HHS Public Access

Author manuscript

J Dev Behav Pediatr. Author manuscript; available in PMC 2017 September 01.

Published in final edited form as:

J Dev Behav Pediatr. 2016 September ; 37(7): 573–578. doi:10.1097/DBP.0000000000000345.

Commentary on USPSTF Final Statement on Universal Screening for Autism

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There has been a growing movement to encourage universal ASD screening and a steady increase in the percent of pediatricians and other pediatric health care providers providing such screening. However, on August 3, 2015, the US Preventive Services Task Force released a draft statement that concluded that "the current evidence is insufficient to assess the balance of benefits and harms of screening for autism spectrum disorder (ASD) in children for whom no concerns of ASD have been raised by their parents or clinical provider." The statement, therefore, failed to endorse universal ASD screening.

Created in 1984 by congressional mandate under the US Public Health Service, and transferred to AHRQ in 1995, the U.S. Preventive Services Task Force is an independent, volunteer panel of national experts in prevention and evidence-based medicine. It evaluates evidence and makes recommendations about preventive services such as screening, counseling, and preventive medications. The charge to USPSTF is to apply rigorous analysis to the best available evidence, and to make recommendations on preventive services to primary care clinicians for adults and children with no signs or symptoms. The USPSTF is not asked to consider ensuing clinical or health care policy implications of its decisions, but public health importance is considered when deciding which conditions to address. Its explicit mission is to:

1. Assess the benefits and harms of preventive services in people asymptomatic for the target condition, based on age, gender, and risk factors for disease; and
2. Make recommendations about which preventive services should be incorporated routinely into primary care practice.

Information about the Task Force's mission, membership, procedures, draft and final reports and the topics it has considered or is considering can be found at the websites of the Agency for Healthcare Research and Quality (www.ahrq.gov) and the Task Force's website: http://www.preventiveservices.ahrq.gov/

When the Task Force's draft statement about autism screening appeared in August, 2015, it caused serious concern among researchers, clinicians, and stakeholders because of its perceived potential negative impact on the welfare of affected children and their families. The Baby Siblings Research Consortium, a group of ASD researchers, together with advisors from the community, studies the emergence of ASD in young children with older affected siblings (i.e., "baby siblings"). Many of us also provide clinical care to children and families affected by ASD as well as studying ASD in other young children. We in the Consortium are very concerned about the effects of the Task Force draft statement in August, and the final statement released on February 17, 2016 in JAMA and available on the USPSTF website. The final statement reiterated the draft position, that evidence was insufficient to recommend population screening for ASD. It did respond to a few points made by stakeholders in response to the August draft, specifically softening the statement that screening and intervention are very low risk, suggesting instead that the risk/benefit ratio is not known, and suggesting research designs other than RCT's that compare screening to no screening.

Our concerns are shared by many other groups such as Autism Speaks and Autism Science Foundation. [1-4] The American Academy of Pediatrics endorses general developmental screening at multiple ages, and ASD-specific screening at 18 and 24 months, and continues to do so despite the Task Force recommendation. In the AAP News of August 4, 2015, Dr. Susan Levy, Chair of the AAP Autism Subcommittee, called the Task Force recommendations "very disturbing" and said it would be "a major step back to stop screening while more research is done". In response to the final Task Force statement, see the Feburary 16 statement by Dr. Dryer, President of the American Academy of Pediatrics on their website, continuing to endorse universal screening. The American Academy of Child Neurology and the American Academy of Child and Adolescent Psychiatry also endorse community screening for ASD. A recent paper in Pediatrics,[5] representing the consensus of an international panel of multidiscliplinary experts in screening and intervention for ASD, after a comprehensive literature review, also endorses universal screening: "Evidence supports the usefulness of ASD-specific screening at 18 and 24 months. ASD screening prior to 24 months may be associated with higher false-positive rates than screening at 24 months or later, but may still be informative." The Interagency Autism Coordinating Committee, a Federal advisory committee that coordinates efforts within the Department of Health and Human Services (HHS) concerning ASD, lists reducing the average age of diagnosis as one of its priorities, as well as identifying risk for ASD *before* full symptoms are present.

In recent years, pediatricians' awareness of ASD and of screening procedures in early childhood has increased; health insurance, including Medicaid, now generally reimburses physicians for ASD screening, removing one of the major barriers to screening. This increase has given many children the opportunity to be evaluated for ASD, diagnosed when

appropriate, and referred for early intervention services significantly earlier than otherwise possible. We are concerned that the Task Force final recommendations will turn the clock back on screening, allowing insurance companies to deny coverage for screening, and discouraging pediatric practitioners from engaging in universal screening. The recommendations could easily encourage a "wait-and-see" attitude by physicians, who are already under much pressure to conduct screening for other health conditions and to increase the number of patients they see. This is likely to result in delaying ASD diagnosis for many children, preventing the timely start of intervention, and thereby costing children the opportunity of reaching the best outcome of which they are capable as well as leading to increased family and societal costs of caring for individuals with ASD.

We believe that current evidence strongly supports early, universal screening for ASD. In what follows, we will consider the logical underpinnings for this claim. We refer to the USPSTF recommendations as the "Task Force statement" and the extensive literature review on which it is based, performed for the Task Force by the Vanderbilt Evidence-Based Practice Center as the "Literature Review".

We offer the following points to argue that there is logical and empirical evidence for the benefits of universal screening and that there are ethical issues related to conducting RCT's of screening vs. case finding.

1. **Universal early screening for ASD can successfully detect cases and lower the average age of detection;** evidence is clear for 18 and 24 month screening[6,7] and 12 month screening is under study by several groups.[8,9] **The Task Force report concedes this crucial point**.

2. **Relying on physician and parent concern to detect ASD in young children misses many cases**. Symptoms and developmental delays can be subtle at younger ages and can be easily missed by parents, especially for their first child, and by physicians in a brief well-child exam.[10]

3. **Many parents do become aware of, and concerned about, developmental anomalies in the first 2 years.** This result has been replicated consistently over the past 20 years;[11-13] nevertheless, the average age of diagnosis in the US, as per the Literature Review, is still around age 4 or 5 years (from the Literature Review: "Current approaches that include pediatric surveillance, general developmental screening, and a reliance on parents to raise concerns do not identify most children with ASD prior to age 4"). CDC monitoring, as described in the Literature Review, finds that only 44% of children with a later ASD diagnosis were assessed for developmental concerns prior to 36 months. In contrast, universal screening can lower the age of detection to 24 months or earlier and significantly reduce the time to diagnosis and referral for services,[8] reducing the family stress associated with delays in diagnosis and intervention. Indeed, two independent studies using different instruments have reported that systematic screening identifies ASD more consistently than an open ended question about concerns,[14,15] no doubt at least in part

because parents may be reluctant to voice these concerns or be unaware of what typical development looks like.

4. **Diagnosis of an ASD at 24 months or even younger, is reliable and valid.** Even though not all children with ASD are symptomatic in the second year of life, in those who are, stability of diagnosis is high and correlates well with later ASD diagnosis.[16-22]

5. **Families of lower socio-economic and minority status are detected and diagnosed later than higher SES and majority ethnic families** (as acknowledged in the Literature Review and the Task Force Final Statement), and therefore have access to intervention at a later age.[23] Elicitation of parent concerns varies by family ethnic status;[24] therefore, relying on parent concern reinforces ethnic disparity in age of diagnosis. Implementing standardized universal screening reduces this health disparity[25,26] and can be implemented successfully with minority families.[27] Thus ASD screening can 'level the playing field' to ensure that children, regardless of minority or socio-economic status, are not disadvantaged in terms of opportunities for early diagnosis.

6. **Risk of harm to families from false positive screening results is low**. Such risks include needless anxiety, and waste of family and clinician time and resources, risks that are common to all screening programs. These risks of harm are low in the case of ASD screening because the overwhelming majority of false positives (i.e., no ASD found) do have other developmental issues that require some form of treatment or monitoring.[6,7] The positive predictive value of ASD screeners is modest (approximately .5) for ASD but quite high (above .95) for a measurable developmental delay or condition.[7] The Task Force Draft Statement concedes that the potential harms of screening are "no greater than small", although that statement is qualified in the Final Statement: "The USPSTF revised the recommendation statement to clarify that, while the screening tools are relatively easy to administer and behavioral interventions are generally safe, the potential effects of extended treatment, in the absence of clear benefit, on families in terms of time and resources are not negligible." The drain on family time and resources would be a reasonable concern if a significant number of children without ASD were subjected to intensive and long-term unnecessary treatment. In reality, a definitive diagnosis of ASD is needed for children to qualify for these services (as the Literature Review states); children with confirmed ASD are much more likely not to be able to access these services than children without ASD are likely to be offered such services.

7. **Early detection leads to opportunities for earlier implementation of effective treatment.** The Task Force concludes that a variety of behaviorally based treatments do result in better outcomes for children, and the Literature Review clearly states that a formal diagnosis of ASD is

usually required for a child to obtain the evidence-based intensive services required for best outcome. The Zwaigenbaum et al review concludes that relative benefits of intervention before 36 months for even core symptoms of ASD have been supported in randomized control trials.[5] The Task Force asserts that participants in such treatment studies are generally more severe cases and older than those detected by screening and that results cannot be generalized to children detected by screening.

The problems with these conclusions are first, that cases detected by screening are not necessarily mild but run the gamut of clinical presentation; second, that even if screen-detected cases were milder, this would likely result in better response to treatment.[20,28] Furthermore, as the Literature Review assesses the efficacy of ASD treatments, it states that virtually all treatment studies compared the treatment under study to an alternative treatment or variant, often community based care as usual. If children are not screened and not detected at a young age, the relevant comparison would be to no treatment; this comparison would no doubt result in even stronger evidence of efficacy, and larger effect sizes.

Finally, the assumption that existing treatment studies[1,29,30] do not enroll children detected by screening is questionable. If the readers examine the method sections of the treatment studies covered in the Literature Review, in most cases, the source of initial suspicion or detection is not specified. For example, in the oft-cited Sallows and Graupner[28] study, children are recruited from local Birth to Three programs, and receive a diagnosis by an independent psychiatrist. Similarly, MacDonald et al.[31] enrolled 83 children independently diagnosed by a child psychologist and aged 17-48 months at entry into their treatment program. Neither study reports on who referred the child to Birth to Three or to the MacDonald program (New England Center for Children), or where the first suspicion arose. In the ongoing Robins et al MCHAT-R study, children are screened at pediatrician sites, screen positive cases are evaluated by the research team, and if a diagnosis of ASD is given, they are referred to an autism-specialty Birth to Three program for services. If they then participate in a treatment study, the screening mode of detection is not likely to be reported. It might be possible to go back to the children's initial records, identify those detected by population screening, and then compare age, response to treatment and later outcome for children picked up by screening to those detected by physician or parent concern.

8. **Younger age at entry into treatment generally leads to greater gains and better ultimate outcome**. The review of literature concludes that there is some "indirect" evidence that younger age at entry into treatment is associated with better outcomes. In actuality, the Literature Review covers multiple studies showing directly that earlier initiation of treatment is more potent. In addition, since this review was completed, there have been several studies of treatment of very young children showing very

promising outcomes for such children. A study of entry into intensive behavioral treatment before age 24, 36, and 48 months[29] showed gains for all groups of children, but with a direct relationship between age and outcome, such that children entering treatment before 24 months had significantly better outcomes. The recent pilot study of the Early Start Denver Model (ESDM) adapted for infants enrolled children aged 7 to 15 months into intensive treatment and reported extremely positive outcomes.[32] One recent long-term prospective study[33] and one recent retrospective study[34] found that children with "very positive" or "optimal" outcomes were disproportionately entered into treatment by 24 months This body of work, taken together, demonstrates that very early entry into treatment is likely to optimize outcome. As noted in the Literature Review, ASD-specific treatments carry low risk of harm to the child or family. Furthermore, as the Literature Review concedes, an ASD diagnosis is needed in most cases for access to intensive, ASD-specific treatment. Without detection through screening, many eligible children will not be referred for evaluation, will not receive a diagnosis, and will not, therefore, begin treatment at the earliest time.

Several additional points in the Task Force conclusions seem questionable:

9 **The Task Force recommendations apply to "asymptomatic" children and those not at known risk for ASD**. The Final Statement says that "Good-quality studies are needed to better understand the intermediate and long-term health outcomes of screening for ASD among children without obvious signs and symptoms." Since ASD is a behaviorally defined syndrome, children detected by screening and diagnosed with ASD are not, by definition, asymptomatic or without signs and symptoms. Whether a child's signs and symptoms are "obvious" depends to a large extent on the physician's training and experience in detecting such signs in very young children in the context of a brief office visit, and on the parent's sophistication in recognizing such signs or openness to concerns expressed by others. In addition, there are many children with elevated ASD risk of which parents or physicians are not aware. These include children with undiagnosed medical conditions that confer ASD risk, children with undiagnosed older siblings with ASD, and children with conditions such as prematurity whose associated ASD risk may not be appreciated. A small portion of baby siblings and premature infants are under intensive longitudinal study by members of our Baby Sibs Research Consortium, but most baby siblings and other children at elevated risk are not involved in this research and may not be recognized as having elevated risk. Universal screening will ensure that these children are included in screening and, hopefully, detected at a very early age.

10 **The Literature Review and Task Force statements stress the variable access to diagnostic and intervention services,** claiming that delays in this access add to potential family stress associated with screening. Surely the solution is to lobby for additional service provision, and not to let some cases

go undetected at an age when therapy can do the most good. As Zwaigenbaum et al.[5] note: "We would argue that screening is a public health intervention; that is, a comprehensive early detection strategy should not be solely based on the selection of a particular screening instrument but rather must include other changes to the overall system of care, such as enhanced training for health professionals and expanded capacity for early diagnosis and intervention by specialized teams. Thus, the outcomes of screening may not simply be related to the measurement properties of a tool, but also to the successful implementation of other aspects to the overall care pathway for children with suspected ASD." We understand that screening is not recommended for conditions with no available treatments, but in the case of ASD, effective treatments *are* identified; if they are not available for all children who need them, the public health solution is surely to increase availability of services, not to forego detection of cases.

11 **The Task Force draft report states that a definitive, randomized control trial, comparing outcomes of screened vs. unscreened children, would be needed to endorse universal ASD screening**, and that these outcomes would have to be long-range clinical outcomes rather than the more proximal measures of age of diagnosis, age of intervention, etc. However, the ethics of conducting such a study are very questionable. This type of study would require one group of pediatricians to follow the AAP recommendations for ASD screening and another to refrain from screening. Given the base rate of ASD, the multiple variables affecting access to diagnostic and intervention services and the large variability in child progress, power considerations would no doubt require that a very large group of pediatricians forego screening on a large number of children. Given the already strong evidence for screening's ability to lower age of diagnosis, and the importance of beginning therapy at the earliest age possible, such a study would be unethical.

In the final version of the Task Force recommendations, other study designs are mentioned as possibly providing sufficient evidence for the efficacy of screening (*numbers added*):

1. RCT's comparing treatments, using cases identified through screening, as in two recent studies.[29,30]
2. Comparison of outcomes in children screened at 18 and 24 months with outcomes in children identified through later screening or case finding, in regions with low screening rates.
3. Randomized clinical trials of screening in locations where screening is not standard practice or recommended.
4. Studies following up large samples of screen-negative children, although resource-intensive, to assess screening specificity.

We agree that additional research on multiple aspects of screening practice and intervention effectiveness is needed. As suggested by the Task Force (research design #1), treatment studies of children ascertained by screening could show the efficacy of treatments

for this group. Also as suggested (research design #4), screen-negative children could be followed to get better estimates of sensitivity. Comparing early screening to later screening or case finding (research design #2) and conducting RCT's of screening vs. no screening (research design #3), restricted to regions where screening is not currently prevalent, while still raising the ethical issues mentioned, would at least not ask physicians who are currently screening to stop screening.

In addition, studies are needed to: identify the best age for universal screening; determine the added value of repeated screening; compare the effectiveness of different screening instruments; identify characteristics of the child (e.g., age, sex, risk status) and family (SES, sibling structure, race/ethnicity) that affect screening accuracy and attrition; identify barriers to screening and appropriate referral in pediatric practice; examine methods for integrating standardized screening into developmental surveillance; identify factors that can facilitate movement from screening to diagnosis to referral for services to uptake of services; and identify characteristics of missed cases and false positives, etc.

However, it is equally important to consider the risk/benefit ratio of universal screening for ASD. Postponing universal early screening for ASD for the years, perhaps the many years, it would take to complete and publish these studies, even assuming that they were all funded, is almost certain to prevent many children with ASD from getting the earliest diagnosis and intervention, resulting in worse outcomes for them than might otherwise be possible. Screening is inexpensive and requires few resources; screening lowers age of detection and referral; earlier treatment produces better outcomes; risk of harm from screening and/or treatment is small. This risk/benefit ratio is obviously quite favorable. Not to recommend continued screening while additional research is carried out would constitute "paralysis by analysis", in which a low-risk, low-cost practice likely to benefit a large number of children and families is not recommended until definitive studies answer every possible question.

Acknowledgments

The BSRC is an international network supported by Autism Speaks that pools data from member research sites to study the development of high-risk infants. The following members of the Baby Sibs Research Consortium Committee of Principal Investigators provided valuable input to this commentary:

Conflicts of Interest and Source of Funding: DF is part owner of the Modified Checklist for Autism in Toddlers (M-CHAT and M-CHAT/R). This is provided free of charge to physicians. Royalties are charged when it is incorporated into a commercial system. Research on the MCHAT is currently supported by NICHD (Robins, PI).

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