# WAKE UP SAFE: (RE)BUILDING A NATIONAL ADVERSE EVENT CASE REPORTING SYSTEM

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**Introduction:** Wake Up Safe (WUS) is a federally designated Patient Safety Organization and a subsidiary of the Society for Pediatric Anesthesia. WUS mission is to improve care processes and outcomes in children receiving anesthesia. WUS collects data on serious adverse events from 41 member hospitals and reports findings to drive its mission. In 2021, WUS announced the need for a new system to improve data collection and management. Our team of CHOP Quality and Safety leaders, the Biomedical Informatics team, and Tsui Informatics Laboratory at CHOP was awarded the opportunity to build the new WUS system. We built a national case-reporting system using industry and informatics best practices in security, data access, and standard terminologies. We are sharing details of this system to encourage and facilitate similar patient-centered initiatives in other specialties and countries.

**System Architecture:** The new WUS system operates on the HIPAA-compliant Amazon Web Services (AWS) as a central repository for data on serious adverse events (**Figure 1**). We adopted industry standards for multi-stage development and deployment cycle: alpha, beta, and production. Alpha and beta environments allow new development and tests before the final production deployment. The database engine is PostgreSQL, an open-source database. The core data model adopts from the Observational Medical Outcomes Partnership (OMOP) model, which is commonly used in research communities and multi-center studies. The production environment with continuous monitoring and backups reports statistical analyses to member hospitals. The data dictionary and questionnaires for case reporting were developed and approved by the nationally recognized quality and safety leaders on the WUS committee.

**System Features:** In the current release, there are eight feature categories: 1) user account management, 2) data security and privacy, 3) interactive case reporting forms, 4) scalable computing resources and data storage, 5) advanced data loss protection (before data submission), 6) data and model standards, 7) comprehensive system logs and user audit, and 8) statistical analysis reporting. The user account management involves email verification, administrative new user review, user role and affiliation management. The new system uses secure HTTPS connections and access control for reporting and retrieving cases. The interactive web-based case-reporting forms use a dynamic list of sub-questions dependent on previous answers and data entry verification (e.g., body mass index [BMI] within an acceptable range). Scalable computing uses on-demand services for alpha and beta environments to minimize costs. The advanced data loss function automatically saves entered data that has not yet been submitted. The data standards include ICD-10 diagnosis codes and CPT-4.0 procedure codes; the case-reporting form enables keyword-based search of those standard codes to minimize the need for free-text data entry. The system routinely records system logs, provides audit options, and reports statistical analyses on patient care and for quality assurance to member hospitals.

**Conclusion:** Our team at CHOP has developed and deployed a national case reporting system for Wake Up Safe to drive its mission, which is actively being spread internationally with the support of WUS leadership. With its adoption of industry and informatics standards, the new WUS system could serve as a blueprint for national case-reporting systems in other specialties and countries.
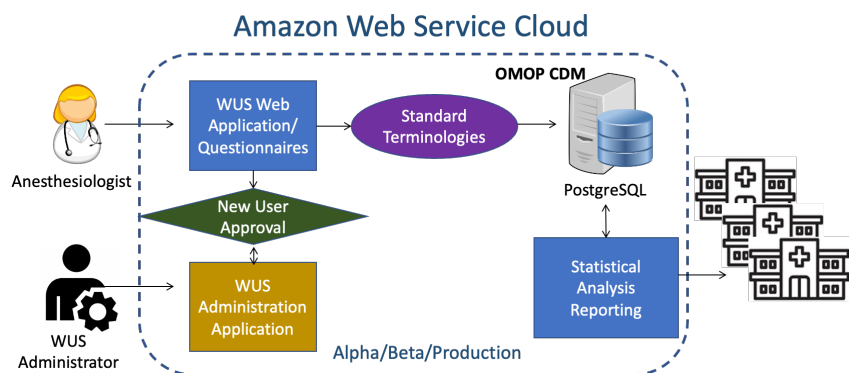


**Figure 1. Wake Up Safe Case Reporting Architecture.**