

A Program of Anticipatory Guidance for the Prevention of Emergency Department Visits for Ear Pain

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Objective: To test whether well-child care visit anticipatory guidance can safely reduce emergency department (ED) visits.

Design: Retrospective analysis comparing an intervention site with control sites using a “difference-in-differences” regression model.

Setting: Primary care practices at the Mayo Clinic.

Participants: Children who attended a 15-month well-child care visit.

Interventions: Nurses provided standardized education and prescribed antipyrine-benzocaine otic drops at the 15-month well-child care visit. Education focused on controlling otalgia, recognizing signs of more serious illness, and decreasing the sense of medical urgency for uncomplicated ear pain.

Main Outcome Measures: Visit rates for ear pain during the ensuing year were compared in 4 retrospective cohorts: the intervention cohort (n=191), a cohort from

the same practice the preceding year (n=168), and as controls, cohorts from these same years at other primary care sites not adopting this intervention (n=133 and 126).

Results: After the intervention, ED visits for ear pain decreased 80%; urgent care visits, 40%; and primary care visits, 28%, with no significant change in the control sites’ visit use during this time. Regression models incorporating patient characteristics and comparing the changes between sites across time supported the belief that the decline in ED use was significant ($P=.009$), with no significant change in urgent care ($P=.33$) or primary care ($P=.14$) use. On questionnaires, more than 80% of parents whose children had experienced subsequent ear pain responded that the program helped them avoid an ED or after-hours visit and strongly recommended continuing the education program.

Conclusion: Nurse-administered anticipatory guidance reduced ED visits for ear pain in toddlers and was well appreciated by parents.

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EAR PAIN AND PARENTAL CONCERN for acute otitis media (AOM) drive a high proportion of acute care visits for children. In the United States, AOM is diagnosed more than 5 million times per year,¹ and it is the most common reason that antibiotics are prescribed for children.^{2,3} Ninety-five percent of children experience at least 1 episode of AOM

emergency department (ED) visits. Meaningful health care cost savings may be possible with small reductions in the number of unnecessary visits.³ We sought to test whether standardized anticipatory guidance at a well-child care visit (WCV) coupled with a prescription for analgesic otic drops would substantially alleviate parental concerns about the medical urgency of routine ear pain, empowering them to better control pain at home and thereby decrease ED use.

*For editorial comment
see page 186*

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by the time they are 3 years old.⁴ This exacts a very high burden on the health care system, resulting in substantial health care utilization and cost (an estimated \$3-\$4 billion a year in the United States),^{3,5} including many medically unnecessary and costly

The Division of Community Pediatric and Adolescent Medicine at the Mayo Clinic instituted a practicewide change March 12, 2003. Nurses provided standardized education and a prescription for generic antipyrine-benzocaine analgesic otic drops, with dosing

METHODS

instructions taken from MicroMedex software as of March 12, 2003 (Thomson Healthcare Inc, Montvale, New Jersey), and *The Harriet Lane Handbook*.⁶ All the parents received this program of intervention at the 15-month WCV unless their children had tympanostomy tubes or were otherwise excluded by their physician. Between March 12, 2003, and June 30, 2003, 191 children received 15-month WCVs; 74.3% of them had medical record documentation of this educational intervention. Ethnicity was determined from Mayo Clinic registration data (as reported by the parent) and is included owing to potential ethnic variation in AOM frequency.⁷ Non-English-speaking families were routinely included in this intervention when a translator was present. On medical record review, most of those not receiving the intervention had documentation of ear tubes, chronic illness, or language/developmental delay. The Mayo Clinic routinely provides medical translation free of charge for all visits. The 15-month WCV was chosen based on epidemiologic patterns of infection^{4,8-13} and developmental milestone expectations for this toddler-aged group.^{14,15}

Nurses followed 10 PowerPoint (Microsoft Inc, Redmond, Washington) slides that focused on 3 main goals: how to identify ear pain, how to relieve ear pain safely, and how to recognize symptoms of more serious illness requiring urgent medical attention. The titles of the slides were "Basics of ear infections," "Now that your child is a toddler . . ." "Why wait until morning to be seen in pediatrics?" "How do I know when my child might have an ear infection?" "What should I do at home?" "When does my child need to be seen right away?" and "What if I have questions or concerns after-hours?" Nurses reminded parents of telephone access to 24-hour medical advice and discussed appropriate administration of antipyrine-benzocaine otic drops, instructing families to withhold drops in children with tympanostomy tubes or otorrhea. They also provided dosing sheets for acetaminophen and ibuprofen and discussed nonpharmacologic ways to alleviate pain.

The educational materials highlighted the potential advantages of seeking care in primary care settings, including convenience (scheduled appointments with decreased waiting time), familiarity and continuity with their health care professional, increased focus on prevention of future otitis media, and identification of those with excessive AOM frequency. Most patients would experience no personal financial disincentive to ED or urgent care use (with no copayments or coinsurance), so the expense of such care was not addressed. Finally, parents were also given the educational information in written form (English only). Total nurse-provided education took 5 to 10 minutes per patient.

This program intervention involved every medical professional at 1 of 4 primary care sites serving children at Mayo Clinic, an academic center in southeast Minnesota in a community of approximately 90 000 people. The area outside of Rochester is rural and not heavily populated for at least 80 miles in each direction. All the primary care sites are within a 10- to 15-minute drive, with 1 shared urgent care center and pediatric ED for care after hours.

STATISTICAL METHODS

Using a method analogous to an intention-to-treat approach, all patients with a 15-month WCV, regardless of whether they received the intervention during the first 3 months of the nursing education program (March 12, 2003, to June 30, 2003), were considered to be part of the intervention. This intervention group was followed up for 12 months after their WCV for any visits for ear pain to Mayo Clinic (ED, urgent care, or primary care). Visits were counted if there was a primary or secondary *International Classification of Diseases, Ninth Revision (ICD-9)*, di-

agnosis reflective of ear pain, including ICD-9 codes 380.10, 380.22, 381.00, 381.01, 381.10, 381.4, 382.00, 382.01, 382.3, 382.4, 382.9, and 388.70. Visit use in this intervention group was compared with that in a historical cohort constructed from the same practice site the previous spring (ie, children receiving a 15-month WCV between March 12, 2002, and June 30, 2002, n=168) to allow comparison of visit utilization before and after the intervention at the same site. For further comparison, analogous cohorts were also constructed from children receiving 15-month WCVs at any of the other Mayo Clinic primary care sites during the same 2 periods (n=133 between March 12, 2003, and June 30, 2003, and n=126 between March 12, 2002, and June 30, 2002).

The mean number of relevant visits per child in the year after the WCVs was compared between the 2 groups during the 2 periods using "difference-in-differences" regression models.¹⁶ These models focused on the interaction term between group (intervention vs control) and year (before vs after intervention) and incorporated patient characteristics to adjust for possible effects of differences between groups or across time, including Medicaid status, heptavalent pneumococcal and influenza vaccination status, length of follow-up in months, and number of visits for ear pain before the 15-month WCV (0, 1, 2, or more). Annual visit rates per 1000 children were reported for convenience.

Parent questionnaires were later added (February 1, 2005, to August 31, 2005) to directly query the impact of this intervention on parents. Questionnaires were randomly administered at the intervention site at the 15- and 24-month WCVs (n=97 and 88, respectively). Three years of medical records were reviewed for all 191 patients in the intervention group, looking for evidence of otolaryngologic, ED, or hospital visits that may have been potential complications of this intervention. This study was approved by the Mayo Clinic institutional review board as a retrospective assessment of a clinical practice change.

RESULTS

In the year preceding the program intervention (January 1, 2002, to December 31, 2002), diagnoses of ear pain (ie, the 12 selected ICD-9 codes) accounted for 19.5% of all ED visits, 35.5% of all urgent care center visits, and 21.6% of all regular-hours primary care visits to Mayo Clinic for children 15 to 27 months of age. This represented 24.3% of all visits to Mayo Clinic for this age group for a total of 10 560 visits in 2002.

The Johns Hopkins Adjusted Clinical Groups and Aggregated Diagnosis Groups software (ACG System; Johns Hopkins University, Baltimore, Maryland) showed no significant differences in risk adjustment between the intervention site and the control sites ($P=.71$ and $.28$, respectively). **Table 1** provides the characteristics of patients attending the 15-month WCV between March 12, 2003, and June 30, 2003, at the intervention and control sites.

Table 2 provides visit use in the cohorts before and after the nurse administered anticipatory guidance was begun. Use of the ED for ear pain decreased by 80.3% during the ensuing year, urgent care center use by 40.3%, and regular-hours primary care center use by 27.8% at the intervention site. There was no statistically significant change in visit use for the control sites during this same period. Regression modeling that incorporated patient characteristics and compared changes between sites

across time supported the hypothesis that the decline in ED use was significant ($P=.009$) after the nursing education intervention, with no significant change in urgent care ($P=.33$) or primary care ($P=.14$) use. There was a significant decline in total visits for ear pain in the intervention group ($P=.045$). When surveyed at the 24-month WCV, 42.0% of parents indicated that their children had in fact experienced ear pain since the 15-month WCV. More than 80% of this subgroup believed that the nursing education helped them avoid an ED or after-hours visit: 54.3% "strongly agreed," 31.4% "somewhat agreed," 8.6% "were unsure," 5.7% "somewhat disagreed," and 0% "strongly disagreed." Likewise, more than 80% of these same parents indicated that access to antipyrine-benzocaine otic drops helped avoid an ED or after-hours visit: 62.9% "strongly agreed," 25.7% "somewhat agreed," 11.4% "were unsure," 0% "somewhat disagreed," and 0% "strongly disagreed."

Using a scoring system from -10 to +10, parents at the 15-month WCV strongly endorsed this intervention, showing support for both aspects of the intervention (nurse teaching and access to prescription) (**Table 3**). Support for this intervention remained high for those seen at the 24-month WCV, even for families who had not experienced an episode of ear pain after the nursing intervention (**Table 4**).

A 3-year medical record review of all 191 children in the intervention group revealed no episodes of mastoiditis. There were no episodes of otolaryngologic, ED, or hospital visits that could be attributed to delay in medical attention or delay in antibiotic therapy, including visits for bacteremia, sepsis, or meningitis. No ED visits documented inappropriate antipyrine-benzocaine otic drop use.

The costs of the project were estimated. Assuming 10 minutes of nurse teaching time per patient (at a rate of \$30 per hour) and assuming that every family filled its prescription for antipyrine-benzocaine otic drops (at \$7.04 per bottle),¹⁷ this intervention would have cost \$12 040 per 1000 patients. In Minnesota, this prescription would have been covered by Minnesota Medical Assistance (Medicaid). Because not all education lasted 10 minutes and because it is unlikely that every patient filled the prescription, this is an overestimate of cost. The 2004 costs for visits at Mayo Clinic were \$317 per ED visit, \$123 per urgent care center visit, and \$108 per regular-hours primary care visit. Thus, as a conservative estimate, this intervention saved \$65 779 (per 1000 patients) in visit costs during the subsequent year, for a net savings of approximately \$50 per child.

COMMENT

At Mayo Clinic, almost 25% of all medical visits for toddlers (including almost 20% of ED visits) were for ear pain as identified by ICD-9 codes. These rates were similar to those reported elsewhere,¹⁸ representing a significant opportunity for improvement in how Mayo Clinic provides care to families for this set of common, typically minor ailments.

The treatment of AOM in younger children is extremely costly because of its high incidence, driving high

Table 1. Characteristics of Patients Seen for a 15-Month Well-Child Care Visit at the Intervention and Control Sites (March 12, 2003, to June 30, 2003)

	Intervention Group (n=191)	Control Group (n=133)	P Value
Sex, No. (%)			.55
F	97 (50.8)	72 (54.1)	
M	94 (49.2)	61 (45.9)	
Ethnicity, No. (%)			.41
White	114 (59.7)	87 (65.4)	
African American	6 (3.1)	4 (3.0)	
Hispanic	3 (1.6)	2 (1.5)	
Asian	8 (4.2)	1 (0.8)	
Other	9 (4.7)	3 (2.3)	
Unknown	51 (26.7)	36 (27.1)	
Insurance type, No. (%)			.04
Medicaid	44 (23.0)	16 (12.0)	
Clinic employee	87 (45.5)	66 (49.6)	
Other insurance	60 (31.4)	51 (38.3)	
Without financial copayments to emergency department/urgent care (total of Medicaid + employees), No. (%)	131 (68.6)	82 (61.7)	.20
Completed 12-mo follow-up			.22
No. (%)	176 (92.1)	127 (95.5)	
Mean (SD) follow-up, mo	11.2 (2.8)	11.6 (1.9)	
Had at least 3 doses of PCV by the 15-mo visit, No. (%) ^a	187 (97.9)	123 (92.5)	.02
Had influenza vaccination, No. (%)	52 (27.2)	13 (9.8)	.001
Otitis proneness (No. of visits for ear pain before the 15-mo well-child care visit)			.85
Mean (SD)	1.70 (2.3)	1.67 (2.2)	
0 Visits, No. (%)	78 (40.8)	57 (42.9)	
1 Visit, No. (%)	33 (17.3)	23 (17.3)	
≥2 Visits, No. (%)	80 (41.9)	53 (39.9)	

Abbreviation: PCV, heptavalent pneumococcal vaccine.

^aOwing to a national shortage of PCV, the fourth dose of PCV was not being routinely administered at the clinic during this period.

visit use. In data from rural Kentucky, 95% of children had an episode of AOM by age 3 years.⁴ Likewise, 40% of all AOM costs occurred in children aged 1 to 3 years (in Colorado Medicaid patients),³ the same age group targeted in the present study. That study also found that the largest component of the direct and indirect expenses for AOM was the cost of the medical visit itself,³ complementing the main goal of our project: to decrease unnecessary visits, especially more costly ED visits.

We found that ED use for ear pain in the intervention group decreased substantially (by 80.3%) and urgent care use by 40.3% during the ensuing year. Subsequent questionnaires showed that when there was an ear pain episode after the 15-month WCV, more than 80% of parents believed that the intervention helped avoid an after-hours visit. Even parents whose children had not experienced subsequent ear pain strongly recommended that our practice continue this program for other parents. The education was highly accepted by parents although it was not directly administered by a physician.

Table 2. Visit Use for Ear Pain Before and After the Nurse-Administered Anticipatory Guidance Program Was Begun at the Intervention Site

Visit Type	Intervention Site, Mean (SD), Rate per 1000			Control Site, Mean (SD), Rate per 1000			P Value
	Before Program (n=168)	After Program (n=191)	Change, %	Before Program (n=126)	After Program (n=133)	Change, %	
Emergency department	107 (410)	21 (144)	-80	48 (248)	60 (295)	25	.009
Urgent care	315 (658)	188 (568)	-40	365 (835)	263 (662)	-28	.33
Primary care	762 (1249)	550 (1064)	-28	667 (1491)	639 (1269)	-4	.14
Total	1184 (1763)	759 (1390)	-36	1080 (2038)	962 (1621)	-11	.045

Table 3. Ninety-seven Parent Responses on the 15-Month Well-Child Care Visit Questionnaire

How Strongly Do You Agree (or Disagree) With the Following Statements? ^a	Score, Mean (SD)
I feel that I could make my child feel better if his or her ears hurt in the future	9.0 (2.4)
I am glad you gave me the numbing ear drops, in case my child needs them later	9.2 (2.4)
I know when I should use the numbing ear drops and how to do it right	9.6 (1.3)
If I thought my child might have an ear infection, I would feel comfortable knowing when to be seen urgently at night (in the emergency department)	8.1 (3.6)
I learned something useful when the nurses talked with me today about ear pain	8.8 (2.3)
You should have nurses do more education on other topics	7.1 (4.1)
You should continue to give out a prescription for numbing ear drops at well-child care visits in the future, not just when kids are sick	8.9 (2.5)

^aThe scale ranges from -10 to 10 ("strongly agree" = 10, "somewhat agree" = 5, "unsure" = 0, "somewhat disagree" = -5, and "strongly disagree" = -10).

Table 4. Eighty-eight Parent Responses on the 24-Month Well-Child Care Visit Questionnaire

How Strongly Do You Agree (or Disagree) With the Following Statements? ^a	Score, Mean (SD)	
	Ear Pain (n=37)	No Ear Pain (n=51)
Looking back, what I learned from the nurses at the 15-mo well-child care visit was helpful	8.1 (2.7)	7.6 (3.4)
You should continue to have nurses talk about ear pain at the 15-mo well-child care visit	8.9 (2.4)	8.6 (2.5)
You should keep giving out prescriptions for numbing ear drops at the 15-mo well-child care visit	8.8 (2.5)	7.8 (3.2)

^aThe scale ranges from -10 to 10 ("strongly agree" = 10, "somewhat agree" = 5, "unsure" = 0, "somewhat disagree" = -5, and "strongly disagree" = -10).

The questionnaires supported the hypotheses that parents could be empowered to better control their child's pain and that education would enable them to better triage the need for urgent medical care. Because total visits for ear pain also decreased significantly, there must have been not

only a potential shift from after-hours visits to primary care but also a realization by parents that much of the ear pain is controllable and transient, not always requiring a medical appointment. This is also supported by other literature,^{19,22} as ear pain is an imperfect predictor of which children will have AOM on examination.

The American Academy of Pediatrics and American Academy of Family Physicians joint clinical practice guidelines include strong recommendations to reduce pain.⁵ However, many times, pain management (including prescriptions for analgesics such as antipyrene-benzocaine otic drops) is provided only after official medical evaluation, not before. Topical antipyrene-benzocaine otic drops provide additional relief compared with acetaminophen to a moderate degree,²³ and ear pain improves with the use of ibuprofen.²⁴ We also talked with families about non-pharmacologic ways to provide comfort to help increase the arsenal of pain relief strategies that families would have access to at home.

With the education program, we encouraged families to provide pain relief if their child seemed well enough not to merit an after-hours visit, but we also focused on recognizing other potential red flags of more serious illness. The modest symptom impact of antibiotic agents on symptom resolution for AOM^{1,25-29} made us feel comfortable asking families to consider avoiding after-hours evaluation for all types of ear pain. Because children with more systemic features of illness are more likely to benefit from immediate antibiotic drug use for AOM,³⁰ we encouraged parents of children who either appeared more ill or whose pain could not be adequately controlled to seek after-hours medical care. We also encouraged more use of their access to after-hours telephone advice. This triage plan is similar to that recommended in the latest American Academy of Pediatrics-supported after-hours version of Barton Schmitt's *Pediatric Telephone Protocols*, which recommends after-hours evaluation "for severe pain not improved 2 hours after analgesic eardrops and ibuprofen" or "if the child has possible signs of a more serious infection, otherwise evaluation within 24 hours."³¹

More than 85% of all these visits were for 1 ICD-9 code (382.9: AOM). Some may question the ability of parents to distinguish AOM (vs other causes of ear pain) at home. Parents have been shown to predict the presence of AOM in their children (aged 0-2 years) with upper respiratory tract symptoms with a sensitivity of 75% and a specificity of 85% (a positive predictive value of 49% and a negative predictive value of 90%).¹⁹ Symptoms such as fever, earache, and excessive crying (which will be present in 90%

of those with AOM) are also found in most children with simple upper respiratory tract illnesses and no evidence of AOM on examination.^{18,19,22} Recognizing this, the teaching focused more on augmenting a parent's ability to distinguish red flags of a potentially serious illness as opposed to trying to hone their ability to make a definitive diagnosis of actual AOM at home.

Thus, we recommended the use of antipyrine-benzocaine otic drops for nonspecific ear pain without a known diagnosis of AOM. Antipyrine-benzocaine otic drops also have Food and Drug Administration indications for other diagnoses, such as otitis externa (MicroMedex software, as of March 12, 2003). We advised not using these drops in patients with tympanostomy tubes or otorrhea in the PowerPoint presentation, in the written parent brochure, and directly on the prescription. No case reports of middle ear sequelae from using these drops with perforated tympanic membranes were found in a literature review. We also believed that it was unlikely that antipyrine-benzocaine otic drops would be used with tympanic membrane perforation because ear pain is typically improved at this point, and the pressure differential should direct the flow of otorrhea from the middle ear to the ear canal.

We also felt medically comfortable delaying a potential diagnosis of AOM (and potential antibiotic drug treatment) until standard clinic hours because studies^{5,26,27,29,32} have shown similar rates of complications whether antibiotics were prescribed or withheld for even longer periods and because entities such as mastoiditis are rare. No episodes of mastoiditis and no ED, otolaryngologic, or hospital visits were found in 3 years of subsequent medical record review to be attributable to the intervention, including visits for entities such as bacteremia, sepsis, pyelonephritis, or meningitis (illnesses that could have caused nonspecific "fussiness" possibly incorrectly attributed by parents to ear pain).

As in recommendation 5 of the American Academy of Pediatrics and American Academy of Family Physicians guidelines (to encourage the prevention of AOM through reduction of risk factors),⁵ we hoped there could also be merit in shifting care from an urgent care or ED visit to a primary care site that would ensure adequate vaccination and counseling longitudinally on the reduction of other risk factors, such as passive smoking. We hoped that education during the transition from infancy to toddlerhood would be a natural time to discuss with parents a shift in the home management strategy for minor illness, as their children would have become more communicative and would likely have already experienced AOM,⁴ making parents more familiar with this illness.

The nurse-administered anticipatory guidance program's PowerPoint presentation attempted to provide a standardized, alternative method of delivering anticipatory guidance in a way not requiring more physician time. This matches recommendations by other groups for using nonphysician specialists in expanded roles of delivering pediatric care to try to bridge the gap between the expanding expectations for anticipatory guidance and actual practice due to barriers such as limited physician time.³³⁻³⁵

There were several limitations to this study, including the absence of randomization and reliance on data

from other local clinic sites serving as controls. Thus, the regression models incorporated the patient characteristics of Medicaid status, heptavalent pneumococcal and influenza vaccination status, length of follow-up in months, and frequency of visits for ear pain before the 15-month WCV.

The intervention and control groups had statistically significant differences in the percentage of Medicaid patients (Medicaid percentage was higher in the intervention group). We have no information on overall educational level in the 2 groups, but the percentage of health care employees (who might conceivably have a different medical comfort level) was similar in the groups. The percentage of patients having no financial disincentive to after-hours care, with no out-of-pocket costs for urgent care or ED visits (Medicaid plus employees), was similar in the 2 groups, but we cannot comment on any other potential differences in the statistically larger Medicaid population of the intervention group that might have affected visit utilization. There was no difference in illness level between the 2 groups or in the frequency of previous ear pain visits before the 15-month WCV. There may have been other unmeasured differences in patients, but each site serves patients from the same small community (presumably sharing the same day care centers, etc). Most patients were seen in the same building, with the farthest site only 10 to 15 minutes away by car.

Only 74.3% of patients seen for the 15-month WCV during the intervention time frame actually received the anticipatory guidance, thereby potentially diluting the effect of the intervention. When medical record review was performed, most of those not receiving education (or antipyrine-benzocaine drops) had documentation of tympanostomy tubes, speech or developmental delay, or chronic illnesses, but we cannot definitively say how many opportunities for teaching were "missed" vs purposely restricted by the physician. With the choice of the 15-month WCV, we also would not reduce the high incidence of AOM visits in younger children.^{4,29,36}

We measured visits only to Mayo Clinic (and not elsewhere). However, patients covered under the Mayo Clinic employee benefits (47.2%) were subject to substantial personal cost for using medical services outside the system. We also identified relevant visits based on billing diagnoses (ICD-9 codes), which may not perfectly reflect visits prompted by concerns of ear pain or possible AOM. For this reason, multiple ICD-9 codes for various diagnoses typically associated with ear discomfort were chosen.

We also did not measure how many patients used (or filled) the prescription for antipyrine-benzocaine otic drops. There is no evidence of high levels of pain relief for these drops, and the prescription itself was just one tool of many in the broader aim of patient education and pain management. Finally, there could be some limitations in the relatively small questionnaire sample sizes in this study; however, the responses were consistently positive.

We invite others to make similar attempts at improving anticipatory guidance at centers caring for children with more diverse patient backgrounds, perhaps implementing additional patient education methods not requiring extra physician or nursing time (such as computer kiosks or self-administered education).

In conclusion, in a community-based practice at an academic medical center, a nurse-administered anticipatory guidance program with a prescription for antipyretic-benzocaine otic analgesic drops at the 15-month WCV empowered parents to better control ear pain and significantly decreased health care use for ear pain, with the largest decline (80.3%) noted in ED visit rates. We believe that this intervention positively changed parental behavior, with high levels of sustained acceptance by parents in a way that was safe, cost-effective, and did not require extra physician time.

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