6 steps to vaccine safety narrative

The Six Steps To Vaccine Safety

Together, we will have the ability to prevent such needless and often devastating injuries. To do so, common sense dictates that the following "Six Steps to Vaccine Safety" must be taken:

1. Subject vaccines to a scientifically rigorous approval process.

Vaccines are regulated by the FDA's CBER division as "biologics" and are not always put through the same level of safety testing as new pharmaceuticals, which are regulated under CDER. Vaccines, which are given to healthy patients, should be tested more rigorously than drugs because they are not given to treat an existing disease. Inadequate testing currently ensures that the *true risk/benefit assessments for the safety and cost of vaccines are impossible to calculate accurately.*

2. Create a national database using existing electronic medical records that can monitor and record 100% of vaccine injuries in real time. Require reporting of vaccine adverse events.

Reporting and studying adverse events after receipt of vaccines is currently haphazard and antiquated. Two databases, VAERS and VSD –the primary sources of U.S. post-licensure surveillance—don't "talk" to each other and outside researchers have a difficult time accessing the data. Therefore, serious side effects of vaccination that were unclear or not seen in clinical trials can be missed. And new studies to assess the short and long-term health outcomes following vaccination are difficult to impossible to undertake. For instance, there has never been a comparative study of broad health outcomes in vaccinated vs. unvaccinated populations.

3. Ensure all parties involved with federal vaccine recommendations and approvals are free from conflicts of interest. A 2009 HHS Office of the Inspector General report found that:

- "CDC had a systemic lack of oversight of the ethics program"
- 97 percent of committee members' conflict disclosures had omissions.
- 58 percent had at least one unidentified potential conflict.
- 32 percent had at least one conflict that remained unresolved.
- CDC continued to grant broad waivers to members with conflicts.

4. Reevaluate all vaccines recommended by Advisory Committee on Immunization Practices (ACIP) prior to the adoption of evidence-based guidelines. *(Prior to 2012, evidence-based guidelines were not used to evaluate their vaccine recommendations which encompasses the majority of vaccines on the childhood vaccine schedule.)* A vote by ACIP results in:

- Mandating the vaccine to millions of children (4 million U.S. births annually)
- Immunity from liability for vaccine manufacturers
- Inclusion in the Vaccines for Children program

5. Study what makes some individuals more susceptible to vaccine injury.

The Institute of Medicine (now National Academy of Medicine) has issued three disturbing reports on the evidence for suspected and/or reported vaccine adverse events. For 80% of the suspected vaccine adverse conditions investigated, there wasn't enough research evidence to accept or reject vaccine

causation. Of the reviews with sufficient evidence, 72% found that the vaccine did likely cause the injury. Yet no systematic research has been done to try and understand the links nor prevent a susceptible child from the same injury. Government/industry must understand vulnerabilities and work toward preventing vaccine injuries at the same level as they work to prevent vaccine preventable diseases.

6. Support fully-informed consent and individual rights to refuse vaccination.

Many states seek to pass laws mandating vaccines for all children against parents' wishes for what is best for their child. Three states have already passed laws taking away parental rights to refuse. Insistence on fully-informed consent and individual rights to refuse a vaccination become imperative given the lack of long-term follow-up and surveillance, only 1% adverse events are captured and reported, vaccine recommendations are tainted by financial conflicts of interest of regulators, the current childhood vaccine schedule was not approved using evidence-based science and policy, the childhood vaccine schedule has never been tested on fully vaccinated vs. unvaccinated, and there is sparse research into which patients are likely to have adverse events.