



International Alliance for
Biological Standardization



The Role of Real-World Evidence for Regulatory and Public Health Decision Making for Accelerated Vaccine Deployment

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Brighton Collaboration's role in establishing a real world evidence (RWE) infrastructure for vaccine safety during early deployment.

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Introduction: The Brighton Collaboration (BC) was officially established in 2000 with the goal to advance the science of vaccine safety, focusing initially on developing standardized case definitions (CD) to harmonize safety assessments. Since then, the import of vaccine safety for vaccine confidence has continued to grow, especially in the context of a) progress towards elimination of many target vaccine-preventable diseases (VPD) through high vaccine coverage, and b) plans to develop new vaccines vs. emerging "Disease X" pathogens in 100 days ("100-Day Mission").

Challenges: Historically, vaccine safety assessments within pre-approval clinical trials tended to be separate from post-approval RWE. A "life cycle" approach integrating both pre- and post-approval processes while ideal, was more an aspiration than a reality. Furthermore, doing so in low- and middle- (as well as high income countries adds another layer of difficulty.

Proposed Approach: The Coalition for Epidemic Preparedness and Innovation (CEPI) funded BC's Safety Platform for Emergency vACcines (SPEAC) project in May 2019. Based on the lessons learned from the COVID-19 pandemic, SPEAC (as SPEAC 2.0) was renewed and expanded in November 2022. Building upon its core of Adverse Events of Special Interest (AESI) CDs, the SPEAC 2.0 project aims to implement the use of standardized safety outcomes throughout the vaccine lifecycle, to ensure both the generation and interpretation of robust evidence of safety for CEPI 2.0's "100-day mission". For each CEPI-funded developer, SPEAC activities start during the pre-approval process (e.g., identify potential AESI for target pathogen and platform technology, develop standard BC CD if needed, identify background rates for AESIs, assign a meta-Data Safety Monitoring Board liaison member, complete vaccine profile template). Using this foundation, SPEAC continues through preparation for post-approval RWE active surveillance (e.g., mobile app for Cohort Event Monitoring, pregnancy exposure registry). Each Work Package is also planning "Living Labs" to Quality Assure and continuously improve their respective products for eventual use by the larger vaccine safety community. A digital transformation of BC CDs seeks to facilitate their greater use in existing processes and infrastructures used to perform vaccine safety surveillance.

Conclusions: BC and CEPI are using SPEAC to establish a "life cycle" approach to vaccine safety, including RWE infrastructure during early deployment.

