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.
Topics to Be Covered

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- Framework for Addressing Recommendations
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.
Topics to Be Covered

• Big Picture Issues – General

• Framework for Addressing Level of Concern

• Framework for Addressing Recommendations
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 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.