Also, this study showed that the detected cesium was mainly derived from the acute intake of radionuclides immediately after the incident. Acute IRE is much more significant than measurable chronic IRE after a certain period in the health risk assessment of the nuclear disaster.

It is important to calculate the internal radiation doses immediately after the incident to predict future health risks, particularly for younger generations; however, we had lost the opportunity to obtain actual values of IRE at the acute stages. Although committed effective dose might be predictable based on the assumed scenarios using available environmental monitoring data or the results of in vivo measurements performed after a certain period from the incident, these estimations could vary with methods and the assumption.6 Our case clearly demonstrates the necessity of personal in vivo measurements as soon as possible after the nuclear disaster to make an accurate prediction for future health risks of radiation.

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Leveraging Electronic Health Records to Notify Pediatric Patients of a Drug Recall

Drug recalls have become an unfortunately frequent event in the United States, with nearly 1 clinically relevant drug recall per month in the last 5 years. A national management strategy on medical device recalls is currently being debated by government and health officials. We report the use of the National Institutes of Health-sponsored Informatics for Integrating Biology & Bedside (i2b2) platform as an approach to speed patient identification and direct notification of a voluntary drug recall by leveraging data available in the electronic health record (EHR).

On November 9, 2012, specific lots of the generic version of atorvastatin calcium, distributed by Ranbaxy Pharmaceuticals Inc, a subsidiary of a multinational corporation, were reported as possibly contaminated with “very small glass particles resembling a fine grain of sand.” A voluntary recall was announced by the company and reported to the general public by news organizations. A US Food and Drug Administration (FDA) notice on November 28, 2012, recommended that patients contact their health care provider with any symptoms related to taking the medication and health care providers report any suspected adverse events to the FDA.

A team of physicians, a nurse practitioner, and a nurse who provide clinical care in the Preventive Cardiology outpatient clinic at Boston Children’s Hospital felt obligated to inform the pediatric patients prescribed atorvastatin and their families of the drug recall in a targeted and efficient approach to (1) identify those at risk and (2) prevent unnecessary discontinuation of beneficial treatment.

Methods | The i2b2 platform was approved for human subjects research by the Boston Children’s Hospital institutional review board; additional approval for the use in this context was not needed. Using the i2b2 platform, we queried patients who were prescribed atorvastatin in the preceding 2 years among those seen in Pediatric Cardiology outpatient clinics. These persons were reidentified using an honest broker intermediary under the guise of a patient safety data request. An intermediate agent allowed the reidentification of clinical data from the deidentified source without revealing the identities of others in the i2b2 system. We corroborated this list in the EHR and informed appropriate patients by telephone and mail.
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.5 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.6 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.

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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 accompanied by severe signs or symptoms, the guideline recommends, as an option, observation without initial antimicrobial therapy.1 The recommendation is based on findings from certain clinical trials that suggested little benefit of antimicrobial treatment in such children.2 In those trials, however, criteria used for the diagnosis of AOM were not as stringent as those called for in the recent AAP guideline,2 allowing for the possibility that some of the subjects in those trials did not actually have AOM. Our findings in 2 independent clinical trials,3,4 both of which used stringent diagnostic criteria consistent with those in the recent guideline,4 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,3 and Turku, Finland.4 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,