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Friday, 20 July 2012

Introduction

Following this introduction page are this researcher's comments to the Institute of Medicine's Committee on Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule that were sent through http://www.surveygizmo.com/s3/927011/BPH-Committee-on-the-Assessment-of-Studies-of-Health-Outcomes-Related-to-the-Childhood-Immunization-Schedule. These comments apply to a revised commissioned paper from a consultant, Martin Kulldorff, Ph.D., titled, *Study Designs for the Safety Evaluation of Different Childhood Immunization Schedules*, which was downloaded on Thursday, July 12, 2012 from: http://www.iom.edu/~/media/Files/Activity%20Files/PublicHealth/ChildhoodImmunization/Commissioned%20Paper/Posting%207182012.pdf. Should anyone else wish to comment, the comment period is open until 31 July 2012.

This researcher's comments begin on the next page.

Introductory Remarks

First, this reviewer's assessments are written in a "Tahoma" font.

Second, when the commissioned paper or other sources are quoted or referenced, the text is in an "Arial Narrow" font.

Finally, should anyone find any significant factual error in this review for which they have independent[a], scientifically sound, peer-reviewed published substantiating documents, please submit that information to this reviewer so that he can improve his understanding of factual reality and, where appropriate, revise his views and this analysis.

Respectfully,

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[To whom all responses should be directed]

[a] To qualify, the study should be published by researchers who have no conflicts of interest from their ties to either those commercial entities who profit from the sale of vaccines or those entities, academic, commercial or governmental, who actively promote inoculation programs using vaccines.

Comments to IOM Committee Concerning
"*Study Designs for the Safety Evaluation of Different Childhood Vaccination Schedules*"

Comments to the Institute of Medicine's BPH Committee of the Assessment of Studies of Health Outcomes Related to the Childhood Immunization Schedule on "*Study Designs for the Safety Evaluation of Different Childhood Immunization Schedules*" submitted to:
http://www.surveygizmo.com/s3/927011/BPH-Committee-on-the-Assessment-of-Studies-of-Health-Outcomes-Related-to-the-Childhood-Immunization-Schedule
on 20 July 2012.

The "Introduction" to "Study Designs for the Safety Evaluation of Different Childhood Immunization Schedules" begins by stating a premise,

> "Before approval by the Food and Drug Administration (FDA), vaccines are evaluated for efficacy and safety using large phase III randomized controlled trials",

that is: **a)** not supported by the facts and **b)** based on trial designs that are not scientifically sound.

Specifically, the safety studies fail to use a "true placebo" **[1]** as the control for safety purposes.

[1] By definition, for injected vaccines or those administered orally or nasally, a "true placebo" would be an equivalent dose of a sterile isotonic pH 7.04, buffered saline solution containing a level of glucose equivalent to the overall level of all of the vaccine antigens.

In addition, the efficacy studies are often flawed because the level of antibodies is not measured using human antiserum but rather an animal antiserum surrogate is used to measure the level of human antibodies that each subject develops.

Further, after: **a)** the initial inoculation series proves that the vaccine is "safe enough" against a "true placebo"; **b)** the level of antibodies developed is measured; and **c)** the percentage of those who are vaccinated who have an adequate antibody titer is computed to determine the efficacy percentage, there is no "disease challenge" **[2]** in a volunteered group of those who are vaccinated and have the sufficient antibody levels (titers) to prove that those individuals have been actually protected by the vaccination series from contracting the disease.

[2] In a "disease challenge", a volunteer group of not less than 10% of those who: a) were inoculated with the vaccine and b) have developed a protective level of antibodies to the disease are naturally exposed to the "wild", "native" or "circulating" strain or strains of the disease and then monitored for twice the disease incubation period to ascertain the percentage of those who were fully protected from contracting the disease after being exposed to it.

Thus, before any scientifically sound and appropriate vaccination program trials can begin to be designed, researchers should first conduct those missing scientifically sound and appropriate studies that prove that each individual vaccine component is: a) "safe enough", b) "efficacious" (produces appropriate levels of antibodies in not less than 95% of those who have received the initial vaccine series of not more than 3 doses of a given vaccine component) and c) "effective" (when an appropriate subset of the "vaccine protected group" is challenged by the most virulent "wild"/"native"/"circulating" strain of the disease, the vaccination series prevents those vaccinated

from contracting the disease in more than 95% of those who have an "protective" antibody titer and attenuates the severity and/or duration of the disease in the remaining 5%).

Lest any raise the issue of ethics concerning the "disease-challenge" of volunteered inoculated children who have an "efficacious" level of disease-specific antibodies that have been claimed to be disease protective, without this disease-challenge to prove that the vaccines are truly effective, then it is clearly unethical to recommend that any child be exposed to vaccine disease-components that are not known/have not been proven to be effective in preventing those so inoculated from contracting the disease for which that vaccine disease-component is claimed to be protective.

Having read several package inserts where the vaccine manufacture makes no claim that the vaccine is effective in preventing those "fully" inoculated with their vaccine from contracting the disease or diseases for which the vaccine is used as a disease preventive measure, it is clear that the in-use effectiveness of each currently FDA-approved vaccine under the current CDC-recommended initial vaccination program must be established for each individual vaccine before any scientifically sound and appropriate program to study the effects of changes to the status quo should be attempted.

In addition, those vaccines for which the number of doses currently recommended by the CDC renders the vaccine not societally cost effective should be excluded from any such study, their CDC recommendations for mass use should be rescinded; and such vaccines should be removed from coverage by the National Vaccine Injury Compensation Program.

IF: under the current CDC-recommended inoculation schedule, a vaccine is not at least societally cost-effective **[3]**, THEN: how can anyone justify continuing the mass use of that vaccine?

[3] For example, though the varicella vaccine was only marginally societally cost effective under its pre-approval assumptions for a single dose; the initial cost of the vaccine was higher than the pre-approval cost for cost-effectiveness; the single-dose program failed to provide the promised results; and even the two-dose program, which is currently not more than 80% efficacious in the short term, is clearly neither effective nor cost-effective on any scientifically sound basis, the CDC continues to recommend what is now a two-dose-plus vaccination program that is clearly a waste of precious healthcare dollars. This waste of healthcare dollars and any other like it should be immediately stopped.

In closing, the simple message is that, before attempting to design any study, each vaccine that is to be included in any such study should first be proven to be truly "safe", "efficacious" and "effective" based on scientifically sound and appropriate studies.

Unfortunately, in many, if not all, instances, the Phase III clinical studies used by the manufacturers to obtain FDA approvals for their vaccines are neither scientifically sound nor designed to provide proof that the vaccine is actually effective in preventing disease in those who: a) are "fully" vaccinated; b) develop more than adequate disease-specific antibody titers (levels); and c) are subsequently exposed to the most virulent form of the "wild"/"native"/"circulating" strain(s) of the disease!

Hopefully, after reading these comments, the Institute of Medicine (IOM) committee seeking these comments will shelve these studies and, for those vaccination programs that are truly cost effective when all of the costs are considered, demand that the missing but required scientifically sound and appropriate studies, as defined in these comments, be conducted for each vaccine before any future studies are conducted on alternatives to the current vaccination schedules.

Until the foundation for each of the existing vaccines is proven to be scientifically sound with respect to safety, efficacy, effectiveness, and cost-effectiveness, all study designs that seek to study the effects of any perturbation of the overall vaccination program will be built on a claimed but non-existent foundation that will, at best, doom them to scientific failure.