

Poster presentation

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PI5-06. Brighton collaboration viral vector vaccines safety working group (V3SWG): maximizing the comparability and value of safety data from HIV vaccine trials

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Background

Various viral vectors are being explored for use in vaccines against diseases such as HIV, TB, and malaria. Although unpredicted, the "STEP" trial results highlight the importance of safety assessments of candidate vaccines. Safety parameters generally can not be measured directly, but require indirect inference from the frequency of multiple adverse events (AEs). We seek harmonization of AE assessments to maximize their comparability and value across trials of multiple vaccine candidates.

Methods

The Brighton Collaboration (BC) was created to develop high quality information about vaccine safety; case definitions on 24 AEs have been published. The BC formed the Viral Vector Vaccines Safety Working Group (V3SWG) in October, 2008. The BC secretariat organizes and supports monthly conference calls.

Results

To date, the V3SWG has 1) recruited ~30 volunteers from stakeholders representing academia, industry, and government for balance between virology and safety expertise, 2) agreed on a standard template developed with IAVI for collection of data on each vector and risk assessment framework, and 3) developed a workplan to harmonize assessment of the following issues: a) potential for vector recombination with wild type pathogenic strains,

b) implications of prior infections on safety, c) genetic stability of replicating vaccine viruses in vivo, d) potential changes of vaccine viral tropism, e) tests for absence of reversion to virulence, f) absence of replication-competent virus when replication incompetent vectors are used, g) vaccine effects on innate immunity and on the induction of an immuno-suppressive window or immune-activation, h) length of time for monitoring AEs, i) inclusion of adventitious agents in cell culture, and j) possible secondary transmission of vaccine virus.

Conclusion

The BC has successfully launched the V3SWG as its first entrée into harmonization of pre-licensure safety assessments. The guidelines in development should improve our ability to prioritize vector selection and interpret safety data of viral vector vaccines.