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Feasibility of Using Existing Public and Private Data Sources for Nationwide Medical Device Post-marketing Safety Surveillance

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Background. The Food and Drug Administration (FDA) initiated a national strategy for monitoring post-market medical product safety using existing public and private electronic data. The Centers for Medicare and Medicaid Services (CMS) publicly report hospital central line-associated bloodstream infection (CLA-BSI) data. We explored the feasibility of expanding the current FDA Sentinel Initiatives on patient-level data to hospital-level data for surveillance of CLA-BSI associated with intravenous needleless connectors (NC).

Methods. We merged the 2013 CMS Hospital Compare CLA-BSI data with the MaxPlus™ Tru-Swab™ Positive Displacement Connector (MP) client database from CareFusion to identify hospitals using the MPs (MP hospitals) vs those not using the MPs (Comparator hospitals). MP is a newer generation of NC with enhanced patient safety engineering design features. We evaluated CLA-BSI rates associated with MPs vs Comparators.

Results. In the CMS Hospital Compare CLA-BSI database, 3,074 hospitals reported central line (CL) days >1, with 25% (n = 758) hospitals using MP NCs. The MP hospitals accounted for 30% (2,923,859/9,887,264) of CL days, and 28% (3,017/10,864) of CLA-BSI episodes. The MP hospitals had a lower observed CLA-BSI rate (1.03 per 1,000 CL days [3,017 CLA-BSIs / 2,923,859 CL-days]) compared to Comparator hospitals (1.13 per 1,000 CL days [7,847 CLA-BSIs / 6,963,405 CL-days], \( P < 0.0001 \)). The univariate relative risk for CLA-BSI of MP hospitals was 0.91 (95% CI: 0.83, 0.98; \( P = 0.02 \)). After adjusting for hospital bed size, teaching, urban status, and geographic regions, the multivariable relative risk for CLA-BSI of MP hospitals was 0.94 (95% CI: 0.86, 1.02; \( P = 0.11 \)).

Conclusion. We demonstrated that it is feasible to link hospital-level data from public-private sources to support the FDA’s electronic post-market medical device safety surveillance efforts. Manufacturers should be encouraged to participate in FDA’s efforts.

Disclosures. Y. P. Tabak, CareFusion: Employee and Shareholder, Salary; R. Johannes, CareFusion: Employee and Shareholder, Salary; X. Sun, CareFusion: Employee, Salary; C. Crosby, CareFusion: Employee and Shareholder, Salary; W. Jarvis, Baxter: Consultant, Consulting fee; CareFusion: Consultant, Consulting fee; Johnson and Johnson: Consultant, Consulting fee; Gojo: Consultant, Consulting fee