

POSTER ABSTRACTS

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Vaccine Safety: Case Study of the Impact of Privacy Concerns on Public Health Research

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Background: This two-phase vaccine safety study with CDC and other managed care organizations investigated the relationship between the childhood rotavirus vaccination and intussusception. Medical record abstraction for case validation took place at two times, before and after HIPAA passage, providing a unique opportunity to compare the effect of privacy concerns over time.

Methods: We identified potential cases of intussusception using administrative claims data, followed by medical record validation of case and vaccination status (exposed and unexposed cohorts). The research was conducted in two stages since there was a need for both immediate (Phase I) and long term results (Phase II), allowing for empirical comparison of the ability to abstract records before and after passage of HIPAA (December 2000). Phase I took place from 11/1/99 to 1/31/00 and Phase II between 5/1/01 and 9/30/01.*

Results: For Phase I, 35 potential cases of intussusception were identified from claims data of 8 UnitedHealth Group-affiliated health plans. Medical record abstraction was completed for all 63 records (35 cases), a 100% completion rate. In Phase II (after HIPAA was passed but not implemented), of the 37 medical records identified, 27 charts (23 cases) were abstracted with a 73% completion rate. Ten could not be abstracted: 4 (11%) with no record; 4 (11%) refused to release the chart or did not respond, and 2 (5%) required site-specific IRB approval (obtained) and informed consent, although the study had IRB approval with a waiver of informed consent.

Conclusions: The difference in our ability to conduct medical records research (73% vs 100% completion rate) due to concerns about privacy, raises questions about the future conduct of scientific public health research. There was greater reluctance by providers to release charts during Phase II. Also, time and effort for medical abstraction activities increased substantially. Finally, nurse abstractors expressed concern about HIPAA and patient privacy.

*Results of the initial study were published in The Pediatric Infectious Diseases Journal in April 2001 by Kramarz, et al. (20(7):410-416).