81	Ages 12–17 months: 151 Ages 18–24 months: 81	Long-term prediction 2 years: n=246 3 years: n=108

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening	Primary or Secondary Outcome of Interest	Unit of Analysis	Timing of Measurement of Outcome	Data Source	N	Sensitivity	Specificity
Frisk et al, 2009[72]	ASQ; BDIST; BPS; ESP	To determine how well 4 extensively used American-normed screening tests identify Ontario preschoolers with language delays	Screen: parent and child Test: child	Mean length followup: 9.9 months	Screen: child and parent Test: child	131; 112 at followup	Compared to PLS-4 Auditory Comprehension Scale (25th and 16th percentile, respectively): ASQ: 44.8, 50.0 BDIST: 51.7, 55.6 BPS: 34.5, 22.2 ESP: 31.0, 33.3 Compared to BBCS-R Total Test (25th and 16th percentile, respectively): ASQ: 48.3, 48 BDIST: 55.2, 52 BPS: 27.6, 32 ESP: 34.5, 40 Compared to PLS-4 Expressive Communication Scale (25th and 16th percentile, respectively): ASQ: 47.1, 59.1 BDIST: 91.7, 95.5 BPS: 75, 90.9 ESP: 27.8, 40.9	Compared to PLS-4 Auditory Comprehension Scale (25th and 16th percentile, respectively): ASQ: 81.5, 79.3 BDIST: 71.6, 69.6 BPS: 90.1, 84.8 ESP: 95.1, 92.4 Compared to BBCS-R Total Test (25th and 16th percentile, respectively): ASQ: 82.7, 81.2 BDIST: 72.8, 70.6 BPS: 87.7, 99.2 ESP: 96.3, 96.5 Compared to PLS-4 Expressive Communication Scale (25th and 16th percentile, respectively): ASQ: 82.4, 83 BDIST: 33.8, 30.7 BPS: 79.7, 75 ESP: 95.9, 95.5
Guiberson and Rodriguez, 2010[73]	Spanish ASQ communication domain; Spanish version of CDI-III (Pilot Inventario-III)	To determine the relationship between Spanish ASQ, Pilot INV-III, and Preschool Language Scale (PLS-4)	Screening: parent Test: child	7–10 days	Screening: parent Test: child	Total: 48 G1: 22 G2: 26	ASQ: 0.59 Pilot INV-III: 0.82	ASQ: 0.92 Pilot INV-III: 0.81

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening	Primary or Secondary Outcome of Interest	Unit of Analysis	Timing of Measurement of Outcome	Data Source	N	Sensitivity	Specificity
Guiberson et al, 2011[74]	Spanish ASQ; Spanish version of CDI Short-form (Inventarios del desarrolo de habilidades comunicativas: palabras y enuciados [INV-II]); mean of 3 longest reported utterances (M3L); demographic and developmental questionnaire	To determine if toddler-age Spanish-speaking children with expressive language delays can be accurately detected with parent-report screening tools	Screening: parent Test: child	7–10 days	Screening: parent Test: child	Total: 45 G1: 23 G2: 22	ASQ: 0.56 Short-form INV-II: 0.87 M3L-W: 0.91	ASQ: 0.95 Short form INV-II: 0.86 M3L-W: 0.86
Heilmann et al, 2005[75]		To determine the validity of the CDI-WS in characterizing language skills of 30-month-olds who were initially identified as LTs at 24 months	Child and parent	6 months	Screening: parent Reference standard: parent-child language samples and child assessments	Study 1: G1: 38 Study 2: G1: 38 G2: 62	Sensitivity at 3 CDI cutoffs: 11th percentile: 0.68 19th percentile: 0.81 49th percentile: 1.00	Specificity at 3 CDI cutoffs: 11th percentile: 0.98 19th percentile: 0.79 49th percentile: 0.44

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening	Primary or Secondary Outcome of Interest	Unit of Analysis	Timing of Measurement of Outcome	Data Source	N	Sensitivity	Specificity
Rigby and Chesham, 1981[86]	Picture cards and spontaneous sentence; Renfrew and Reynell Test; Edinburgh Articulation Test	To analyze usefulness of screening for speech and language capabilities	Child	NA	Child	438	Pass full 12 elements of articulation test only: 75.6% Pass any 10 elements of articulation test only: 46.7% Pass spontaneous sentence only: 48.9% Pass either 12 elements of articulation or spontaneous sentence: 44.4% Pass either 10 elements of articulation or spontaneous sentence: 35.6% Pass both 12 elements of articulation and spontaneous sentence: 80% Pass both 10 elements of articulation and spontaneous sentence: 62.2%	NR
Sachse and Von Suchodoletz, 2008[76] Sachse and Von Suchodoletz, 2009[77]	ELFRA-2	Comparison of ELFRA-2 with SETK-2 and SETK-3/5	Child	Exact timing between screening and testing NR	Screening: parent Test: child	N=117 at 2 year N=102	SETK-2: 93% SETK-3/5: 94% SETK-2 to SETK-3/5: 94%	SETK-2: 88% SETK-3/5: 61% SETK-2 to SETK-3/5: 64%

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Screening	Primary or Secondary Outcome of Interest	Unit of Analysis	Timing of Measurement of Outcome	Data Source	N	Sensitivity	Specificity
Westerlund et al, 2006[78]	G1: Swedish Communication Screening at age 18 months (SCS-18); derived from CDI G2: Traditional 18-month assessment: child's use of at least 8 words and understanding of more	To evaluate SCS-18 in accuracy of prediction in children's later performance at 3 years and to compare effectiveness with standard screening question	Child/ Parent	18 months after screening	Screening: parent Test: child	G1: 891 G2: 1,189	G1: 0.50 G2: 0.32	G1: 0.90 G2: 0.91
Wetherby et al, 2003[88]	Infant-Toddler Checklist	NR	NR	Within 2 months	Parent	G1: 151 G2: 81	Younger sample: 88.7% Older sample: 85.7%	Younger sample: 74.5% Older sample: 76.9%

Author, Year	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio	Other Results	Receiver Operator Curve Characteristics	Unit of Analysis If Not the Patient
Frisk et al, 2009[72]	NR	NR	ASQ (2nd ed) PLS-4 Receptive: 2.4 ASQ (2nd ed) PLS-4 Expressive: 3.0 BDIST Receptive PLS-4 Receptive: 1.8 BDIST Receptive PLS-4 Expressive: 5.0 BPS Receptive: 4.2 BPS Expressive: 1.5 Early Screening Profile Verbal Concepts PLS-4 Auditory: 3.0 Early Screening Profile Verbal Concepts PLS-4 Expressive: 4.5	ASQ (2nd ed) PLS-4 Receptive: 0.46 ASQ (2nd ed) PLS-4 Expressive: 0.36 BDIST Receptive PLS-4 Receptive: 0.89 PLS-4 Expressive: 0.37 BPS Receptive: 0.12 BPS Expressive: 0.65 Early Screening Profile Verbal Concepts PLS-4 Auditory: 0.08 Early Screening Profile Verbal Concepts PLS-4 Expressive: 0.17	NA	NR	Child and parent

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio	Other Results	Receiver Operator Curve Characteristics	Unit of Analysis If Not the Patient
Guiberson et al, 2010[73]	ASQ: 0.87 Pilot INV-III: 0.78	ASQ: 0.73 Pilot-INV-III: 0.84	Spanish ASQ: 7.7 Spanish CDI III: 4.2	Spanish ASQ: 0.44 Spanish CDI III: 0.22	Positive likelihood ratio: ASQ: 7.68 (95% CI, 1.93 to 30.41) Pilot INV-III: 4.25 (95% CI, 1.88 to 9.58) Negative likelihood ratio: ASQ: 0.44 (95% CI, 0.26 to 0.74) Pilot INV-III: 0.22 (95% CI, 0.09 to 0.55)	NA	Screening: parent Test: parent and child
Guiberson et al, 2011[74]	ASQ: 0.92 Short-form INV-II: 0.87 M3L-W: 0.88	ASQ: 0.67 Short-form INV-II: 0.86 M3L-W: 0.90	Spanish ASQ: 12.4 Short-form INV Spanish CDI: 6.4	Spanish ASQ: 0.46 Short-form INV Spanish CDI: 0.15	NA	INV-II: 0.87 M3L-W: 0.93	Screening: parent Test: parent and child
Heilmann et al, 2005[75]	11th percentile: 0.96 19th percentile: 0.70 49th percentile: 0.51	11th percentile: 0.81 19th percentile: 0.89 49th percentile: 0.97	CDI-WS: 3.9	CDI-WS: 0.23	NA	Values not provided; only graphic presented	Screening: parent Test: parent and child

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio	Other Results	Receiver Operator Curve Characteristics	Unit of Analysis If Not the Patient
Rigby and Chesham, 1981[86]	Pass full 12 elements of articulation test only: 59.7% Pass any 10 elements of articulation test only: 80.8% Pass spontaneous sentence only: 73.3% Pass either 12 elements of articulation or spontaneous sentence: 74.1% Pass either 10 elements of articulation or spontaneous sentence: 84.2% Pass both 12 elements of articulation and spontaneous sentence: 58.1% Pass both 10 elements of articulation and spontaneous sentence: 68.3%	NR	Trial Speech Screening Test: 12.1	Trial Speech Screening Test: 0.21	Accuracy: Pass full 12 elements of articulation test only: 92.2% Pass any 10 elements of articulation test only: 93.4% Pass spontaneous sentence only: 92.9% Pass either 12 elements of articulation or spontaneous sentence: 92.7% Pass either 10 elements of articulation or spontaneous sentence: 92.7% Pass both 12 elements of articulation and spontaneous sentence: 92% Pass both 10 elements of articulation and spontaneous sentence: 93.2%	NR	NA
Sachse and Von Suchodoletz, 2008[76] Sachse and Von Suchodoletz, 2009[77]	SETK-2: 91% SETK-3/5: 56% SETK-2 to SETK-3/5: 58%	SETK-2: 89% SETK-3/5: 95% SETK-2 to SETK-3/5: 96%	ELFRA-2: 7.3	ELFRA-2: 0.08	Predictive validity of ELFRA-2 and SETK-2 with SETK-3/5 TLD at 2 & normal at 3 ELFRA-2: 95% SETK-2: 96% LT at 2 and below normal at 3: ELFRA-2: 56% SETK-2: 58%	NA	NA

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio	Other Results	Receiver Operator Curve Characteristics	Unit of Analysis If Not the Patient
Westerlund et al, 2006[78]	G1: 0.18 G2: 0.14	G1: 0.98 G2: 0.96	SCS-18: 4.8	SCS-18: 0.56	NA	NA	NA
Wetherby et al, 2003[88]	Younger sample: 65.3% Older sample: 80%	Younger sample: 92.4% Older sample: 83.3%	Younger sample: 3.5 Older sample: 3.7	Younger sample: 0.15 Older sample: 0.19	Prevalence Younger sample: 35% Older sample: 52%	NR	NR

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Timing of Measurement of Outcome	Data Source	N	Results	Subgroup(s)
Frisk et al, 2009[72]	Mean age at screening (SD): 54 months (0.6) Mean age at test (SD): 63.9 months (2.8)	Child and parent	131; 112 at followup	PLS-4 Auditory Comprehension based on ROC curve cutoff: Sensitivity (25th, 16th percentile): ASQ: 58.6, 66.7 BDIST: 93.1, 55.6 BPS: 48.3, 61.1 ESP: 93.1, 94.4 Specificity (25th, 16th percentile): ASQ: 75.3, 72.8 BDIST: 37, 69.6 BPS: 85.2, 59.8 ESP: 74.1, 68.5 Bracken based on ROC curve: Sensitivity (25th, 16th percentile) ASQ: 82.8, 84 BDIST: 75.9, 76 BPS: 41.4, 58 ESP: 86.2, 80 Specificity (25th, 16th percentile): ASQ: 67.9, 65.9 BDIST: 59.3, 57.6 BPS: 82.7, 83.5 ESP: 74.1, 85.9 PLS-4 Expressive Communication based on ROC curve: Sensitivity (25th, 16th percentile): ASQ: 58.3, 72.7 BDIST: 50, 68.2 BPS: 75, 90.9 ESP: 69.4, 86.4 Specificity (25th, 16th percentile): ASQ: 78.4, 76.1 BDIST: 97.8, 86.4 BPS: 83.8, 78.4 ESP: 85.1, 80.7	NR
Guiberson and Rodriguez, 2010[73]	Screening done at home and test given 7–10 days later	Screening: parent Test: child (observed by SLP)	Total: 48 G1: 22 G2: 26	NA	NR
Guiberson et al, 2011[74]	Screening done at home and test given 7–10 days later	Screening: parent Test: child (observed by SLP)	Total: 45 G1: 23 G2: 22	Short-form INV-II: 0.87 M3L-W: 0.93	NR

Appendix D Table 1. Evidence Tables for Screening for Speech and Language Delays in Children: KQ 2 Outcomes

Author, Year	Timing of Measurement of Outcome	Data Source	N	Results	Subgroup(s)
Heilmann et al, 2005[75]	Screened at 24 months; tested at 30 months	Screening reported by parent; testing of child observed by ASHA examiners and reports by parents	Study 1: G1: 38 Study 2: G1: 38 G2: 62	NA	NR
Rigby and Chesham, 1981[86]	NA	NA	NA	NA	NR
Sachse and Von Suchodoletz, 2008[76] Sachse and Von Suchodoletz, 2009[77]	NA	NA	NA	NA	Less educated mother related to lower score on vocabulary subscale of parent report and word production subscale of language test, but no association was found in relation to accuracy of judgement
Westerlund et al, 2006[78]	NA	NA	G1: 891 G2: 1,189	G1 (SE): Word production: 0.765 (0.044) Word comprehension: 0.658 (0.049) Communicative gestures: 0.617 (0.047) Combined: 0.716 (0.044)	NR
Wetherby et al, 2003[88]	2 years; 3 years	Child assessment	246	2 years Sensitivity: 80.5% Specificity: 79.3% 3 years Sensitivity: 83.3% Specificity: 70.2%	NR

Abbreviations: ASHA = American Speech-Language-Hearing Association; ASQ = Ages and Stages Questionnaire; BBCS-R = Bracken Basic Concepts Scale-Revised; BDIST = Battelle Developmental Inventory Screening Test; BPS = Brigance Preschool Screen; CDI = Communicative Development Inventory; CDI-III = Communicative Development Inventory Part Three; CDI-WS = Communicative Development Inventory Words and Sentences; ELD = expressive language delay; ELFRA-2 = Elternfragebogen fur die Fruberkennung von Riskokindern; ESL = English as a second language; ESP = Early Screening Profile; f/u = followup; G = group; INV-II = Inventario II: Palabras y enunciados; INV-III = Inventario III: Palabras y enunciados; LT = late talker; N = number; NA = not applicable; NR = not reported; PLS = Preschool Language Scale; RCT = randomized, controlled trial; ROC = receiver operating characteristic; SCS-18 = Swedish Communication Screening at 18 months of age; SD = standard deviation; SE = standard error; SETK-2 = Sprachentwicklungstest fur sweijahrige slindes; SETK-3/5 = Sprachentwicklungstest fur dreibis funfjahrige kinder; SPLS-4 = Spanish-version Preschool Language Scale; TLD = typical language development.

Appendix D Table 2. Evidence Tables for Interventions From 2006 USPSTF Review

Author, Year, Title	Objectives	Area of Intervention	Setting	N	Subjects
Almost, 1998[134] Effectiveness of speech intervention for phonological disorders: a randomized controlled trial	To examine effectiveness of treatment of children with severe phonological disorders as typically seen in an ambulatory care speech-language pathology clinic in a community hospital	Phonology	Speech-language pathology clinic in a community hospital in southwest Ontario, Canada; assessment from May 1993 to May 1994	26	G1: mean age, 42.5 months (range, 33 to 61 months) Male: 12 Female: 1 G2: mean age, 41.4 months (range, 33 to 55 months) Male: 9 Female: 4
Gibbard, 1994[136] Study 1 Parental-based intervention with preschool language delayed children	To examine the effectiveness of a parent-trained intervention versus no intervention	Expressive language	Local health center where children were referred for speech-language therapy	36	Male: 25 Female: 11 Age range: 27 to 39 months Majority of participants in social classes I, II, or IIIM Mean mother age: 30 years Mean father age: 33 years
Girolametto, 1996[137] Interactive focused stimulation for toddlers with expressive vocabulary delays	To examine the effects of a focused stimulation language intervention on children's' vocabulary and language development	Expressive vocabulary	Children were recruited from waiting lists for parent programs offered at two agencies in metropolitan Toronto, Canada	25	Age range: 23 to 35 months No sex details given
Girolametto, 1997[138] Effects of lexical intervention on the phonology of late talkers	To examine the impact of a focused stimulation intervention on the vocabulary, language, and emerging phonological skills of late talkers	Phonology	Children were recruited from waiting lists for parent programs offered at two agencies in metropolitan Toronto, Canada	25	Male: 22 Female: 3 Age range: 23 to 35 months
Glogowska, 2000[135] Randomised controlled trial of community based speech and language therapy in preschool children	To compare routine speech and language therapy against 12 months of “watchful waiting”	Expressive and receptive language and phonology	16 community clinics in Bristol; children were enrolled between December 1995 and March 1998	159	Male: 120 Female: 39 Age range: 18 to 42 months Just over half of the children were receiving child care. Most mothers had completed “O” level education. A minority either had no qualifications or had “A” levels.
Robertson, 1997[140] Study 2 The influence of peer models on the play scripts of children with specific language impairment	To examine the effects of peer modeling using the same peer throughout the intervention on children with speech and language impairments	Expressive and receptive language	Children were enrolled in a language-based early childhood classroom	6	Male: 4 Female: 2 Mean age: 54 months (range, 48 to 57 months)

Appendix D Table 2. Evidence Tables for Interventions From 2006 USPSTF Review

Author, Year, Title	Objectives	Area of Intervention	Setting	N	Subjects
Robertson, 1997[140] Study 1 The influence of peer models on the play scripts of children with specific language impairment	To examine the effects of peer modeling on children with speech and language impairments	Expressive and receptive language	Children were enrolled in a language-based early childhood classroom	20	Male: 13 Female: 7 Mean age: 50 months (range, 36 to 60 months) Mean maternal education: 14 years
Robertson, 1999[139] Effects of treatment on linguistic and social skills in toddlers with delayed language development	To examine the effects of early language intervention on the development of late-talking toddlers	Expressive and receptive language and phonology	Children were recruited from the community and seen at a research clinic	21	Male: 12 Female: 9 Age range: 21 to 30 months All participants from middle class households
Shelton, 1978[141] Study 1 Assessment of parent administered listening training for preschool children with articulation deficits	To compare two parent-administered listening treatments and a control group	Articulation/ Phonology	Children were from nursery schools or pediatric offices; they were seen either at their school or in their home	60	Age range: 36 to 54 months Bilingual children were included, with two in each condition

Author, Year, Title	Screening Criteria/Diagnostic Evaluation	Time from Screen to Intervention	Intervention
Almost, 1998[134] Effectiveness of speech intervention for phonological disorders: a randomized controlled trial	Severe phonological disorder as determined by the phonological deviancy score on the Assessment of Phonological Processes-Revised receptive language skills >1 SD below the mean on the Reynell Developmental Language Scale-Revised	G1: immediate treatment implied G2: 4 months	G1: 4 months treatment followed by 4 months no treatment G2: 4 months no treatment followed by 4 months treatment Assessments at baseline, 4, and 8 months Treatment: remediation for phonological disorders. Individual 30-minute sessions twice per week. 4 to 6 target phonological deviations chosen for each child at treatment cycle initiation. Each target repeated 2 to 3 times or until correct in conversation.
Gibbard, 1994[136] Study 1 Parental-based intervention with preschool language delayed children	Vocabulary of <30 single words	Immediate	Parental-administered expressive syntax intervention emphasizing how to maximize language use in everyday environment: 18 received parental intervention 18 received delayed intervention
Girolametto, 1996[137] Interactive focused stimulation for toddlers with expressive vocabulary delays	Vocabulary size in the lower 5th percentile for age measured by Communicative Development Inventory	Immediate	Parental-administered expressive vocabulary intervention based on Hanen principles and adapted for focused stimulation: 12 received parent intervention 13 received delayed intervention

Appendix D Table 2. Evidence Tables for Interventions From 2006 USPSTF Review

Author, Year, Title	Screening Criteria/Diagnostic Evaluation	Time from Screen to Intervention	Intervention
Girolametto, 1997[138] Effects of lexical intervention on the phonology of late talkers	Vocabulary size in the lower 5th percentile for age measured by Communicative Development Inventory	Immediate	Parental-administered expressive vocabulary intervention based on Hanen principles and adapted for focused stimulation: 12 received parent intervention 13 received delayed intervention
Glogowska, 2000[135] Randomised controlled trial of community based speech and language therapy in preschool children	Standardized score <1.2 SD below the mean on the auditory comprehension part of the Preschool Language Scale; standardized score >1.2 SD below the mean on auditory comprehension but <1.2 SD on expressive language; auditory and expressive language scores >1.2 SD below the mean, but with an error rate of ≥40% in production of fricative and/or velar consonants and/or sounds occurring after a vowel among the 22 words included in the phonological analysis	Immediate treatment implied	Clinician-administered intervention focusing on a variety of language areas: 71 received clinician intervention 88 received delayed intervention
Robertson, 1997[140] Study 2 The influence of peer models on the play scripts of children with specific language impairment	Performance at or near 2 SD below the mean on standardized measures of receptive and expressive language; measures not reported	Immediate	Play intervention for expressive narrative language: 4 participants played with each other in pairs 2 participants were paired with a normal peer
Robertson, 1997[140] Study 1 The influence of peer models on the play scripts of children with specific language impairment	Performance at or near 2 SD below the mean on standardized measures of receptive and expressive language; measures not reported	Immediate	Play intervention for expressive narrative language: 10 participants played with each other in pairs 10 participants were paired with a normal peer
Robertson, 1999[139] Effects of treatment on linguistic and social skills in toddlers with delayed language development	Demonstrated significant delays in the acquisition of language measured by the Preschool Language Scale-3 and the Bayley Scale of Infant Development	≤1 week	Clinician-administered intervention for expressive vocabulary and syntax; child-centered approach to provide general stimulation: 11 received clinician intervention 10 received delayed intervention
Shelton, 1978[141] Study 1 Assessment of parent administered listening training for preschool children with articulation deficits	Below the cutoff score for age on the Templin-Darley Articulation Screening Test	Immediate treatment implied	Parent-administered speech programs; listening therapy based on auditory discrimination compared to more traditional reading and talking therapy and delayed treatment: 20 received experimental listening therapy 20 received reading and talking therapy 20 received delayed treatment

Appendix D Table 2. Evidence Tables for Interventions From 2006 USPSTF Review

Author, Year, Title	Length of Intervention	Outcome Measures	Speech and Language Outcomes	Nonspeech and Language Outcomes
Almost, 1998[134] Effectiveness of speech intervention for phonological disorders: a randomized controlled trial	4 months	APP-R (Assessment of Phonological Processes-Revised) score; GFTA (Goldman-Fristoe Test of Articulation) score; PCC (percentage consonants correct) score; MLU (mean length of utterance) score	4-month assessment: G1: scores of phonological measures reflect improvement: APPR (p=0.05), GFTA (p=0.05), PCC (p=0.01) 8-month assessment: G1: higher measures for speech intelligibility (PCC, p=0.05), but no statistically significant difference on single-word phonological skills Expressive language measure (MLU): no significant differences between groups at any assessment point. G1 had consistently higher (improved) scores than G2.	None
Gibbard, 1994[136] Study 1 Parental-based intervention with preschool language delayed children	An average of 40 minutes per week over 6 months	Reynell Expressive measure; language sample one-word scores and total scores; Renfrew Action Picture Test information; mother's description of vocabulary and phrase complexity; mean length of utterances from language sample	The mean scores improved for both the experimental and the no-intervention control groups, but the experimental group had larger gains on all measures (p=0.008 for language sample one-word scores and p=0.000 for all other measures).	None
Girolametto, 1996[137] Interactive focused stimulation for toddlers with expressive vocabulary delays	150 minutes per week for 11 weeks	Vocabulary and phrase complexity as determined by the Communicative Development Inventory; number of different words and utterances from a language sample; posttest probes for target words; control word measures, target words in interaction, multiword utterances	Children who received treatment had larger vocabularies (p<0.02) and used a greater number of different words (p<0.01) compared to the control group. Those who received treatment used more structurally complete and more multiword utterances than those in the control group (p<0.04 and p<0.01, respectively)	Mother's language interactions with child changed (language input slower, less complex, and more focused after treatment). Few words/minute p<0.01 Shorter utterances p<0.01 Used more target words and focused stimulation of target words p<0.01
Girolametto, 1997[138] Effects of lexical intervention on the phonology of late talkers	11 weeks Eight 2.5-hour evening sessions Three home sessions	Different vocalization; syllable structure at level 1, 2, 3; consonants inventory: early, middle, late; consonant position: initial and final; proportion of consonants correct	There was no difference between groups on the number of vocalizations made. Children who received treatment used level 3 vocalizations more than the controls (p<0.01). Those who received treatment also used a greater inventory of consonants in all three classes	None

Appendix D Table 2. Evidence Tables for Interventions From 2006 USPSTF Review

Author, Year, Title	Length of Intervention	Outcome Measures	Speech and Language Outcomes	Nonspeech and Language Outcomes
Glogowska, 2000[135] Randomised controlled trial of community based speech and language therapy in preschool children	Therapy continued for an average of 10 minutes per week for 8.4 months	Preschool Language Scale auditory comprehension and expressive language; phonological errors	Although all outcome measures were in favor of the therapy group, only one measure reached the significant level (auditory comprehension, p=0.025)	No significant difference for play level or attention level
Robertson, 1997[140] Study 2 The influence of peer models on the play scripts of children with specific language impairment	15 minutes per week for 3 weeks	Language sample: number of words in script, number of different words, number of play related themes	Both children in the experimental group showed significant gains in number of words used, number of different words used, and number of linguistic markers used	Both children in the experimental group showed significant increases in the number of play theme-related acts
Robertson, 1997[140] Study 1 The influence of peer models on the play scripts of children with specific language impairment	20 minutes per week for 3 weeks	Language sample: number of words in script, number of different words, number of play related themes	Those in the experimental group produced significantly more words than those in the control group immediately after treatment and at followup (p<0.0001). The experimental group demonstrated greater verbal productivity and employed more lexical diversity than the control group. Also, the experimental group made significantly more gains in the use of linguistic markers than the control group (p<0.0001)	Play-theme related acts increased (p<0.0001) for the treatment group
Robertson, 1999[139] Effects of treatment on linguistic and social skills in toddlers with delayed language development	150 minutes per week for 12 weeks	Language sample: mean length of utterances, total number of words; parent report of vocabulary (Communicative Developmental Inventory-Words and Sentences)	Compared to children in the control group, children in the treatment group demonstrated significantly greater increases in mean length of utterances (p=0.003), the total number of words used (p=0.000), lexical diversity (p=0.000), reported vocabulary size (p=0.000), and percentage of intelligible utterances (p=0.000)	Treatment group had an increase in socialization skills (p=0.003) not merely reflective of the language increases; parental stress decreased (p=0.000) for the treatment group
Shelton, 1978[141] Study 1 Assessment of parent administered listening training for preschool children with articulation deficits	57 days (listening for 5 minutes per day and reading and talking for 15 minutes per day)	Auditory association subtest of the Illinois Test of Psycholinguistic Abilities; McDonald Screening Articulation Test	Only the noise subtest of the Test of Auditory Discrimination showed a significant improvement for the listening and control groups compared to the reading-talking group (p=0.03). There were no other significant differences between groups	None

Abbreviations: G = group; SD = standard deviation.

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Treatment Interventions/ Comparators	Goal of Screening/ Intervention	Inclusion Criteria	Exclusion Criteria	Study Design	Other Study Design	Study Duration or Length of Observation	Funding Source
Wake et al, 2011[128]	G1: Modified "You Make a Difference" program G2: Control group	To determine the benefits of a low-intensity parent-toddler language promotion program delivered to toddlers identified as slow to talk on screening in universal services	Score ≤20th percentile on the expressive vocabulary checklist, based on population norms	Children who had already been referred for cognitive delay, major medical conditions, or suspected autism spectrum disorder or if parents had insufficient English to complete the questionnaires (written at a year 6 level of English) or participate in the program	RCT cluster	NA	2 years	Australian National Health and Medical Research Council
Lewis et al, 2008[127]	G1: Experimental group G2: Control group	To evaluate the efficacy of telehealth delivery of the Lidcombe Program of Early Stuttering Intervention	Preschool-age children who stuttered, and their families, from Australia; age at randomization of 3 years 0 months to 4 years 6 months, inclusive; history of stuttering >6 months at randomization; no previous or current treatment for stuttering; history of normal development apart from stuttering; and parent and child proficiency in English	See inclusion criteria	RCT parallel	NA	9 months	National Health and Medical Research Council of Australia
Jones et al, 2005[126]	G1: Lidcombe program G2: Control group	Reduction of stuttering	Age at recruitment of 3 to 6 years, stuttering as diagnosed by using standard procedures and at least 2% of syllables stuttered, and parent and child proficiency in English	Treatment for stuttering during the previous 12 months and onset of stuttering in the 6 months before recruitment	RCT parallel	NA	9 months	None

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Treatment Interventions/ Comparators	Goal of Screening/ Intervention	Inclusion Criteria	Exclusion Criteria	Study Design	Other Study Design	Study Duration or Length of Observation	Funding Source
Fricke et al, 2013[125]	G1: Oral language intervention G2: Wait-list control group	To improve children's vocabulary, develop narrative skills, encourage active listening, and build confidence in independent speaking	12 children from each of the nursery schools with the lowest mean verbal composite score. In addition, 6 children in each school matched on sex and date of birth to a random sample of 3 children from the intervention and control groups acted as a representative peer comparison group	See inclusion criteria	RCT parallel	NA	30 weeks	The Nuffield Foundation
Yoder et al, 2005[129]	G1: Broad target recasts G2: Control	To facilitate sentence length and speech intelligibility (i.e., broad target recast), and to explore whether pretreatment speech accuracy predicted response to treatment in children with severe phonological and expressive language impairment	MLU of at least 1.3 SD below chronological age expectation or a standard score of ≤80 on the expressive scale of the Preschool Language Scale-3rd edition; nonverbal IQ on the Leiter International Performance Scale-Revised >80; and passing a 25 db threshold hearing screening. Also, children scored no higher than a T-score of 37 on the Arizona Articulation Proficiency Scale to document speech accuracy impairments. Children had to have initial MLUs <2.5 and use ≥10 different words in a 20-minute language sample. English had to be the only language spoken in the home.	Children with evidence of oral motor disorders were excluded	RCT parallel	NA	14 months	Scottish Rite Foundation of Nashville, the National Institute on Deafness and Other Communication Disorders, and the National Institute of Child Health and Human Development

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Treatment Interventions/ Comparators	Goal of Screening/ Intervention	Inclusion Criteria	Exclusion Criteria	Study Design	Other Study Design	Study Duration or Length of Observation	Funding Source
Wake et al, 2013[130]	G1: 18 in-home sessions by "language assistant" over 1 year G2: Parents contacted and given information on local speech pathology services	Improved expressive and receptive language at age 5 years	Expressive and/or receptive language scores >1.25 SD below normal on CELF-P2	Intellectual disability, major medical condition, hearing loss, autism spectrum disorder, parents with insufficient English	RCT	NA	12 months	Australian National Health and Medical Research Council

Author, Year	Diagnosis	Overall Age	% Female	% Race/Ethnicity	Comments
Wake et al, 2011[128]	Children with delay in language development	Mean age at baseline (SD) G1: 13.3 (1.2) G2: 13.3 (1.1)	G1: 48 G2: 51	NR	NA
Lewis et al, 2008[127]	Stuttering	Ages 3 to 4 years, n (%) Overall: 15 (68) G1: 5 (56) G2: 10 (76) Ages 4 to 5 years, n (%) Overall: 6 (27) G1: 3 (33) G2: 3 (23) Ages 5 to 6 years, n (%) Overall: 1 (5) G1: 1 (11) G2: 3 (23)	Overall: 64 G1: 78 G2: 54	NR	NA
Jones et al, 2005[126]	Stuttering	Ages 3 to 4 years, n (%) Overall: 29 (54) G1: 17 (59) G2: 12 (48) Ages 4 to 5 years, n (%) Overall: 21 (39) G1: 9 (31) G2: 12 (48) Ages 5 to 6 years, n (%) Overall: 4 (7) G1: 3 (10) G2: 1 (4)	Overall: 22 G1: 24 G2: 20	NR	NA

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Diagnosis	Overall Age	% Female	% Race/Ethnicity	Comments
Fricke et al, 2013[125]	NR	Overall: 36 (4) G1: 36 (4) G2: 36 (4)	NR	NR	NA
Yoder et al, 2005[129]	Grammatical and speech intelligibility impairments	Overall age in years (SD): 3.65 (0.71) Mean age in months (SD): G1: 43.2 (9.6) G2: 44.3 (7.6)	Overall: 27	% Euro-American: 71% % African American: 13% % Asian: 2% % Other: 12%	NA
Wake et al, 2013[130]	Expressive/receptive language delay	G1: 4.2 (0.1) G2: 4.1 (0.1)	32/36	NR	

Author, Year	Treatment Interventions/ Comparators	Cointerventions	Description of Interventions and Comparators	Fidelity or Adherence to Treatment Regimen	Does Study Examine Modifying Effects of Any Demographic or Other Patient Characteristics?	Country
Wake et al, 2011[128]	G1: Modified "You Make a Difference" program G2: Control group	NR	Modified version of "You Make the Difference" that was shortened from 9 to 6 weekly sessions and supported by resources (guidebook, videotapes) for parents and training workshops for program leaders. Promoted child centered, interaction promoting, and language modeling responsive interaction strategies. 2-hour weekly sessions were held over 6 weeks at a local community center with child care. In total, 20 programs were offered; each included three to eight children and was led by one of three interventionists who had attended a 3-day Hanen training program followed by specific training in the modified version. Parents attended the first 1.5 hours while children were supervised in an adjacent room. In each session, the group leader started by reviewing the previous week's home practice and showing video clips of parent-child interactions to highlight previously learnt strategies; this was followed by a participative lecture. In the last 30 minutes, each parent-child pair was videotaped practicing the new strategies with coaching as needed, from which a short positive clip was drawn to view the following week to reinforce specific strategies. The control group received "usual care," which was not further defined.	In the intervention arm, 115 (73%) parents attended at least one session (mean, 4.5 [SD, 1.6]; range, 1 to 6), and 90 (57%) parents attended four or more sessions	NR	Melbourne, Australia

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Treatment Interventions/ Comparators	Cointerventions	Description of Interventions and Comparators	Fidelity or Adherence to Treatment Regimen	Does Study Examine Modifying Effects of Any Demographic or Other Patient Characteristics?	Country
Lewis et al, 2008[127]	G1: Experimental group G2: Control group	None	Children were treated via weekly telephone consultations with procedures as similar as possible to those in the Lidcombe treatment manual, including the following adaptations: regularly scheduled telephone consultations, video demonstrations of speech-language professionals conducting treatment replaced the individual demonstration of treatment, additional support was provided by phone or email, measures of % syllables stuttered were made from recorded speech samples, parent training was done with recorded speech samples and telephone conversations, observation and evaluation of parent implementation and treatment were based on audio recorded samples	The treating SLP established from audio recordings on a weekly basis that parents were adhering to the recommended treatment procedures and delivering contingencies as directed. The SLP noted the following averages per recording per parent for the five contingencies: acknowledgment of stutter-free speech, 19; praise for stutter-free speech, 25; request for self-evaluation of stutter-free speech, 3.5; acknowledgment of stuttering, 1.3; and request for self-correction for stuttering, 4.5. This indicates that parents were delivering all the program contingencies and with a high ratio of reinforcement to punishment, as stipulated in the program manual.	No	Australia

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Treatment Interventions/ Comparators	Cointerventions	Description of Interventions and Comparators	Fidelity or Adherence to Treatment Regimen	Does Study Examine Modifying Effects of Any Demographic or Other Patient Characteristics?	Country
Jones et al, 2005[126]	G1: Lidcombe program G2: Control group	Children in the control arm could receive treatment during the trial at other clinics, provided it was not the Lidcombe program	G1: Children allocated to the Lidcombe program arm received treatment according to the program manual. Throughout, parents provided verbal contingencies for periods of stutter-free speech and for moments of stuttering. The program is conducted under the guidance of a SLP. During the first stage, the parent conducts the treatment for prescribed periods each day, and the parent and child visit the SLP once a week. The second stage starts when stuttering has been maintained at a frequency of <1.0% of syllables stuttered over 3 consecutive weeks inside and outside the clinic and is designed to maintain those low levels. Treatment is withdrawn, and the frequency of clinic visits decreases over a period of ≥1 year, providing stuttering remains at <1.0% of syllables stuttered. G2: Children did not receive treatment as part of the study; they could receive treatment at other clinics during the trial, provided it was not the Lidcombe program	Four children in the control arm received some Lidcombe program treatment and one child allocated to the intervention group received only 3 weeks of treatment	Yes; treatment site, sex, age, family history of recovery, baseline severity in % syllables stuttered	New Zealand
Fricke et al, 2013[125]	G1: Oral language intervention G2: Wait-list control group	NR	G1: Children allocated to the intervention group took part in a 30-week intervention program delivered by teaching assistants selected by their nursery/school. The first 10 weeks involved three 15-minute group sessions (2 to 4 children per group) per week delivered in preschool. Once the children entered school, this increased to three 30-minute sessions plus two 15-minute individual sessions. G2: Group received no additional teaching during the study.	NR	NR	United Kingdom

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Treatment Interventions/ Comparators	Cointerventions	Description of Interventions and Comparators	Fidelity or Adherence to Treatment Regimen	Does Study Examine Modifying Effects of Any Demographic or Other Patient Characteristics?	Country
Yoder et al, 2005[129]	G1: Broad target recasts G2: Control	NR	Children in the broad target recasts group received three 30-minute treatment sessions per week for 6 months. Children in the control group were free to participate in community-based treatments but were not provided broad target recasts.	Children assigned to the broad target recasts group attended an average of 74 treatment sessions (SD, 5.6). Only one participant did not meet the attendance criterion after enrolling in the study (missed treatment in excess of nine sessions).	Yes; percent consonants correct at baseline; raw score on the Arizona Articulation Proficiency Scale	United States
Wake et al, 2013[130]	G1: 18 in-home sessions by "language assistant" over 1 year G2: Parents contacted and given information on local speech pathology services	NR	18 in-home 1-hour targeted sessions in three blocks per week for 6 weeks, with 6 weeks of no intervention between blocks; trained language assistant	10 language assistants trained with 1-day workshop, individual 2-hour training with head SLP, observed on two occasions, ongoing guidance of 0.5-hour/week by SLP	Yes: type of delay (expressive vs. receptive), nonspecific vs. specific language delay (per IQ test), and maternal education level	Melbourne, Australia

Author, Year	Recruitment Setting	Intervention Setting	Patient Recruitment Method	N Eligible	N Randomized or Enrolled	N Completers	N Analyzed
Wake et al, 2011[128]	Maternal and child health center	Parents administered intervention in the home, following training sessions at local community centers	All newborn infants in Melbourne were allocated to a local maternal and child health nurse who provided developmental care to age 5 years. Nurses preidentified all infants born in May to October 2006 (Banyule, Kingston) or June to December 2006 (Frankston) and, at the 12-month visit (or by mail if they did not attend), ascertained interest in the trial. The research team then contacted interested families and mailed baseline questionnaires and written informed consent forms. Parents consented simultaneously to the baseline survey and entry into the trial if subsequently eligible. At 18 months, the research team mailed recruited parents the screening expressive vocabulary and behaviour checklists.	Overall: 1,451 G1: NR G2: NR	Overall: 301 G1: 158 G2: 143	G1: 140 G2: 127	G1: 140 G2: 127

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Recruitment Setting	Intervention Setting	Patient Recruitment Method	N Eligible	N Randomized or Enrolled	N Completers	N Analyzed
Lewis et al, 2008[127]	Trial was advertised in the press, and interested parents were invited to inquire via telephone	Home	Interested patients were invited to telephone the study team	Overall: 37 G1: NR G2: NR	Overall: 22 G1: 9 G2: 13	G1: 8 G2: 10	G1: 8 G2: 10
Jones et al, 2005[126]	Clinic	Clinic	Patients consisted of preschool children who presented to the speech clinics for treatment	Overall: 134	G1: 29 G2: 25	G1: 27 G2: 20	G1: 27 G2: 20
Fricke et al, 2013[125]	School	School	Screening was conducted in all children entering 19 nursery schools in the United Kingdom; children with the lowest mean composite verbal scores were selected as possible participants	Overall: 229	G1: 90 G2: 90	G1: 83 G2: 82	G1: NR G2: NR
Yoder et al, 2005[129]	NR	NR	NR	G1: 33 G2: 31	G1: 26 G2: 26	G1: 25 G2: 26	G1: NR G2: NR
Wake et al, 2013[130]	Local government areas	Home	Mail	G1: 123 G2: 143	G1: 99 G2: 101	G1: 93 G2: 91	G1: 93 G2: 91

Author, Year	Treatment Interventions and Comparators	Primary Outcomes of Interest	Speech	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results
Wake et al, 2011[128]	G1: Modified "You Make a Difference" program G2: Control group	Vocabulary, expressive communication, auditory comprehension, sentence use, language use/complexity	No	NA	NA	NA	NA	NA

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Treatment Interventions and Comparators	Primary Outcomes of Interest	Speech	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results
Lewis et al, 2008[127]	G1: Experimental group G2: Control group	% syllables stuttered	Yes	NA	9 months after randomization	Parents recorded samples of their children's speech, which was sent to speech-language professionals for assessment	G1: 8 G2: 10	Mean % syllables stuttered (no variance reported) At randomization G1: 6.7 G2: 4.5 9 months G1: 1.1 G2: 1.9 Between-group difference: -69 (95% CI, 13 to 89) p=0.04 Adjusted between-group difference: 73 (95% CI, 25 to 90) % decrease in syllables stuttered at 9 months by participant G1 P1: 97 P2: 36 P3: 89 P4: 88 P5: 96 P6: 100 P7: 37 P8: 89 G2 P1: 82 P2: 25 P3: -41 P4: 70 P5: 39 P6: 76 P7: 79 P8: 71 P9: 88 P10: 38

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Treatment Interventions and Comparators	Primary Outcomes of Interest	Speech	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results
Jones et al, 2005[126]	G1: Lidcombe program G2: Control group	% syllables stuttered	Yes	NA	Before randomization and at 9 months	Data was collected from recorded speech samples made by parents	G1: 27 G2: 20	% of syllables stuttered before randomization, mean (SD) G1: 6.4 (4.3) G2: 6.8 (4.9) % of syllables stuttered at 9 months, mean (SD) G1: 1.5 (1.4) G2: 3.9 (3.5) Between-group difference in % syllables stuttered: 2.3 (95% CI, 0.8 to 3.9) p=0.03
Fricke et al, 2013[125]	G1: Oral language intervention G2: Wait-list control group	Grammar and language	No	NA	NA	NA	NA	NA
Yoder et al, 2005[129]	G1: Broad target recasts G2: Control group	Mean length of utterance, intelligibility	Yes	NA	14 months	Study team	G1:25* G2: 26	Growth in intelligibility over time for both groups: $F(1.77, 50)=10.89$; $p<0.001$; $\eta^2=0.24$ No statistically significant differences between groups p>0.38
Wake et al, 2013[130]	G1: 18 in-home sessions by "language assistant" over 1 year G2: Parents contacted and given information on local speech pathology services	Standardized measures of expressive and receptive language	NA	NA	NA	NA	NA	NA

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Language	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results	Subgroup(s)
Wake et al, 2011[128]	Yes	NA	6 months post-randomization (12 weeks post-program); 18 months post-randomization	Parents and trained research assistants	Unadjusted 6 months G1: 135–140 G2: 133–134 18 months G1: 103–133 G2: 100–124 Adjusted 6 months G1: 119–125 G2: 121–122 18 months G1: 89–116 G2: 91–112	MCDI vocabulary raw score, mean (SD) 6 months G1: 34.5 (22.4) G2: 34.4 (23.4) Unadjusted mean difference: 0.1 Adjusted mean difference: 2.1 (95% CI, -3.0 to 7.2) p=0.42 18 months G1: 53.5 (27.9) G2: 51.4 (25.2) Unadjusted mean difference: 2.1 Adjusted mean difference: 4.1 (95% CI, -2.3 to 10.6) p=0.21 EVT expressive vocabulary standard score, mean (SD), 18 months G1: 100.5 (15.6) G2: 101.6 (12.0) Unadjusted mean difference: -1.1 Adjusted mean difference: -0.5 (95% CI, -4.4 to 3.4) p=0.80 PLS expressive communication standard score, mean (SD) 6 months G1: 90.4 (12.9) G2: 90.1 (11.2) Unadjusted mean difference: 0.3 Adjusted mean difference: 1.2 (95% CI, -1.6 to 4.0) p=0.41 18 months G1: 97.7 (16.1) G2: 100.7 (14.0) Unadjusted mean difference: -3.1 Adjusted mean difference: -2.4 (95% CI, -6.2 to 1.4) p=0.21	NR

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Language	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results	Subgroup(s)
Wake et al, 2011[128] (continued)						PLS auditory comprehension standard score, mean (SD) 6 months Unadjusted mean difference: -0.1 Adjusted mean difference: 1.4 (95% CI, -2.2 to 5.0) p=0.44 18 months G1: 96.1 (17.5) G2: 97.0 (14.7) Unadjusted mean difference: -0.8 Adjusted mean difference: -0.3 (95% CI, -4.2 to 3.7) p=0.90 MCDI sentence use raw score, mean (SD) 18 months G1: 5.6 (4.1) G2: 5.7 (3.8) Unadjusted mean difference: -0.2 Adjusted mean difference: 0.3 (95% CI, -0.6 to 1.3) p=0.51 MCDI language use/complexity raw score, mean (SD), 18 months G1: 6.7 (2.9) G2: 7.0 (2.8) Unadjusted mean difference: -0.3 Adjusted mean difference: -0.1 (95% CI, -0.9 to 0.6) p=0.74	
Lewis et al, 2008[127]	No	NA	NA	NA	NA	NA	NR
Jones et al, 2005[126]	NA	NA	NA	NA	NA	NA	Treatment site; sex; age; family history of recovery; baseline severity in % syllables stuttered

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Language	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results	Subgroup(s)
Fricke et al, 2013[125]	Yes	NA	Measures were taken at screening, during pretest, at 30 weeks, and 6 months later at maintenance test	NR (likely clinicians)	G1: 90 G2: 90	Grammar skills: CELF-Expressive Vocabulary At screening G1: 12.60 (6.09) G2: 12.37 (5.97) 30 weeks G1: 32.16 (10.02) G2: 27.84 (9.60) Cohen's d=0.681 6 months: G1: 36.27 (8.54) G2: 32.17 (9.14) Cohen's d=0.641 Grammar: CELF-Sentence Structure Pretest G1: 10.15 (4.06) G2: 10.20 (4.45) 30 weeks G1: 23.45 (5.16) G2: 22.86 (4.50) Cohen's d=0.151 Vocabulary-APT information Pretest G1: 20.65 (6.16) G2: 21.06 (5.87) 30 weeks G1: 31.40 (4.91) G2: 29.65 (4.88) Cohen's d=0.361 6 months G1: 31.37 (4.73) G2: 28.90 (5.08) Cohen's d=0481 Grammar-APT grammar Pretest G1: 12.09 (5.41) G2: 14.44 (5.26) 30 weeks G1: 24.60 (5.43) G2: 22.05 (5.71) Cohen's d=0.921	NR

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Language	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results	Subgroup(s)
Fricke et al, 2013[125] (continued)						6 months G1: 25.11 (4.98) G2: 21.60 (5.15) Cohen's d=1.101 Listening comprehension Pretest G1: 3.05 (2.43) G2: 3.14 (2.99) 30 weeks G1: 6.41 (3.34) G2: 5.59 (3.33) Cohen's d=0.331 6 months G1: 7.57 (3.00) G2: 6.11 (2.75) Cohen's d=0.571 Narrative mean length of utterance Pretest: G1: 4.28 (1.96) G2: 4.74 (1.66) 30 weeks G1: 6.81 (2.16) G2: 6.79 (1.78) Cohen's d=0.271 6 months G1: 7.62 (1.95) G2: 7.81 (2.38) Cohen's d=0.151 Narrative number of words used Pretest G1: 50.50 (32.77) G2: 55.25 (34.80) 30 weeks G1: 102.81 (47.97) G2: 86.58 (38.57) Cohen's d=0.621 6 months G1: 113.15 (44.52) G2: 101.51 (45.10) Cohen's d=0.481	

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Language	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results	Subgroup(s)
Fricke et al, 2013[125] (continued)						Narrative number of different words Pretest: G1: 12.49 (7.16) G2: 13.27 (6.93) 30 weeks G1: 26.23 (9.97) G2: 23.15 (8.85) Cohen's d=0.551 6 months G1: 27.36 (8.86) G2: 24.42 (9.68) Cohen's d=0.531 Reading comprehension Marginal mean group difference: 0.97 (95% CI, 0.40 to 1.54; z=3.32, p=0.001) With additional covariate reading accuracy: 0.91 (95% CI, 0.42 to 1.41; z=3.63; p<0.001) Latent variable model analyses: Effects of intervention: Language: Immediate post-test d=0.80; z=6.57; p<0.001 Maintenance test d=0.83; z=2.41; p<0.001 Narrative: Immediate post-test d=0.39; z=2.97; p=0.003 Maintenance test d=0.30; z=2.04; p=0.041 Phoneme awareness: Immediate post-test d=0.49; z=2.16; p=0.031 Maintenance test d=0.49; z=2.58; p=0.01 Literacy: Immediate post-test d=0.31; z=1.81; p=0.07 Maintenance test d=0.14; z=0.93; p=0.354	
Yoder et al, 2005[129]	Yes	NA	14 months	Study team	G1: 25* G2: 26	Growth in mean language utterance over time for both groups: F(1.43, 50)=67.18; p<0.001; η^2=0.62 No statistically significant differences between groups p>0.38	% consonants correct at baseline; raw score on the Arizona Articulation Proficiency Scale

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Language	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results	Subgroup(s)
Wake et al, 2013[130]	NA	NA	Post-test 12 months from initial ascertainment	Child's score on CELF-P2	200	G1: Expressive CELF-P2 score, 87.5; receptive, 87.6 G2: Expressive CELF-P2 score, 84.6; receptive, 86.5 Difference(s) between groups: expressive, 2.0 (adjusted); receptive, 0.6 (adjusted)	NA

Author, Year	Subgroup for Speech Outcome	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results
Wake et al, 2011[128]	NA	NA	NA	NA	NA	NA
Lewis et al, 2008[127]	NA	NA	NA	NA	NA	NA
Jones et al, 2005[126]	Yes	NA	Before randomization and at 9 months	Data was collected from recorded speech samples made by parents	Treatment site: Auckland: 22 Christchurch: 25 Sex: Male: 37 Female: 10 Age: <4 years: 28 >4 years: 19 Family history of recovery: No: 26 Yes: 21 Baseline severity in % syllables stuttered: <5: 19 >5: 28	Effect size as % syllables stuttered (95% CI) Treatment site: Auckland: 1.1 (-0.6 to 2.8) Christchurch: 3.3 (0.9 to 5.8) p=0.15 Sex: Male: 2.4 (0.6 to 4.2) Female: 2.0 (-1.6 to 5.5) p=0.8 Age: <4 years: 2.4 (0.1 to 4.7) >4 years: 2.3 (0.4 to 4.2) p=0.9 Family history of recovery: No: 3.8 (1.5 to 6.2) Yes: 0.5 (-1.6 to 2.7) p=0.027 Baseline severity in % syllables stuttered: <5: 2.1 (0.2 to 4.0) >5: 2.7 (0.5 to 4.9) p=0.6

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Subgroup for Speech Outcome	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results
Fricke et al, 2013[125]	NA	NA	NA	NA	NA	NA
Yoder et al, 2005[129]	Yes	NA	14 months	Study team	G1: 25* G2: 26	Change in intelligibility by raw score on the Arizona Articulation Proficiency Scale Intelligibility at followup: R^2=0.08; t=-2.02; p=0.03 Uncentered value on pretreatment variable below which the treatment groups differ: 45.63
Wake et al, 2013[130]	NA	NA	NA	NA	NA	NA

Author, Year	Subgroups for Speech or Language Outcomes	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results	Comments
Wake et al, 2011[128]	NA	NA	NA	NA	NA	NA	NA
Lewis et al, 2008[127]	NA	NA	NA	NA	NA	NA	NA
Jones et al, 2005[126]	NA	NA	NA	NA	NA	NA	Subgroup data may not be useful, as it is not broken down by treatment arm
Fricke et al, 2013[125]	NA	NA	NA	NA	NA	NA	NA
Yoder et al, 2005[129]	Yes	NA	6 months, 14 months	Study team	G1: 25* G2: 26	Change in MLU by % consonants correct at baseline MLU at posttreatment (6 months) R^2 change=0.12; t=-2.06; p=0.01 Uncentered value on pretreatment variable below which the treatment groups differ: 49 MLU at followup (14 months) R^2 change=0.09; t=-2.3; p=0.03 Uncentered value on pretreatment variable below which the treatment groups differ: 50.86	NA
Wake et al, 2013[130]	NA	NA	NA	NA	NA	NA	NA

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Screening or Treatment Interventions and Comparators	Secondary Outcomes of Interest	Academic Achievement	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results
Wake et al, 2011[128]	G1: Modified "You Make a Difference" program G2: Control group	Externalizing behavior, internalizing behavior	No	NA	NA	NA	NA	NA
Lewis et al, 2008[127]	G1: Experimental group G2: Control group	NR	NA	NA	NA	NA	NA	NA
Jones et al, 2005[126]	G1: Lidcombe program G2: Control group	NR	NA	NA	NA	NA	NA	NA
Fricke et al, 2013[125]	G1: Oral language intervention G2: Wait-list control group	Phonological awareness, literacy skills, and general cognitive ability	Yes	NA	Measures taken at screening, during pretest, during mid-test 1 and 2, at 30 weeks, and 6 months later at maintenance test	NR (likely clinicians)	G1: 90 G2: 90	Alliteration matching Pretest G1: 3.72 (2.31) G2: 4.31 (2.18) 30 weeks G1: 7.17 (2.28) G2: 6.59 (2.28) Cohen's d=0.521 Sound isolation Pretest G1: 0.09 (0.36) G2: 0.29 (0.87) 30 weeks G1: 5.83 (3.70) G2: 5.46 (3.56) Cohen's d=0.132 Segmentation, blending, and deletion 6 months G1: 8.42 (4.11) G2: 7.55 (4.32) Cohen's d=0.212 Letter knowledge Pretest G1: 1.36 (1.70) G2: 1.35 (2.35) 30 weeks G1: 13.62 (3.68) G2: 12.50 (3.53) Cohen's d=0.541

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Screening or Treatment Interventions and Comparators	Secondary Outcomes of Interest	Academic Achievement	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results
Fricke et al, 2013[125] (continued)								Early word reading Pretest G1: 0.00 (0.00) G2: 0.03 (0.18) 30 weeks G1: 7.73 (6.34) G2: 6.68 (6.98) Cohen's d=0.162 6 months G1: 11.94 (7.03) G2: 11.57 (8.73) Cohen's d=0.052 Text reading accuracy (errors) 6 months G1: 8.57 (5.41) G2: 8.32 (5.84) Cohen's d=-0.052 Reading comprehension 6 months G1: 4.80 (1.58) G2: 3.91 (1.83) Cohen's d=0.522 Spelling At test 2 (no time specified) G1: 4.07 (5.20) G2: 5.42 (7.59) 30 weeks G1: 35.75 (18.17) G2: 31.78 (18.24) Cohen's d=0.821 6 months G1: 70.86 (30.21) G2: 69.94 (32.44) Cohen's d=0.351 General cognitive ability: WPPSI block design At test 1 (no time specified) G1: 9.00 (2.65) G2: 8.91 (3.02)

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Screening or Treatment Interventions and Comparators	Secondary Outcomes of Interest	Academic Achievement	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results
Yoder et al, 2005[129]	G1: Broad target recasts G2: Control group	NR	NA	NA	NA	NA	NA	NA
Wake et al, 2013[130]	G1: 18 in-home sessions by "language assistant" over 1 year G2: Parents contacted and given information on local speech pathology services	Health-related quality of life (PedsQL and HUI3)	Yes	NA	12 months between pre- and post-test	Parent	200	G1: PedsQL, 76.6; HUI3, 0.9 G2: PedsQL, 76.4; HUI3, 0.9 Difference(s) between groups: PedsQL, -0.8; HUI3, -0.02

Author, Year	Behavioral Competence	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results
Wake et al, 2011[128]	Yes	NA	6 months post-randomization (12 weeks post-program); 18 months post-randomization	Parents and trained research assistants	Unadjusted 6 months G1: 135–140 G2: 133–134 18 months G1: 103–133 G2: 100–124 Adjusted 6 months G1: 119–125 G2: 121–122 18 months G1: 89–116 G2: 91–112	CBCL externalising behaviour raw score, mean (SD) 6 months G1: 12.3 (7.8) G2: 12.0 (7.3) Unadjusted mean difference: 0.3 Adjusted mean difference (95% CI): -0.3 (-1.6 to 1.1) p=0.71 18 months G1: 10.8 (7.9) G2: 10.7 (6.9) Unadjusted mean difference: 0.1 Adjusted mean difference (95% CI): -0.1 (-1.6 to 1.4) p=0.86 CBCL internalising behaviour raw score, mean (SD) 6 months G1: 5.7 (5.2) G2: 5.4 (3.9) Unadjusted mean difference: 0.3 Adjusted mean difference (95% CI): 0.1 (-0.9 to 1.1) p=0.78 18 months G1: 6.3 (5.7) G2: 6.0 (4.6) Unadjusted mean difference: 0.2 Adjusted mean difference (95% CI): -0.1 (-1.3 to 1.2) p=0.92

Appendix D Table 3. Evidence Tables for Interventions for Speech and Language Delays in Children Age 5 Years or Younger: KQ 5 Outcomes

Author, Year	Behavioral Competence	Unit of Analysis if Not the Patient	Timing of Outcome Measurement	Data Source	N	Results
Lewis et al, 2008[127]	No	NA	NA	NA	NA	NA
Jones et al, 2005[126]	No	NA	NA	NA	NA	NA
Fricke et al, 2013[125]	No	NA	NA	NA	NA	NA
Yoder et al, 2005[129]	No	NA	NA	NA	NA	NA
Wake et al, 2013[130]	No	NA	NA	NA	NA	NA

* It is not clear if the one drop-out was included in analysis.

Abbreviations: APT = aptitude; CBCL = Child Behavior Checklist; CELF-P2 = Clinical Evaluation of Language Fundamentals–Preschool, 2nd edition; CI = confidence interval; EVT = Expressive Vocabulary Test; G = group; HUI3 = Health Utilities Index, Mark 3; IQ = intelligence quotient; MCDI = MacArthur Communicative Development Inventory for Infants; MLU = mean length of utterance; N = number; NA = not applicable; NR = not reported; PedsQL = Pediatric Quality of Life Inventory; PLS = Preschool Language Scale; RCT = randomized, controlled trial; SD =standard deviation; SLP = speech-language pathologist; WPPSI = Wechsler Preschool and Primary Scale of Intelligence.

Formula for calculating 95% confidence interval for sensitivity:
95% confidence interval = sensitivity +/- 1.96 ($SE_{sensitivity}$)
Where $SE_{sensitivity}$ = square root [sensitivity – (1-sensitivity)]/$n_{sensitivity}$)

Formula for calculating 95% confidence interval for specificity:
95% confidence interval = specificity +/- 1.96 ($SE_{specificity}$)
Where $SE_{specificity}$ = square root [specificity – (1-specificity)]/$n_{specificity}$)

From Robert M. Hamm, PhD; http://www.fammed.ouhsc.edu/robhamm/cdmcalc.htm

Derivation of formula for any proportion or probability:
pi*n =(p/n)*n
(1-pi)*n = (q/n)*n

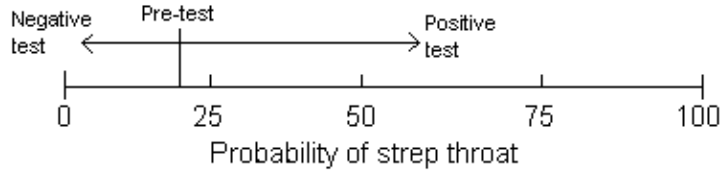
The normal approximation is not trustable as pi nears 0 or nears 1.

From Ott L. An Introduction to Statistical Methods and Data Analysis. 3rd ed. Boston: PWS-Kent Publishing; 1988.

Confidence interval = best estimate +/- (z for desired (1-alpha)) times (standard error of pi)
Best estimate is pi
Pi z for 95% CI, 2 tailed is 1.96
standard error of pi is square root of (pq/nnn) pq/nnn or sqrt(pi*(1-pi)/n)
Confidence interval = Pi+/-1.96*pq/nnn

From Ebell E, Barry H. Evidence-Based Medicine Course. East Lansing, MI: Michigan State University; 2008. http://omerad.msu.edu/ebm/index.html

Likelihood Ratios Part 1: Introduction
When we decide to order a diagnostic test, we want to know which test (or tests) will best help us rule-in or rule-out disease in our patient. In the language of clinical epidemiology, we take our initial assessment of the likelihood of disease ("pre-test probability"), do a test to help us shift our suspicion one way or the other, and then determine a final assessment of the likelihood of disease ("post-test probability"). Take a look at the diagram below, which graphically illustrates this process of "revising the probability of disease."



Likelihood ratios tell us how much we should shift our suspicion for a particular test result. Because tests can be positive or negative, there are at least two likelihood ratios for each test. The "positive likelihood ratio" (LR+) tells us how much to increase the probability of disease if

the test is positive, while the "negative likelihood ratio" (LR-) tells us how much to decrease it if the test is negative. The formula for calculating the likelihood ratio is:

$$\text{LR} = \frac{\text{probability of an individual } \textbf{with} \text{ the condition having the test result}}{\text{probability of an individual } \textbf{without} \text{ the condition having the test result}}$$

Thus, the positive likelihood ratio is:

$$\text{LR+} = \frac{\text{probability of an individual } \textbf{with} \text{ the condition having a positive test}}{\text{probability of an individual } \textbf{without} \text{ the condition having a positive test}}$$

Similarly, the negative likelihood ratio is:

$$\text{LR-} = \frac{\text{probability of an individual } \textbf{with} \text{ the condition having a negative test}}{\text{probability of an individual } \textbf{without} \text{ the condition having a negative test}}$$

You can also define the LR+ and LR- in terms of sensitivity and specificity:

$$\text{LR+} = \frac{\text{sensitivity}}{\text{1-specificity}}$$

$$\text{LR-} = \frac{\text{1-sensitivity}}{\text{specificity}}$$

(Of course, if you're using sensitivity and specificity on a scale of 0 to 100 instead of 0 to 1, the equations would be sensitivity / (100-specificity) and (100-sensitivity)/specificity, respectively).

Let's consider an example. In a study of the ability of rapid antigen tests to diagnose strep pharyngitis, 90% of patients with strep pharyngitis have a positive rapid antigen test, while only 5% of those without strep pharyngitis have a positive test. The LR+ for the ability of rapid antigen tests to diagnose strep pharyngitis is (select one):

LR+ = 90% / 5% = 18 (http://omerad.msu.edu/ebm/Diagnosis/strepanswer18.html)
LR+ = 95% / 10% = 9.5 (http://omerad.msu.edu/ebm/Diagnosis/strepanswer9.html)
LR+ = 90% / 95% = 0.95 (http://omerad.msu.edu/ebm/Diagnosis/strepanswer95.html)

Interpreting Likelihood Ratios: General Guidelines

The first thing to realize about LR's is that an LR > 1 indicates an increased probability that the target disorder is present, and an LR < 1 indicates a decreased probability that the target disorder is present. Correspondingly, an LR = 1 means that the test result does not change the probability of disease at all! The following are general guidelines, which must be correlated with the clinical scenario:

LR	Interpretation
> 10	Large and often conclusive increase in the likelihood of disease
5 - 10	Moderate increase in the likelihood of disease
2 - 5	Small increase in the likelihood of disease
1 – 2	Minimal increase in the likelihood of disease
1	**No change in the likelihood of disease**
0.5 - 1.0	Minimal decrease in the likelihood of disease
0.2 - 0.5	Small decrease in the likelihood of disease
0.1 - 0.2	Moderate decrease in the likelihood of disease
< 0.1	Large and often conclusive decrease in the likelihood of disease

The decision to order a test is also based on our initial assessment of the likelihood of the target disorder, and how important it is to rule-in or rule-out disease. For example, a chest x-ray might have a good likelihood ratio for pneumonia. But if you believe a patient has a simple cold, this test, no matter how good the LR, probably shouldn't be ordered. It is sometimes helpful to be able to calculate the exact probability of disease given a positive or negative test. We saw that this is next to impossible using sensitivity and specificity at the bedside (unless you can do Bayes' Theorem in your head).

Appendix F Table 1. External Validity of Screening Studies

Author, Year	Screening/Treatment Interventions and Comparators	Study Design	Is the Study Population Broadly Applicable?	Comments	Is the Intervention/ Screening Broadly Applicable?	Comments
Sachse and Von Suchodoletz, 2008[76] Sachse and Von Suchodoletz, 2009[77]	German version of the CDI Toddler form (ELFRA-2)	Prospective followup of screened group	Yes	Population appears to be representative of 2-year-olds in one community in Germany; 71% response rate to screening	Yes	German version of CDI
Westerlund et al, 2006[78]	G1: Swedish Communication Screening at age 18 months (SCS-18) (derived from CDI) G2: Traditional 18-month assessment (child's use of at least 8 words and understanding of more)	RCT cluster	Yes	Population is representative of 18-month-olds in Sweden	Yes	Swedish version of CDI
Heilmann et al, 2005[75]	Communicative Development Inventory Words and Sentences	Other	Yes	NA	Yes	NA
Guiberson et al, 2011[74]	Spanish version of Ages and Stages Questionnaire; Spanish version of CDI-short form (Inventarios del desarrolo de habilidades comunicativas: palabras y enuciados [INV-II]); mean of three longest reported utterances; demographic and developmental questionnaire	0	Yes	Spanish-speaking population from Head Start and early intervention programs; probably representative of lower-income Spanish-speaking families	Yes	Screening information is applicable for Spanish-speaking toddlers
Guiberson and Rodriguez, 2010[73]	Spanish Ages and Stages Questionnaire Communication Domain; Spanish version of CDI-III (Pilot Inventario-III)	Prospective followup of screened group	Yes	Applicable to Spanish-speaking preschool children in Head Start	Yes	Applicable to Spanish-speaking children
Frisk et al, 2009[72]	Ages and Stages Questionnaire; Battelle Developmental Inventory Screening Test; Brigance Preschool Screen; Early Screening Profile	Prospective followup of screened group	No	Very high risk group in which the majority has evidence of one or more risk factors and 42% displaying less than average intelligence	Yes	NA
Rigby and Chesham, 1981[86]	Trial speech screening test	0	Cannot be determined	No information other than participants were the total population of children (somewhere in the United Kingdom) who came for school entry medical examination who were being seen by a speech therapist.	Cannot be determined	NA

Appendix F Table 1. External Validity of Screening Studies

Author, Year	Screening/Treatment Interventions and Comparators	Study Design	Is the Study Population Broadly Applicable?	Comments	Is the Intervention/ Screening Broadly Applicable?	Comments
Wetherby et al, 2003[88]	Infant-Child Checklist, a 5- to 10-minute checklist completed by parents	Other	Yes	Racially/ethnically diverse, though fewer with low socioeconomic status; sample was weighted with more children who screened positive	Yes	NA

Author, Year	Is the Comparator Broadly Applicable?	Comments	Are Outcomes Broadly Applicable?	Comments	External Validity Assessment	Comment
Sachse and Von Suchodoletz, 2008[76] Sachse and Von Suchodoletz, 2009[77]	NA	NA	NA	NA	Fair	German health care system may be different
Westerlund et al, 2006[78]	Yes	Comparison screening is single question	NA	NA	Fair	Swedish health care system may be different
Heilmann et al, 2005[75]	NA	NA	NA	NA	Good	Study was conducted in United States and includes children who are broadly representative of those who are late talkers with typical language development, although not quite as demographically and racially diverse as would be desired
Guiberson et al, 2011[74]	NA	NA	NA	NA	Fair	Small sample of lower-income families (Spanish-speaking)
Guiberson and Rodriguez, 2010[73]	NA	NA	NA	NA	Fair	Small sample of lower-income families
Frisk et al, 2009[72]	NA	NA	NA	NA	Poor	While the study may have applicability for an at risk population, the findings may not apply to a U.S. primary care population
Rigby and Chesham, 1981[86]	NA	NA	NA	NA	Fair	The screening instrument was used in primary care settings in the United Kingdom, so presumably it could be done in the United States, but little is known about other aspects of the population of children or the settings
Wetherby et al, 2003[88]	NA	NA	NA	NA	Fair	Fewer low socioeconomic status children and greater weighting of children who screened positive

Abbreviations: CDI = MacArthur Bates Communicative Development Inventory; ELFRA-2 = Elternfragebogen fur die Fruberkennung von Riskokindern; NA = not applicable; RCT = randomized, controlled trial; SCS-18 = Swedish Communication Screening at 18 months of age.

Appendix F Table 2. External Validity of Intervention Studies

Author, Year	Screening/Treatment Interventions and Comparators	Study Design	Is the Study Population Broadly Applicable?	Comments	Is the Intervention/ Screening Broadly Applicable?	Comments
Fricke et al, 2013[125]	G1: Oral language intervention; 30-week program to improve vocabulary, narrative skills, listening, and speaking G2: Wait-list control group	RCT parallel	Yes	NA	No	School-based study implemented in the United Kingdom with children in Nursery (ages 3 to 4 years) and Reception (age 5 years) classrooms; intervention spanned both classrooms. Dissimilarites with U.S. early education system constrain applicability.
Jones et al, 2005[126]	G2: Lidcombe Programme of Early Stuttering	RCT parallel	Yes	NA	No	Lidcombe program not widely available in United States; training in Lidcombe program not widely available and currently costs ~$500
Lewis et al, 2008[127]	G3: None	RCT parallel	Yes	NA	No	Lidcombe program not widely available in United States; training in Lidcombe program not widely available and currently costs ~$500
Wake et al, 2011[128]	G1: Modified "You Make a Difference" (Hanen parent training program) G2: Control group	RCT cluster	Yes	NA	No	Study implemented in Australia; use of Hanen requires certification; many certified providers of Hanen parent training programs in United States, especially in private practice; current cost of 3-day certification workshop is ~$850
Gibbard, 1994[136] Study 1	G1: Parent group-training sessions 60–75 minutes every other week for 6 months focusing on language activities to use with children G2: Wait-list control group	RCT parallel	No	Excluded children with medical conditions associated with speech and language delays, including otitis media, which occurs frequently in this age group	Yes	Study was implemented in the United Kingdom but seems feasible in U.S. context
Girolametto et al, 1996[137] Girolametto et al, 1997[138]	G1: Hanen parent training program, comprising eight 2.5-hour parent group sessions and three home visits to teach parents focused stimulation of children's language G2: Wait-list control	RCT parallel	Yes	NA	No	Study implemented in Canada; use of Hanen requires certification; many certified providers of Hanen parent training programs in United States, especially in private practice; current cost of 3-day certification workshop is ~$850

Appendix F Table 2. External Validity of Intervention Studies

Author, Year	Screening/Treatment Interventions and Comparators	Study Design	Is the Study Population Broadly Applicable?	Comments	Is the Intervention/ Screening Broadly Applicable?	Comments
Robertson and Weismer, 1999[139]	G1: Speech-language pathologist–directed small group therapy 150 minutes per week for 12 weeks G2: Wait-list control	RCT parallel	Yes	NA	No	Study in a U.S. center-based birth-to-3-years program; current public IDEA part C programs are primarily home-based
Robertson and Weismer, 1997[140]	G1: At least four 15- to 20-minute unstructured play sessions in "house" area with normal peers over 3 weeks G2: No play sessions with normal peers	RCT parallel	Yes	NA	Yes	NA
Almost and Rosenbaum, 1998[134]	G1: Speech-language therapy for phonology using a cycles approach, two 30-minute sessions per week for 4 months G2: Wait-list control	RCT parallel	Yes	NA	Yes	Study conducted through a secondary care facility in Canada, but the approach is widely used in the United States across varied settings
Shelton et al, 1978[141]	G1: Parent-directed speech sound listening/ discrimination activities for 5 minutes per day G2: 15 minutes per day of parent-child storybook interaction (reading and talking group) for 57 days G3: Control group	RCT parallel	Yes	NA	No	Use of parents to provide explicit treatment of articulation (G1) is not currently a common practice in the United States; group that used storybook interactions would be applicable
Glogowska et al, 2000[135]	G1: Clinician-directed individual intervention routinely offered by the therapist for 12 months (mean of 6.2 total hours of therapy) G2: Watchful waiting control group	RCT parallel	Yes	NA	Yes	Study conducted in the United Kingdom but level of service is feasible within the U.S. system of care
Yoder et al, 2005[129]	G1: Broad target recasts intervention G2: No intervention control; "free to participate in community-based treatments"	RCT parallel	Yes	NA	Cannot be determined	Study did not limit community-based services and so replication of comparison would be difficult

Appendix F Table 2. External Validity of Intervention Studies

Author, Year	Screening/Treatment Interventions and Comparators	Study Design	Is the Study Population Broadly Applicable?	Comments	Is the Intervention/ Screening Broadly Applicable?	Comments
Wake et al, 2013[130]	G1: 18 in-home sessions by "language assistant" over 1 year G2: Parents contacted and given information on local speech pathology services	RCT	Yes	NA	Yes	Manualized intervention that can be delivered by nonspecialist staff

Author, Year	Is the Comparator Broadly Applicable?	Comments	Are the Outcomes Broadly Applicable?	Comments	External Validity Assessment
Fricke et al, 2013[10]	No	Comparator (wait-list control) involved children enrolled in Nursery and Reception classrooms in the United Kingdom who did not receive the experimental program	Yes	NA	Fair
Jones et al, 2005[126]	Yes	NA	Yes	NA	Fair
Lewis et al, 2008[127]	Yes	NA	Yes	NA	Fair
Wake et al, 2011[128]	Yes	NA	Yes	NA	Fair
Gibbard, 1994[136] Study 1	Yes	NA	Yes	NA	Fair
Girolametto et al, 1996[137] Girolametto et al, 1997[138]	Yes	NA	Yes	NA	Fair
Robertson and Weismer, 1999[139]	No	Wait list for same intervention	Yes	NA	Fair
Robertson and Weismer, 1997[140]	Yes	NA	No	Outcomes are tied closely to the context of the intervention; they were maintained across time, but evidence of generalization to broader gains in language was not provided	Fair
Almost and Rosenbaum, 1998[134]	Yes	NA	Yes	NA	Good
Shelton et al, 1978[141]	Yes	NA	Yes	NA	Fair

Appendix F Table 2. External Validity of Intervention Studies

Author, Year	Is the Comparator Broadly Applicable?	Comments	Are the Outcomes Broadly Applicable?	Comments	External Validity Assessment
Glogowska et al, 2000[135]	Yes	NA	Yes	NA	Good
Yoder et al, 2005[129]	Cannot be determined	Study did not limit community-based services and so replication of comparison would be difficult	Yes	NA	Fair
Wake et al, 2013[130]	Yes	NA	Yes	NA	Good

Abbreviations: G = group; RCT = randomized controlled trial.

Appendix G. Ongoing Trials

Principal Investigators	Location	Population	Approximate Size	Investigations	Outcomes	Status as of 2014
Magalie Demilly and Gabriela Certad, MD, PhD	France	Children, ages 28 to 32 months, born preterm	140	Parent-implemented language intervention	Language score of the developmental neuropsychological assessment (NEPSY)	Not yet recruiting
Alan L. Mendelsohn, MD	US	Infant-mother dyads receiving care at Bellevue Hospital Center	675	Parenting programs to promote language development and school readiness for at-risk children	Language development Parenting Literacy development School readiness	Data collection anticipated to be completed June 2017
Holly Storkel	US	Children with specific language impairment, ages 5 to 6 years, normal intelligence	104	Use of interactive book reading to optimize word learning	Naming Ability to define words	Recruiting, anticipated to be completed September 2018
Shuvo Ghosh, MD	Canada	Children ages 24 to 42 months with diagnosed language impairment	30	Use of omega-3 supplementation to improve fast-mapping language skills	Change in learning assessed by a fast-mapping task	Recruiting, completion date unknown
Ann Kaiser	US	Children ages 24 to 42 months with language delay	120	RCT of Enhanced Milieu teaching with parents (language support services to improve their children's language skills)	Expressive language at 4 months Number of words and average sentence length	Final data collection completion anticipated to be September 2015
Anke Buschmann, MA	Germany	Children ages 24 to 27 months with receptive or expressive language delays	150	RCT of highly-structured parent-based language intervention	Parent report through screening instruments	Start date 2003, completion date unknown
Aravind Namasivayam, PhD	Canada	Children ages 3 to 10 years, moderate to severe speech sound disorder	44	RCT of Prompts for Restructuring Oral Muscular Phonetic Targets (PROMPT) approach	Change in speech motor control Change in speech articulation Change in word-level speech intelligibility Change in phonological processes	Recruiting, anticipated completion December 2015
Mark Onslow, MD	Australia	Children ages 3 to 7 years who have completed Lidcombe program on stuttering	180	RCT of short message service reminders	Percentage of syllables stuttered	Estimated completion December 2011, actual completion unknown

Appendix G. Ongoing Trials

Principal Investigators	Location	Population	Approximate Size	Investigations	Outcomes	Status as of 2014
Mark Onslow, MD	Australia	Children ages 3 to 6 years with early stuttering	120	RCT of Lidcombe method, varying the time between clinic visits during the first stage of the program	Number of clinic visits needed to achieve various stages of reduction in stuttering	Estimated completion December 2009, actual completion unknown

Abbreviations: RCT = randomized, controlled trial; US = United States.