Centers for Disease Control and Prevention's Immunization Safety Office Scientific Agenda:

Draft Recommendations: Addendum on April 10, 2008

EMBARGOED UNTIL 9AM EST ON APRIL 11, 2008

This draft document was prepared for the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group for its scientific review on April 11, 2008. It does not represent Centers for Disease Control and Prevention (CDC) or Department of Health and Human Services policy, nor does it necessarily reflect which ideas will be incorporated into CDC's final Immunization Safety Offices Scientific Agenda.[1]

Section 3: 5-Year Research Needs

Table 3B: ISO 5-Year Research Needs: Vaccines and Vaccination Practices

Item	Thematic Area	Background
B-VI	**Safety of different products within the same vaccine category**	▪ Within the same vaccine category, certain vaccines are available from different manufacturers; these vaccines have different antigen and non-antigen compositions. ▪ Some examples of vaccines with more than one formulation on the US market are: trivalent inactivated influenza vaccines (TIV), diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccines, and rotavirus vaccines. A quadrivalent human papillomavirus (HPV) vaccine is routinely recommended; a bivalent HPV vaccine is under FDA review for licensure. ▪ The ACIP recommends that "for vaccines in general, vaccination should not be deferred because the brand used for previous doses is not available or is unknown," (CDC, ACIP, 2006). ▪ Information about the interchangeable use of vaccine of the same category form different manufacturers is generally limited.
B-VII	**Off label use of vaccines**	▪ Off label use is defined as use of a product other than the indication for which it was approved by the Food and Drug Administration. ▪ Off label use may be inadvertent or intentional. Examples of off label use might include use of a product in an age group outside the recommended age group or use in a population for whom the vaccine is contraindicated. For example, administering live, attenuated influenza vaccine (LAIV) to a person with asthma would be an off-label use. ▪ Safety data about the off label use is generally not available at the time of licensure.

[1] Address comments to CDC Immunization Safety Office Scientific Agenda: isoagenda@cdc.gov or 404-639-8256

Item	Thematic Area	Background
B-VIII	**Vaccine-drug interactions**	▪ From the standpoint of safety, few vaccine-drug interactions have been systematically studied. ▪ Jackson et al. conducted a cohort study in adults on warfarin therapy. The results, "do not suggest that vaccinations lead to clinically significant alterations in coagulation measures among adults on chronic warfarin therapy" (Jackson, Pharacoepimemiology and Drug Safety, 2007). ▪ Oral contraceptive use is a known risk factor for venous thromboembolic events (VTE) (Petitti, NEJM, 2007). In 2002, 31% of the US women aged 15–44 years used oral contraceptives (CDC, National Center of Health Statistics, 2007). The Vaccine Adverse Event Report System (VAERS) has received reports of thromboembolic events in women who were vaccinated with human papillomavirus (HPV) vaccine who were taking oral contraceptives (CDC, ACIP presentation, 2007).

References

CDC, National Center for Health Statistics, Health, United States, 2007 with Chartbook on Trends in the Health of Americans Hyattsville, MD: 2007.

CDC. General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practicies (ACIP). 2006;55(RR15):1-48.

CDC. Advisory Committee on Immunization Practices (ACIP) Presentation, Quadrivalent HPV Vaccine Safety Update, June 28, 2007, available at http://www.cdc.gov/vaccines/recs/ACIP/slides-jun07.htm#hpv, accessed on April 9, 2008.

Jackson ML, Nelson JC, Chen RT et al. Vaccines and changes in coagulation parameters in adults on chronic warfarin therapy: a cohort study. . Pharmacoepidemiol and Drug Safety 2007;16(7):790-796.

Petitti DB. Combination Estrogen–Progestin Oral Contraceptives. New England Journal of Medicine. 2003;349:1443-1450.