Objective: To determine hearing screening failure rates in primary care settings and to examine the referral practices in response to an abnormal screening test.

Methods: We enrolled a convenience sample of children between 3 and 19 years of age who were undergoing hearing screening during a well-child visit. A failure was defined as missing any frequency (1000, 2000, or 4000 Hz) in either ear at 20-dB hearing level. The pediatrician made the decision of whether to refer the patient for further evaluation.

Results: Three academic and 5 private practices enrolled 1061 children. Sixty-seven children (7%) were unable to complete the screening. Of the 948 children who completed the screening, a total of 852 children (90%) passed the screening and 96 children (10%) failed. After multivariable logistic regression analysis, the only statistically significant factor predictive of a failed screen was developmental delay (P = .02). Of the 96 children who failed the hearing screening, 57 (59%) had no further evaluation, 12 (13%) were rechecked, and 27 (28%) were referred. Similar percentages were seen with children who could not be screened.

Conclusions: Although 10% of the children failed hearing screening, pediatricians neither rechecked nor referred more than half of these children. Screening that does not result in action for those failing the screening wastes resources and fails to properly identify hearing impairment in children.

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The goal of hearing screening is early detection of hearing loss to improve developmental and language outcomes. Hearing impairment in childhood has a detrimental impact on global development, particularly in communication and educational performance, regardless of age, sex, ethnicity, or socioeconomic status. Both receptive and expressive language skills improve with early identification and subsequent intervention for hearing deficits.

The Joint Committee on Infant Hearing not only advocates universal newborn hearing screening, but also recommends periodic hearing screening throughout childhood as an important means of detecting acquired hearing loss as well as congenital cases missed by inadequate or inaccurate newborn screening. Current recommendations for preventive pediatric health care from the American Academy of Pediatrics (AAP) advocates hearing screening at 4, 5, and 6 years of age, as well as at 8, 10, 12, 15, and 18 years of age, regardless of the presence or absence of risk factors for hearing loss. Prior to 2000, the AAP also recommended hearing screening for 3-year-olds, but the current standard is to start periodic childhood screening at 4 years of age. In February 2003, the AAP published guidelines regarding hearing screening throughout childhood but did not address obstacles to implementation in a busy practice. No studies to our knowledge have assessed periodic hearing screening in the pediatric primary care setting.

The purpose of our study was to determine the outcomes of hearing screening in children aged 3 to 19 years during well-child visits and to examine referral practices of pediatricians in response to abnormal screening outcomes.
Hearing screening guidelines were developed by local audiologists based on a comprehensive literature review (guidelines available from us on request). Guidelines covered who should be screened, which methods should be used, what constituted a failed screening, and what follow-up was necessary for children who failed the screening. No national guidelines for hearing screening existed to designate screening thresholds; however, normal hearing is considered 15-dB hearing level (HL).14 Studies have used a variety of screening thresholds in different settings.15-17 Therefore, based on review of the current literature at the time and the expertise of local audiologists, the local hearing screening guidelines recommended screening at 20-dB HL. Data were collected independently for each ear at frequencies of 1000, 2000, and 4000 Hz with a pass/fail result recorded. A screening failure was defined by the guidelines as the inability to detect 1 or more frequencies at 20-dB HL in either ear. The guidelines recommended tympanometry on any child who failed a screening, with appropriate follow-up recommendations based on the tympanometry results.

Prior to initiating the study, the guidelines were distributed to the practices during a training session conducted by the principal investigator (T.C.W.) and assisting audiologist (Deborah B. Friend, MS, CCC-A) with the clinic staff and/or physicians at each practice. The audiologist also checked the hearing screening equipment and met with available nursing staff to answer questions about the screening process. The training session covered the study methods and proper hearing screening techniques. Because the study would include children as young as 3 years, each practice was instructed on the use of play audiometry for children who were unable to complete conventional audiometry. Although hearing screening guidelines were distributed and discussed, no mechanism was created to force compliance or alter the decisions made by individual physicians.

Between February 17, 1998, and March 13, 2000, a convenience sample of 1061 children was recruited from the various practices. Given the extensive and time-consuming nature of the enrollment process, patients were recruited when patient load permitted recruitment without significantly interrupting the flow of the office or when a research assistant was available to complete the enrollment. Children between the ages of 3 and 19 years were recruited when they went in for a well-child visit. The practices were provided with research assistants who had undergone instruction on hearing screening by both us and the office staff. Children currently under the care of an audiologist were excluded from the study.

A 1-page standardized data collection form was administered to the caregivers of each child. Collected data included the child's sex, age, ethnic group, and type of insurance, as well as the presence of risk factors associated with hearing loss. Information on developmental delay was based on the clinical assessment documented in the record. Lastly, subjective data were collected regarding the presence or absence of parental concern for hearing impairment.

Hearing screening was performed using headphones and pure-tone audiometers in designated areas in accordance with the routine of each practice. Although audiologic evaluation ideally occurs in a soundproof environment, that is not the case in primary care practices in this community. The study was designed to assess the hearing screening process that currently exists in primary care settings. Rather than create a highly controlled laboratory setting, practices were instructed to continue screening according to the routine used by the clinic, which varied among practices. For example, one practice screened in the examination room using a portable pure-tone audiometer while another practice used a designated screening area or alcove for its evaluations. Screening areas were not necessarily insulated from the noise in the clinic. No practice used a soundproof booth.

The screener then completed the data collection form based on the documented physical examination and plan. The pediatrician seeing the patient was able to review and edit the form for accuracy so that information would not be missed owing to a lack of clear documentation in the record. The physicians were given the opportunity to review the form after the appointment or at the end of the day. There was no record kept of whether the physician reviewed or edited the form. Follow-up arrangements were made at the discretion of the pediatrician and were categorized as referral, recheck, or no follow-up. Data were not gathered regarding the reasoning used by pediatricians when determining follow-up, as attempts to gather this information could potentially alter the physician's plan of action.

Statistical analyses were performed using Statistical Package for the Social Sciences, version 11.0 (SPSS Inc, Chicago, Ill). Bivariate analyses of the data were performed using χ2 tests. Binary logistic regression was used to perform multivariable analyses. Originally, 8 distinct medical practices were identified. Given the similarities in the composition of their patient populations with respect to race and type of insurance, the individual practices were dichotomized into private and academic practices. For statistical analyses, the enrolled children were grouped into 4 age categories based on developmental skills pertaining to screening performance: 3 years, 4 years, 5 years, and 6 years or older.

Exploratory analysis revealed that less than 3% of the children were described as a race/ethnicity other than African American or white. As this other race/ethnicity comprised only 29 children, we were unable to control for the unique experience of each racial/ethnic group and therefore excluded them from further analyses. Additionally, less than 1% of children lacked insurance coverage. Because a lack of insurance may influence a pediatrician's decision to refer a child for further evaluation, any meaningful analysis requires a larger sample of patients. Therefore, these 11 children were also excluded from further analyses. These 40 children who were excluded from further analyses had a similar failure rate to children included in all of the analyses.

The study was approved by the institutional review boards of the University of Alabama at Birmingham and the University of Alabama at Tuscaloosa. Informed consent was obtained for all of the children enrolled in the study.

### RESULTS

#### DEMOGRAPHIC DATA

Of the 1061 children who were enrolled, 449 (42%) were from the 5 nonacademic practices (“private practices”) and 612 (58%) were from the 3 academically affiliated practices (“academic practices”). Comparison of the demographic characteristics of the children from the academic vs private practices revealed statistically significant differences with respect to race, age, and type of insurance (all \(P<.001\)) ([Table 1](#table1)). The majority of African-American children and children with Medicaid insurance were recruited from the academic practices. The academic practices also enrolled younger patients, including the majority of 3- and 4-year-olds. After excluding children without insurance and of race/ethnicity other than African American or white, 1015 children remained for analysis.

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The children were screened for established risk factors for hearing loss based on the Joint Committee on Infant Hearing position statement. Thirty-one children (3%) reported having at least 1 risk factor for hearing loss, including a history of speech or language delay (14 children), a history of birth weight less than 1500 g (7 children), a family history of childhood hearing loss (6 children), and recurrent or persistent otitis media for at least 3 months (3 children). Parental concern, a subjective risk factor for hearing loss, was elicited in 14 children (1%).

Based on review of the medical records, the majority of enrolled children were considered developmentally normal (983 children, or 97%) whereas severe, moderate, or mild developmental delay were reported in 1 child (0.1%), 3 children (0.3%), and 20 children (2%), respectively.

SCREENING TECHNIQUES

The majority (961, or 95%) of the children underwent conventional audiometry whereas 54 (5%) were screened using play audiometry. Using bivariate analysis, play audiometry was used more often at the private practices, in white children, and in the youngest age groups (3- and 4-year-olds). A physical examination of the tympanic membrane (TM) was documented in 840 children (83%). A total of 9 children (<1%) had tympanometry documented.

AUDIOMETRY RESULTS

A total of 67 children (7%) were unable to complete the screening. Table 2 compares the characteristics of children who could not be tested with those who completed the screening. Children who were unable to complete the screening were 2.5 times more likely to be African American and 8.5 times more likely to be recruited from the academic practices. Children in the 3-year-old age group were most likely to be recorded as “could not test” (P<.001). Forty-five percent of the 3-year-olds did not complete the screening as compared with 7% of the 4-year-olds, 3% of the 5-year-olds, and less than 1% of the children aged 6 years of age or older.

A multivariable logistic regression analysis including sex, race, age, practice setting, and risk factors was performed to determine the factors that predicted that a child’s hearing could not be tested. Three-year-olds were 33 times more likely to be unable to complete the screening than all of the children older than 3 years (P<.001). In addition, children recruited from an academic practice were 5 times more likely to be classified as “could not test” than children recruited from a private practice (P<.01) after controlling for other variables.

Of the 948 children who completed the screening, a total of 852 children (90%) passed the hearing screening whereas 96 children (10%) failed to detect 1 or more frequencies in at least 1 ear. Table 3 presents characteristics of these children by screening result, showing similarities across age, race, and sex; however, children enrolled from academic practices were 1.8 times more likely to fail the hearing screening (P<.05). Children were
4 times more likely to fail if they had developmental delay ($P<.001$) or if their parents reported concern for hearing loss ($P<.05$).

After multivariable logistic regression analysis including sex, race, age, practice, and risk factors, only developmental delay remained statistically significant as a predictor of a failed hearing screening. A child with developmental delay was 3 times more likely to fail the hearing screening than those children without developmental delay ($P<.05$).

### ACTION

The pediatricians decided whether to refer the patients for further evaluation, to recheck the child at a later date, or to take no further action. Of the 67 children who could not be tested, no action was taken for 49 (73%), 16 (24%) were scheduled for a recheck, and 2 (7%) were referred for further evaluation. There were 3 children with developmental delay who could not be tested, 1 of whom was referred. Based on bivariate analysis, there were no statistically significant predictors of whether any action was taken or which action was taken. Owing to the small number of children who could not be tested, multivariable logistic regression was not performed.

Of the 96 children who failed the screening, the action taken by pediatricians was as follows: 27 (28%) were referred, 12 (13%) were rechecked, and 57 (59%) had no further action taken. All of the 852 children who passed the hearing screening had no further action taken.

Using bivariate analysis, private practices were almost 5 times more likely to take no action ($P<.01$), although 81% of the total referrals (for 22 of 27 children) were made by the single academic practice in which the study was based. White children were 2 times more likely to have no action taken and were primarily from the private practices ($P<.05$). In contrast, children with developmental delay and parental concern for hearing impairment were more likely to have some type of action taken ($P<.001$). Multivariable logistic regression was not performed because of the small sample size of children who failed the screening.

When considering only those 39 children who had some action taken, 12 were rechecked and 27 were referred. All of these children with developmental delay or parental concern for hearing impairment were referred rather than rechecked. There were no factors that were statistically significant predictors of the type of action taken based on bivariate analysis. Because of the small sample size of children with abnormal screening results, multivariable logistic regression was not performed.

In this sample of 1015 children who were enrolled during routine hearing screening in a primary care setting, 67 children (7%) could not complete the hearing screening. Of the 948 children who completed the screening, 96 (10%) missed at least 1 frequency (1000, 2000, or 4000 Hz) in at least 1 ear at 20-dB HL. For those children who failed the screening, the majority (59%) had no follow-up scheduled for either referral or recheck. Similarly, 73% of the children who could not complete the screening were not scheduled for any type of follow-up.

Although several demographic variables were examined, multivariable analyses identified developmental delay as the only significant predictor of a failed screen. The presence of objective risk factors did not predict a failed screening despite previous studies that have found that risk factors may detect as many as 50% of children with hearing loss and, theoretically, a failed screening.

It is important to remember that a failed screening does not equate with hearing loss. The 10% failure rate detected in this study is higher than the estimated prevalence of hearing loss in newborns, which is 1 to 3 newborns with hearing loss per 1000 newborns, but is lower than the rate of abnormal hearing thresholds detected during the Third National Health and Nutrition Examination Survey. As part of that study, a nationally representative sample of more than 5000 children underwent audiometry, revealing that 12.5% of school-aged children have abnormal hearing thresholds. However, the prevalence of hearing loss depends on the criteria used. Newborn screening detects hearing loss greater than 30- or 40-dB HL, and the Third National Health and Nutrition Examination Survey study used a threshold of 16-dB HL; this study examined hearing loss at 20-dB HL. The variable rates may also be owing to the fact that hearing loss.
impairment may be acquired later in life, resulting in increased prevalence with age.\textsuperscript{14,21} Formal testing of children who failed the screening in this study would likely decrease the true prevalence of hearing loss suggested by the number of abnormal screening tests. Each of these factors is likely to have contributed to the different findings among these studies.

Previously, no studies to our knowledge have focused on hearing screening in pediatric primary care, leaving pediatricians with little guidance on screening and referral criteria beyond the neonatal period. This changed in February 2003 when the AAP published recommendations for hearing screening beyond the newborn period and set a goal of improving identification of hearing impairment in children of all ages.\textsuperscript{12} The AAP recommended referral for children who fail screening at 25-dB HL or higher and also discussed the importance of further evaluation once a child fails a hearing screening. Although changes in recommendations are ideally based on outcome studies, given the high failure rate of 10% detected here using 20-dB HL and the lack of appropriate follow-up, this study supports the recommendations from the AAP to use a higher screening threshold when conducting hearing screening in the primary care setting.

The current study, which took place prior to the publication of the AAP hearing screening recommendations,\textsuperscript{12} used a threshold of 20-dB HL and found that the majority (59%) of children who failed their hearing screening had no further action taken. Surprisingly, even children with known risk factors for hearing loss (3/17 of the children in this study), including developmental delay or parental concern for hearing impairment, had no action taken following a failed screening.

There are several possible reasons why so few children were scheduled for some type of follow-up. First, pediatricians in this study may have chosen to retest their patients at a later date. Nine children had documented hearing screening follow-up scheduled in 1 year. These children were not included in the analyses as a recheck because annual screening took place at each practice and would have been performed regardless of the current screening result. In addition, physicians may have intended to repeat screening in 1 year as a part of their follow-up plan and failed to document this decision. Second, although financial issues may play a role in a physician’s decision of whether to refer a patient for further evaluation, all of the children included in these analyses were covered by either Medicaid insurance or private insurance that should cover any expenses related to a referral. As a result, we believe that financial constraints did not play an important role in the decision making of physicians in this study. Further studies that include a larger proportion of uninsured children would allow for assessment of the effect that finances have on physician referral practices. Lastly, little is known of the accuracy of conventional audiometry in the primary care setting; therefore, pediatricians may distrust their screening results and rely primarily on the history and physical examination or may seek stronger evidence of hearing loss in the form of a second failed screening prior to referral. Physicians in this study may have considered the use of 20-dB HL to be too rigorous given the often noisy primary care setting in which the screening took place; therefore, they may have been less likely to take definitive action at this level of screening.

The higher rate of failure to follow-up noted in private practices may be related to variable physician practice. Physicians in private practice often have long-standing relationships with families and, therefore, may feel comfortable with continued monitoring for signs and symptoms of hearing loss. Private pediatricians may also perceive their patients to be at lower risk because of generally higher socioeconomic status and lower rates of low birth weight, prenatal drug exposure, congenital infections, and other known risk factors for hearing loss, although we are not aware of any data that would support this perception.\textsuperscript{24-27} Most referrals (80%) came from the academic practice in which the study was based. This site is a resident training clinic that follows a higher-risk population and, because of its teaching role, may be more likely to adhere to guideline recommendations.

The reliance on signs and symptoms of hearing loss is particularly concerning when attempting to detect minimal hearing loss in children. Studies have shown that the prevalence of severe to profound hearing loss may be declining while the prevalence of milder hearing loss appears to be increasing.\textsuperscript{28} No studies to our knowledge have documented consistent behavioral abnormalities in these children. In addition, studies that document improved outcomes in children with hearing impairment and early intervention focus on children with moderate to severe hearing loss. To our knowledge, only 1 study\textsuperscript{29} analyzed children with mild unilateral hearing loss, and it found no improved outcomes with early intervention.

The majority of the 67 children who could not be tested were in the 3-year-old age group (47 children [69%]) and had no further action taken (36 children [54%]). In this situation, pediatricians may prefer to clinically follow up these younger patients for signs and symptoms of hearing loss rather than take action based on a single screening at 3 years of age. Physicians may have been planning to repeat hearing screening of these patients at 4 years of age. The changes found in the AAP recommendations for preventive pediatric health care issued in 2000,\textsuperscript{10} which recommend beginning screening at 4 years rather than 3 years of age, appear to reflect how physicians were actually practicing. Our data demonstrate that 4-year-olds are much more likely to complete screening, and our data thus support the changes that appear in the 2000 recommendations.

Based on guidelines published in February 2003,\textsuperscript{12} while it is acceptable to repeat the screening during the visit, the AAP recommends referral for any child who fails the screening and has a normal TM. The results of the physical examination of the TM, however, did not strongly correlate with the decision to recheck the child. Physicians do not appear to use the physical examination of the TM to decide follow-up for an abnormal hearing screening.

Although tympanometry does not play a primary role in hearing screening, it may provide important evidence to help physicians in the decision-making process regarding appropriate action following a failed screening.\textsuperscript{28} Individuals can fail a hearing screening as a result
of serous fluid behind the TM, perforation of the TM, or cerumen impaction in the external auditory canal. If tympanometry and TM examination results are normal, there is little reason to delay referral. If tympanometry results are abnormal, repeat screening accompanied by repeat tympanometry is a reasonable alternative for a limited period of time. The guidelines distributed to practices in this study advised the use of tympanometry for decision making, encouraging physicians to refer or recheck children who failed the screening based on tympanometry results. However, tympanometry was only used in 9 patients enrolled in the study, revealing little physician compliance with this portion of the guidelines.

Although the majority of children for whom an action was taken were scheduled for a recheck rather than referred, children with developmental delay or parental concern for hearing loss were referred, if any action was taken at all. However, several children with these risk factors had no action taken. This supports other studies that have documented delays in the diagnosis of hearing loss in children with parental concern. Referral appears to be the most appropriate action for these children. Overall, there were no characteristics that predicted the type of action that a physician will take following a failed hearing screening. The small sample size in this subset of patients limits the predictive power of these findings.

Although there were no published hearing screening guidelines to our knowledge at the time of this study, each practice was provided with local audiology guidelines prior to the start of the study. Physicians in this study failed to adhere to these guidelines with respect to decision making based on screening results. A national survey of general pediatrics found that guidelines were more likely to be followed if they were simple, feasible, and demonstrated improved outcomes. With the publication of the AAP guidelines in 2003, studies are now needed to assess the degree to which physicians adhere to the guidelines. In addition, outcome studies are needed to further guide hearing screening practices.

LIMITATIONS

Children in this study were recruited as a convenience sample from a diverse population and a variety of clinic settings. Use of a convenience sample may raise concerns regarding the generalizability of our findings. The recruited children were representative of the population seen in the participating clinics with a reasonable distribution of sex, African American and white race, age, and insurance. Our goal of recruiting a diverse population representative of the community was achieved. While sex and race should not affect screening practices, age and insurance may. The demographic characteristics were dramatically different between the academic and private practices, with patients of private practices being primarily white and having non-Medicaid insurance and patients of academic practices being primarily African American and having Medicaid insurance. Therefore, in a multivariable analysis, it is difficult to distinguish between the effects of race, insurance, and practice setting because of issues of confounding.

A potential limitation of this study was the lack of standardization of screening techniques across practices. The study was, in fact, designed with this in mind, and we view this as a strength of the study. Screening in primary care settings is highly dependent on operator technique and practice characteristics. One of our goals was to determine the results of current hearing screening as practiced in the community. Hearing evaluations in a primary care office do not occur in an exceptionally controlled environment, and to perform this study in such a manner would not truly reflect typical screening practices.

Physician referral practices varied in this study. To avoid altering the physician’s plan of action, the reasoning behind referral decisions was not obtained prospectively or retrospectively. Because this information was not obtained, further studies are needed to explain why physicians referred all, some, or none of the children who failed hearing screening tests as noted in this study.

No gold-standard audiologic evaluation was used in this study, which prevents us from identifying the rate of true hearing loss in the population of those who failed the screening; however, the goal of this study was not to establish the validity of hearing screening in the primary care setting. This study was designed to observe the results of current screening practices. More research is needed to examine the sensitivity and specificity of hearing screening in this setting.

CONCLUSIONS/IMPLICATIONS

Performing hearing screening as recommended at well-child visits remains critical to the detection of hearing impairment throughout childhood and complements the goals of universal newborn hearing screening. The findings from this study are worrisome because physicians took no further action in more than 50% of the children who failed the hearing screening and more than 70% of the children who could not be tested. In addition, a significant number of children were scheduled for a recheck rather than referred. While this makes intuitive sense if the time interval is appropriate, there is a lack of literature to support this practice. Further evaluation or intervention must take place to allow children with possible hearing impairment to benefit from screening practices. Screening that does not result in action for those failing the screening wastes resources and fails to initiate necessary intervention for hearing loss.

This study supports screening children at the higher hearing threshold of 25 dB, as recommended by the AAP in February 2003, to decrease the number of failed screening tests for which physicians would be expected to take action. Furthermore, adherence to the AAP guidelines published in 2000, which advocate screening children beginning at 4 years of age, will likely decrease the number of children who cannot be tested. Ideally, recommendations for hearing screening should be based on outcome studies that, unfortunately, are lacking at this time.

We know little about the process used by pediatricians to decide the type of action, if any, that should be taken when confronted with abnormal screening re-
results. Physicians in this study were not taking action based on an abnormal result. We cannot assume that they are currently following the 2003 guidelines. Further research is needed to identify the reasoning behind referral practices of pediatricians and to determine to what extent physicians are following these new AAP recommendations.

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REFERENCES