Proposed ACCV Workgroup Resource Reference

VACCINATED VS UNVACCINATED EPIDEMIOLOGICAL HEALTH OUTCOMES ASSESSMENT WORKGROUP PROPOSAL

Provided by Commissioner Karen Kain

1) **Workgroup Formation Process Information**
   a) ACCV Charter – Requires members of Commission; approval of Secretary or designee; and fall within ACCV's jurisdiction.
   b) Federal Advisory Committee Act (FACA) Final Rule governing ACCV - Requires Commission to "provide the opportunity for reasonable participation by the public in advisory committee activities".
   c) Sister ACCV FACA committees with subcommittees/workgroups in charters - The National Vaccine Advisory Committee (NVAC) and Advisory Committee on Immunization Practices (ACIP). Currently, ACIP has 14 active workgroups and NVAC has one active workgroup and since 2012 formed five previous workgroups that have met their charge and are no longer active.

2) **Key ACCV Statutory Functions**
   a) Advise Secretary on Implementation of (42 U.S.C. §§ 300aa-19(f);
      i) the Vaccine Injury Compensation Program – VICP;
      ii) the responsibility to promote the development and refining of childhood vaccines resulting in fewer and less serious adverse reactions (42 U.S.C. §§ 300aa-27).
      iii) ACCV also makes research recommendations to the Director of the National Vaccine Program.
3) **ACCV Guiding Principles for Assessing Research -** Adopted by ACCV in 2006 to provide guidance in Commission's evidence assessment process.
4) **Known vaccine safety research deficts preventing additions and/or changes to the Vaccine Injury Table (VIT).**
   a) 2011 - National Vaccine Advisory Committee White Paper reiterated that the National Academies of Science Institute of Medicine (IOM) was charged by Congress in 1986 Act to review the evidence for causality assessments. These reports are used by ACCV to make recommendations to the Secretary to make changes/additions to the Vaccine Injury Table and guide research recommendations. NVAC also stated 11 reviews had been conducted since 1986 and for 60% of vaccine adverse events reviewed were prevented from making causality statements due to inadequate evidence and that further research may lead to definitive causality statements (page 17).

2012 - National Academies of Science Institute of Medicine – Highlighted vaccine safety research deficits. This report is the largest to date by the IOM, which reviewed evidence for 158 of the most commonly reported vaccine adverse events for 8 routinely recommended childhood vaccines and found that for 85%, or 135 events, the IOM was prevented from making causality statements that either supported or went against a vaccine causing the adverse event due to "inadequate" evidence. The IOM defines "inadequate" as follows:

> *"The evidence is not reasonably convincing either in support of or against causality; evidence that is sparse, conflicting, of weak quality, or merely suggestive—whether toward or away from causality—falls into this category. Where there is no evidence meeting the standards described above, the committee also uses this causal conclusion."*

b) **2013 – National Academies of Science Institute of Medicine** – A report on the childhood vaccination schedule's safety. The report found that key elements of childhood schedule had not been systematically studied and no study had compared vaccinated/unvaccinated for health outcomes of concern to the public. The IOM also found the CDC's Vaccine Safety Datalink (VSD) to be the best resource for studying the safety of the childhood schedule.

5) **Additional Resources and Considerations**

a) **2016 – CDC White Paper on Studying the Safety of the Childhood Immunization Schedule for the Vaccine Safety Datalink (VSD) –** Confirmed IOM's finding that the VSD is best resource and feasible for studying the safety of the childhood schedule.

b) **Scientific Process** - The IOM reported in 1991 that replication of findings is essential to the scientific process.

c) **2005 - National Academies of Science Institute of Medicine Report: Vaccine Safety Research, Data Access, and Public Trust -** Reviewed VSD data-sharing program to *"assess compliance with the current standards of practice for data sharing in the scientific community".* Findings included that the VSD data-sharing program did not conform to standards of practice. Many recommendations for improvements were provided by the IOM, including independent researcher access to core VSD data for formulation of alternative hypotheses and analyses. The report also noted the legitimate cause for public concern relating to transparency and possible conflicts within the VSD data-sharing program relating to federal laws requiring public access to research data used to published research findings.

The IOM additionally stated, *"Trust can be enhanced only if the public has confidence in the independence and fairness of the decision-making process for VSD research priorities and approval of VSD data sharing proposals."*