

**Results** | The established i2b2 platform retrieved deidentified information for 68 patients in Preventive Cardiology prescribed atorvastatin among the approximately 1800 patients seen during the 2-year search period. After reidentification and EHR review, 14 patients (21%) were found to be no longer taking atorvastatin. We completed targeted telephone calls and mailouts by December 6, 2012, approximately 1 week after the FDA notification. Among patients reached by telephone, only 36% (10 of 28) had heard about the recall from media reports or other sources. Overall, the team of physicians, a nurse practitioner, and a nurse reported that patients and their families were grateful for the notification. None of the families contacted or seen in follow-up in the subsequent 2 months were found to be taking the affected lots and none had inappropriately discontinued their medication because of the recall.

**Discussion** | The utility of informatics tools to facilitate and target the response to drug recalls is underrecognized. This approach has been successfully adopted in retail; for example, Costco Wholesale Corporation uses their vast customer purchasing records and demographic profiles to contact customers of retail recalls.<sup>5</sup> The FDA notices and news reports had not reached most of our patients, as the majority of identified patients were unaware of the recall 1 month after the initial news reports. Our patients were grateful for the additional information, consistent with previous reports that patients seek out information after recall notices.<sup>6</sup> There were no unwarranted medication discontinuations, which may have been sustained by proactive discussions with patients about the recall. We report the improved efficiencies and quality of care benefit of the i2b2 informatics platform in managing a voluntary drug recall in a special population. We encourage any local or national drug and device recall strategy to incorporate the EHR and further develop integrated informatics tools.

Michael M. Mendelson, MD  
Justin P. Zachariah, MD, MPH  
Sarah D. de Ferranti, MD, MPH  
Jonathan P. Bickel, MD

**Author Affiliations:** Department of Cardiology, Boston Children's Hospital, Boston, Massachusetts (Mendelson, Zachariah, de Ferranti); Division of Information Services, Boston Children's Hospital, Boston, Massachusetts (Bickel); Division of Emergency Medicine, Department of Medicine, Boston Children's Hospital, Boston, Massachusetts (Bickel).

**Corresponding Author:** Jonathan P. Bickel, MD, Division of Information Services and Division of Emergency Medicine, Department of Medicine, Boston Children's Hospital, 300 Longwood Ave, Boston, MA 02115 (jonathan.bickel@childrens.harvard.edu).

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**Study concept and design:** Mendelson, Zachariah, de Ferranti.

**Acquisition of data:** Mendelson, Zachariah, de Ferranti, Bickel.

**Analysis and interpretation of data:** Mendelson, Zachariah, de Ferranti.

**Drafting of the manuscript:** Mendelson.

**Critical revision of the manuscript for important intellectual content:** Mendelson, Zachariah, de Ferranti, Bickel.

**Statistical analysis:** Mendelson.

**Administrative, technical, or material support:** Mendelson, Zachariah, Bickel.

**Study supervision:** Zachariah, de Ferranti.

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## Acute Otitis Media in Children Younger Than 2 Years

A recent American Academy of Pediatrics (AAP) guideline recommends prompt antimicrobial treatment for children aged 6 months to 2 years with acute otitis media (AOM), with 1 exception: for children in whom the disease is unilateral and also unaccompanied by severe signs or symptoms, the guideline recommends, as an option, observation without initial antimicrobial therapy.<sup>1</sup> The recommendation is based on findings from certain clinical trials that suggested little benefit of antimicrobial treatment in such children.<sup>2</sup> In those trials, however, criteria used for the diagnosis of AOM were not as stringent as those called for in the recent AAP guideline,<sup>1</sup> allowing for the possibility that some of the subjects in those trials did not actually have AOM. Our findings in 2 independent clinical trials,<sup>3,4</sup> both of which used stringent diagnostic criteria consistent with those in the recent guideline,<sup>1</sup> offer a differing perspective on the relative efficacy of antimicrobial treatment in children younger than 2 years with unilateral, nonsevere AOM.

**Methods** | Our trials were conducted in Pittsburgh, Pennsylvania,<sup>3</sup> and Turku, Finland.<sup>4</sup> In both trials, stringent criteria were used for diagnosing AOM, children were assigned randomly to receive either amoxicillin-clavulanate potassium or placebo, and parents and research personnel were kept unaware of treatment assignments. In the Pittsburgh trial,

Table. Treatment Failure Rates in Children at or Before the End-of-Treatment Visit, According to Laterality and Severity of Illness at Entry

Laterality and Severity of AOM at Entry	No. of Children With Treatment Failure/Total No. (%)						RR, AMOX/CLAV vs Placebo (95% CI)	ARR (95% CI)	No. Needed to Treat
	Pittsburgh Study <sup>a</sup>		Turku Study <sup>b</sup>		Combined Studies				
	AMOX/CLAV	Placebo	AMOX/CLAV	Placebo	AMOX/CLAV	Placebo			
Unilateral nonsevere	4/39 (10)	15/42 (36)	6/33 (18)	11/23 (48)	10/72 (14)	26/65 (40)	0.34 (0.18-0.65)	0.27 (0.13-0.41)	4
Unilateral severe	2/29 (7)	14/28 (50)	9/48 (19)	19/42 (45)	11/77 (14)	33/70 (47)	0.28 (0.10-0.79)	0.34 (0.18-0.50)	3
Bilateral nonsevere	7/40 (18)	18/35 (51)	6/20 (30)	11/20 (55)	13/60 (22)	29/55 (53)	0.43 (0.25-0.73)	0.31 (0.14-0.48)	4
Bilateral severe	10/34 (29)	26/38 (68)	7/34 (21)	18/37 (49)	17/68 (25)	44/75 (59)	0.43 (0.27-0.67)	0.34 (0.18-0.48)	3

Abbreviations: AMOX/CLAV, amoxicillin-clavulanate potassium; AOM, acute otitis media; ARR, absolute risk reduction; RR, relative risk.

<sup>a</sup> Pittsburgh, Pennsylvania.

<sup>b</sup> Turku, Finland.

treatment failure was defined on day 4 or 5 as lack of substantial improvement in symptoms, worsening of otoscopic signs, or both and on days 10 to 12 as failure to achieve complete or nearly complete resolution of symptoms and otoscopic signs.<sup>3</sup> In the Turku trial, treatment failure was defined on day 3 as lack of improvement in the child's overall condition, on day 8 as lack of improvement in otoscopic signs, and at any time as worsening of the overall condition, the occurrence of tympanic membrane perforation, or inability to continue assigned medication.<sup>4</sup> For the present analysis, we combined results from children younger than 2 years in the 2 trials. In keeping with the recent AAP guideline, we defined illness as severe if otalgia was described by parents as moderate or severe or if the child's temperature had been recorded as, or was estimated to have been, 39°C or more within 24 hours.<sup>1</sup> Overall efficacy of amoxicillin-clavulanate was measured by pooling results from the 2 trials in a random-effects model using inverse-variance weighting.<sup>5</sup>

**Results** | Results are summarized in the **Table**. Among children whose infection was unilateral and/or whose illness was nonsevere, those treated with placebo had relatively high rates of treatment failure, whereas those treated with amoxicillin-clavulanate had substantially lower rates. Overall, the effects of antimicrobial treatment were similar across the various laterality and severity subgroups.

**Discussion** | These findings make a case for a uniform approach to antimicrobial treatment in children younger than 2 years with stringently diagnosed AOM, irrespective of laterality or apparent severity of their illness, and suggest that the AAP guideline's recommendation of prompt antimicrobial treatment for children younger than 2 years with AOM that is bilateral and/or apparently severe should be extended to include also those children whose disease is unilateral and apparently nonsevere.

**Alejandro Hoberman, MD**  
**Aino Ruohola, MD, PhD**  
**Nader Shaikh, MD, MPH**  
**Paula A. Tähtinen, MD, PhD**  
**Jack L. Paradise, MD**

**Author Affiliations:** Department of Pediatrics, University of Pittsburgh School of Medicine, Children's Hospital of Pittsburgh of UPMC, Pittsburgh, Pennsylvania (Hoberman, Shaikh, Paradise); Department of Pediatrics, Turku University Hospital, Turku, Finland (Ruohola, Tähtinen).

**Corresponding Author:** Alejandro Hoberman, MD, Division of General Academic Pediatrics, Children's Hospital of Pittsburgh of UPMC, 4401 Penn Ave, Children's Hospital Office Bldg, 3rd Floor, Pittsburgh, PA 15201 (hoberman@chp.edu).

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**Author Contributions:** *Study concept and design:* All authors.

*Acquisition of data:* Hoberman, Ruohola, Shaikh, Tähtinen.

*Analysis and interpretation of data:* Hoberman, Ruohola, Shaikh, Paradise.

*Drafting of the manuscript:* Hoberman, Ruohola, Shaikh, Paradise.

*Critical revision of the manuscript for important intellectual content:* All authors.

*Statistical analysis:* Hoberman, Ruohola, Shaikh, Paradise.

*Obtained funding:* Hoberman, Ruohola, Shaikh, Tähtinen.

*Administrative, technical, or material support:* Hoberman.

*Study supervision:* Hoberman.

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## CORRECTION

**Alphabet Designators Omitted From Table 1:** In the Original Investigation titled "Extreme Binge Drinking Among 12th-Grade Students in the United States: Prevalence and Predictors" published online September 16, 2013, and published in the November 1, 2013, print issue of *JAMA Pediatrics* (2013;167[11]:1019-1025), the alphabet designators were omitted from the body of Table 1.