

FRAMEWORK FOR CONSIDERING IMMUNIZATION SAFETY ISSUES AND RECOMMENDATIONS

**National Academy of Sciences/ Institute of Medicine
Immunization Safety Review Committee Meeting**

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Topics to Be Covered

- **Big Picture Issues – General**
- **Framework for Addressing Level of Concern**
- **Framework for Addressing Recommendations**

Starting Assumptions

- Public health efforts can and do make a difference in promoting health and well-being of the population.
- Vaccines can and do play an important role in combating devastating diseases.
- Consumers can and do play an important role in developing strong public health policies.
- What we do in immunization reflects on all of public health. If we don't get it right, it reflects *poorly* on all of public health.

Starting Assumptions (cont'd)

- We can and should do better in assuring vaccine safety, and in assuring public confidence in vaccine safety and in immunization policies.
- The efforts of this committee/panel can make an important contribution.

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1. Immunization as an “Intersectional” Issue.

- *Science and public policy*
- *Individual health and community health*
- *Public sector and private sector*
- *Individual rights vs. rights of the State*

Bottom Line: frameworks for findings and recommendations need to take intersections into consideration

2. Thoughts on Data/Evidence

- *For issues chosen, data will not be clear-cut.*
- *Caveat on “hierarchy of evidence”: rare and very rare events will not show up on clinical trials.*
- *Clarify what you are evaluating: consider evaluation from two perspectives.*
 - Immunization community asks: Is this vaccine safe enough to give it to the public?
 - Consumers/affected individuals ask: Is it possible that this adverse event is related to vaccine administration?

• *Bottom Line on Data/Evidence*

- Need a rigorous assessment of what we do know.
- Need a rigorous assessment of what we don't know.
- Need to identify what we still need to know and how likely we are to obtain this information.
- Evaluate safety from two perspectives:
 1. Is the vaccine safe enough?
 2. Could it be related to specific adverse events?

3. Individual vs. Systemic Approach

- *You have been asked to look at individual issues.*

- Important contribution
- Use rigorous approach

- *There are limitations to evaluating issues individually/ one at a time.*

- Yields a “snapshot” approach – albeit an important one
- Addresses, at most, 9-10 conditions altogether (and likely 1-2 from each major category of safety issues)
- Assumes early, full development of framework for analysis and recommendations (less dynamic, less room for improvement)

• ***Consider combining individual analyses with a more systemic approach.***

- Look for commonalities/lessons learned across findings and recommendations.
- Look across the board and by type of disease/disorder/mechanism/etc.
- Periodically during the study and more in-depth at the end of the study.

4. Issues Raised by Consumers and Others

- *Cumulative effect*
- *Impact on identifiable sub-populations (premature infants; infants/children with developmental disabilities; etc.)*
- *Affected individuals – look for commonalities*
- *Size of clinical trials for pre-licensure testing*

Bottom line: Look for data that will shed light on these issues (rare); frame findings/recommendations with these issues in mind.

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Framework for Thinking About “Level of Concern”

- **“Appropriate Level of Societal Concern” – not a useful concept.**
- **Instead, think about assessing current level of public concern.**
 - a systematic assessment of varying levels of concern
 - clarification of specific concerns.

• **How Do We Define “the Public?”**

- *General public*
- *Those most vocal/concerned about vaccines*
- *Those most concerned about specific conditions/disorders*

- **Approaches to Assessing Current Level of Public Concern**
 - *Review of Passive Reporting Systems – VAERS*
 - *Review of Websites*
 - *Review of Media Coverage*

- ☞ *Focus Groups*

- ☞ *Work with those Most Vocal and Concerned*
 - Identify /prioritize issues

 - Develop a framework for analysis that will be understandable and helpful to consumers.

- **May also want to consider the *alignment* of concerns with known evidence.**

- **Perhaps the best approach is to present findings (evidence base) on 3 separate, but related concepts**

 - *Level and nature of public concerns*

 - *Risks and benefits for the individual vaccinee*

 - *Risks and benefits to population as a whole (societal considerations)*

- **Together, information on these 3 areas can help stakeholders**

 - *assess alignment between concerns and evidence base*

 - *assess appropriateness of policies and programs*

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Thoughts on Developing Recommendations

•Focus on 3 Broad Areas

(1) Guidelines or schedules for specific vaccines

Continuum: “maintain with routine, periodic review” to “suspend and immediately pull in existing advisory bodies.”

(2) Additional studies/ analysis.

Threshold Q’s: Needed? Useful? If Yes, provide listing of most promising options (brief description, potential yield, investment in time and money)

(3) Systemic changes

Recommendations that go beyond specific safety issue/vaccine (mechanism to enable additional post-licensure studies, formal linkages among research groups.)

Thoughts on Developing Recommendations (Cont'd)

- **Use an Iterative Process**

- **Develop Cross-Cutting Findings/Recommendations**
 - Consistent themes across all issues
 - Similarities and differences by types of issue

Closing Thoughts

- This study is a key part of a broader effort to better address vaccine safety issues.
- The work is going to be very important.
 - can contribute to our understanding of specific safety issues.
 - can contribute to our understanding of how to better address safety issues in general.
- Won't be able to address all the issues raised, but do give them consideration.