World Health Organization

4th MEETING OF THE SAGE WORKING GROUP ON INFLUENZA VACCINES AND IMMUNIZATION (SAGE WG)

14 – 15 February 2012

WHO Geneva, Salle M105

1. Welcome and objectives of the 4th meeting

Joachim Hombach welcomed meeting participants and presented the objectives for the 4th SAGE Working Group on Influenza Vaccines and Immunization (WGIVI). These objectives were:

- To review available vaccine performance data for key group: children <2 years
- To review progress on background document
- To draft recommendations for the April SAGE meeting, informed by data presented to date, including:
    - Defining target groups
    - Deciding on relative prioritization
    - Determining how to address coverage goals

Discussion of Meeting Goals

General points raised by the WGIVI included:

- The importance of the current recommendations targeting low/middle income countries (LMIC), without undermining previous recommendations.
- Accounting for major developments the since 2005 recommendations, such as: additional epidemiology data in developing and tropical countries (including Argentina, Mexico, Bangladesh, India, Hong Kong) and new evidence base for pregnant women.
- How specific should recommendations be regarding different vaccine types?

Grading of the available evidence:

- A formal evidence review is needed, but what evidence requires grading?
- The WG will need to be transparent on what is graded/not, and on the grading process.
- This can build on existing systematic reviews.

Prioritization of target populations:

- The previous position paper considered groups in order of priority (informed by data from industrialized countries), starting with the elderly. Even without reprioritization, leaving a choice for countries would be a change from 2005.
- Prioritization would need to take into account both evidence base and issues such as operational feasibility.
- Prioritization should not be prescriptive, instead provide tools/criteria for countries to apply their own prioritization based on their circumstances.

Administrative Note: Comments have been received for previous meeting's minutes; John Tam will update and post the final version of the minutes on the SharePoint site.

2. Influenza in Young Children and Infants (Tony Mounts)

Hospitalization data for children (US, Hong Kong) show a consistent elevated risk for those <6 months versus those 6 months and older, particularly those aged 2-6 months, although there was variation in magnitude of burden from year to year. Pediatric mortality analysis (US) also show higher risk of death

in the <6 month age group, versus other children. A systematic review[1] of influenza-associated acute lower respiratory infection (ALRI) in children showed similar trends in developing and industrialized countries, with the highest burden of influenza-associated ALRI and severe ALRI in children <6 months. Rates among children 6 months – 5 years were higher in developing countries, compared to industrialized countries. However, rates of severe influenza-associated ALRI among children <6 months were similar between developing and industrialized settings.

Data also indicate that hospitalized infants <6 months with influenza were less likely to have underlying conditions than those >6 months. Overall, children <5 years admitted to hospital rarely had chronic disease, although neurological, neuromuscular, and asthma were most frequently present among those who did. Pneumonia was only identified in 10-36% of influenza-positive admissions, but was present in at least 49% of fatal cases.

Discussion/Implications for Recommendations

- The evidence of burden for <6 month age group is particularly relevant for maternal immunization, due to the protective effect of transplacentally-acquired maternal antibodies among vaccinated mothers.
- It would be useful to have additional relative incidence data to compare children to other risk groups (such as the elderly), for prioritization considerations.

3. Influenza Vaccines for Young Children: Immunogenicity in Children < 2 Years (Janet Englund)

Data show reduced immunogenicity of trivalent inactivated vaccine (TIV) in toddlers 6 – 23 months, compared to older children. Antibodies substantially increase after second dose, even if the second dose is given up to 1 year after the first dose. However, the boosting effect is only seen when they are the same vaccine (would not apply if different strains in the two vaccines). Antibody response increases with age in the 6-23 month age group.

MF59-adjuvanted vaccine showed a good immune response in the 6-23 month age group after two doses, and for certain strains, after a single dose (currently not licensed for that age group).
For infants <6 months, inactivated vaccine is safe and immunogenic, but there is a lower antibody response than older age groups after two doses; antibody responses were better among babies with no transplacental antibodies.

Recent data from one study suggests that a titer of 1:110 (rather than 1:40) would provide 50% protection in children[2], which is an additional challenge to interpretation of immunogenicity data.
Live-attenuated influenza vaccine (LAIV) is not licensed for children <2 years, but data show good antibody responses in children 6-23 months after a single dose as well as infants <6 months after two doses, with no interference found with other vaccines. LAIV also has the advantage of heterotypic protection. HAI tests for seroconversion may underestimate protection from LAIV. For both LAIV and TIV, the neutralizing antibody may be more sensitive, although it is not often performed.

Repeated annual dosing of LAIV and TIV indicate that first year of vaccination elicits strongest antibody response, compared to later years.

Discussion/Implications for Recommendations

- Children <2 years respond to inactivated vaccine, and need 2 doses, although the timing of the second dose is flexible. Cannot make positive recommendations for LAIV in <2 at this time.

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[1] Nair et al, Lancet. 2011 Dec 3;378(9807):1917-30.
[2] Black et al, Pediatr Infect Dis J. 2011 Dec;30(12):1081-5.

- Adjuvanted vaccine seems to have priming capacity in children, resulting in increased immunogenicity and efficacy. However, no vaccine is currently licensed for that age group. How can immunogenicity data inform recommendations? It was felt that it could be used as further supportive evidence where efficacy and effectiveness data are not available, and where the inference is biologically plausible.

4. **Influenza Vaccine Efficacy and Effectiveness in Children < 2 Years (Joseph Bresee)**

The evidence base of TIV in children <2 includes 2 randomized controlled trials (RCTs) and 9 observational studies. The two RCTs found that point estimates did not change with decreasing age within the <2 category. From the 9 observational studies, many vaccine effectiveness point estimates were not significant; however, these originated from study years where vaccine was not well matched to circulating strains. The studies that had better vaccine match to circulating strains showed consistent effectiveness estimates, also with little difference in the point estimates by age sub-group for children <2 years compared with older age groups.

LAIV studies presented were all RCTs, with vaccine effectiveness from 70-80% for well-matched vaccines (some diminished efficacy for drifted strains).

Overall, TIV has a demonstrated effectiveness in this age group, but depends on the vaccine match. There is a lower estimated effectiveness for TIV in <2 year age group in some studies, but not in others. LAIV effectiveness in this age group is similar to that for older children.

Discussion/Implications for Recommendations

- Vaccine match is key for understanding seemingly contradictory findings in effectiveness for children <2 years. Country-level mismatch data between vaccine and circulating strains (if surveillance is ongoing) could help determine utility of TIV, especially in this age group.
- The use of half-dose vaccine in the <3 year age group is based on very little data, and switching to a full dose may increase the number of years where vaccine impact is seen in the youngest age groups. This should be mentioned in the position paper: there is no evidence supporting use of half-dose.
- Knowledge gaps: would TIV effectiveness be different in tropical countries with year-round circulation, or could existing effectiveness data be generalized to apply to tropical settings? Where data on effectiveness in tropical settings are not available, immunogenicity on the level and duration of protection in this age group may be helpful. Even locations with year-round influenza have regular peaks in circulation. Apart from this consideration, and from variations in risk factor profiles, effectiveness data are generalizable.
- Programmatic considerations: it is not always clear in tropical regions which formulation is best, and what time of year is optimal. Would vaccine be available year-round? In considering influenza vaccines as part of EPI program, this would be an additional contact unless it was timed coincidentally with the 9-month contact. In Laos and Latin America, influenza vaccine delivery has been accomplished through campaigns.

5. Influenza Vaccine Safety in Children < 2 Years Old (David Wood)

2010 CSL vaccine was associated with febrile seizures in children <5 years of age in Australia, with no clear clinical or epidemiological explanations. The Australia CMO advised suspension of all flu vaccines in healthy children <5, but allowed for monovalent/seasonal vaccine for children with risk factors. There have been no safety issues with CSL vaccine in Australia since.

As a result of these findings, the US put enhanced monitoring in place to detect febrile seizures, and data mining did find a signal for febrile seizures from Fluzone in Dec 2010-Jan 2011. A concomitant

vaccine analysis showed that risk existed when Fluzone was given in combination with pneumococcal vaccine (PCV13). The conclusion of the analysis was that risk was only present among 6-23 month olds when receiving TIV/PCV13 jointly. Both Australia and US responses were focused on the CSL product.

Discussion/Implications for Recommendations

- Apart from product-specific issues, there are no generic safety issues for influenza vaccines in young children.
- Reactogenicity findings, such as fever, can be documented in the text of the position paper. But if they do not drive decision, they do not need a grade table.
- The working group identified no concerns about vaccine safety in pregnant women.

6. Comparative Vaccine Effectiveness of TIV, Adjuvanted TIV, and LAIV in Children <2 Years (Martin Friede)

Adjuvanted vaccine (MF59) shows enhanced priming and boosting, as well as efficacy in infants, although need for two doses remains. It also demonstrates an increased breadth of response, although not broad enough for protection against H1N1pdm virus. Adjuvanted TIV does not show a similar effect in adults, only naïve individuals.

All TIV/Adjuvanted TIV comparisons are not the same, since there are whole, split, subunit formulations of TIV in addition to multiple types of Adjuvanted vaccines. TIV/Adjuvanted TIV knowledge gaps include: do other oil-based adjuvants have a similar effect to MF59? Do adjuvants such as alum boost protection in infants? One type of study design to address some of these differences would compare whole virus TIV with and without adjuvant to split TIV with and without adjuvant.

Meta-analysis of LAIV (Ambrose) shows LAIV to be much more effective than inactivated vaccines (most comparisons compare it to unadjuvanted TIV). LAIV knowledge gaps include: efficacy of Leningrad-backbone LAIV in <5 year olds, comparison of delivery by spray versus drops, and the effect of environmental parameters (humidity, temperature) on efficacy of LAIV.

Discussion/Implications for Recommendations

- Although LAIV and aTIV both look promising, they cannot be recommended as they are not available/licensed. They could instead be included in a "future look" section of the position paper, with wording to help steer future research in this age group, especially given the commitment of the new developing country manufacturers to produce LAIV. e.g., "Recognize potential advantages of LAIV for priming of naïve and acknowledge knowledge gap…"
- Is the risk of excess hospitalization from wheezing high in context of other vaccines' adverse effects, such as febrile seizures from measles vaccine? Wheezing data is complicated, and findings that motivated FDA decision were not statistically significant.
- If WHO paper mentions possible strong health benefit, this could drive studies to build evidence base. Do not want to close issue because of ACIP/FDA decision.

Summary Discussion: Recommendations for <2 year olds

Content of the recommendation:

- The WG agreed to include a statement on morbidity of children <2 relative to other age groups.
- Efficacy of TIV in this age group: it appears that it does work moderately, with a caveat about vaccine match. Gradable statement.
- The previous recommendation mentioned 6-23 month olds at the bottom of the prioritized list. It should not be moved to the top of the list, but not at the bottom either.

- There are limited data for TIV, in special populations such as malnourished and HIV, and limited availability of LAIV and Adjuvanted TIV, especially in developing countries. Raising priority of children could serve to drive development. The draft recommendations should not fully endorse, but should provide some impetus.
- Innovation needs as stated above

Programmatic considerations:

- The recommendation has to factor in other considerations, including the accessibility of this population for targeting. It is unclear if they are easier to target versus other risk groups, and likely depends on the existing programs.
- Country-level vaccine programs also rely on motivation, driven by evidence of disease burden especially compared to other diseases. However, there is not sufficient data to prioritize influenza versus other vaccines. Country-level seasonality data would also guide local decisions about best formulation and timing of vaccination, particularly in tropical settings.
- Programs looking to integrate delivery of influenza vaccine into existing childhood vaccination platforms (e.g. EPI, OPV campaigns) or other (non-vaccination) contacts could reduce the overall number of public health visits for children, but would have significant logistical hurdles(timing of vaccination in relation to seasonality, need for two doses). For pregnant women, influenza could build on tetanus toxoid platform, with similar hurdle of timing but no need for administration of two doses.
- For children requiring two doses, the timing of the second dose could be flexible (based on immunogenicity data) to integrate into existing programs and it is not required that the 2 doses be one month apart.

Prioritization of target groups:

- Previous recommendation listed elderly at the top, and existing programs do target elderly. If we reorder so that elderly are lower on the target group list than children, there should be some qualification/acknowledgement of limitations. It needs to be clear in the wording that programs targeting elderly are not wrong. The group is not suggesting that places such as the US that already have programs should re-prioritize, or suggest that they scale back, but guide places where vaccine is not being used on where to consider starting a new program.
- There is wide recognition of the evidence showing that TIV does not work as well in the elderly as was previously thought, so the recommendation should strongly reflect the currently available evidence.
- Young children could be listed as a second priority group, but phrased in order to indicate the challenges of influenza vaccination in this group.
- Country-level decision should be based on their individual disease burden and other considerations. However, burden and seasonality rely on baseline surveillance data, as mentioned in materials such as the PAHO guidelines.

Quadrivalent vaccine recommendations:

- For 4 of the previous 8 seasons, use of QIV instead of TIV would have had substantially improved match. The lead recommendation should come from strain selection meetings, but we can mention in the position paper that there is potential public health benefit for QIV, in order to open up channels. Cost-effectiveness evaluations would also be needed.

Coverage goals:

- The paper should mention goals where they already exist (e.g., WHO targets for those 65 and older), but should not include explicit setting of coverage target. Instead, refer to the utility of coverage goals, and indicate need for system in place to evaluate/measure coverage goals.

7. Experience from H1N1pdm vaccines (Michael Pfleiderer)

Dr. Pfleiderer provided a review of the H1N1pdm vaccine literature, including 4 representative studies:

- Canada[3]: case-control study of Arepanrix (AS03) showed very high effectiveness, including multivariate and sensitivity analysis by age and other conditions. Effectiveness increased steadily over time, showing the development of protection.
- Germany[4]: a study of single-dose Pandemrix in individuals 14 and up, based on routine surveillance data, was limited due to vaccines becoming available very late, coinciding with peak activity.
- I-MOVE[5]: case-control study in 7 European countries of multiple vaccines (adjuvanted and non-adjuvanted) also had a narrow window between circulation of cases and availability of vaccine. Analysis does not distinguish between the different vaccine types used. VE increased as delay between vaccination and symptom onset increased.
- US Flu-VE network[6]: study of unadjuvanted and LAIV in 4 communities. The number of cases again drops coincidentally with the availability of vaccines. The inactivated vaccine effectiveness point estimate was 88.6% among individuals 10-49 years, lower in those 6m-9y and over 50. LAIV had an increased effectiveness in children 6m-9y.

Summary findings from pandemic vaccine evaluations for children <2 years include:

- A short-term benefit may be achieved by at least two doses of an unadjuvanted influenza vaccine, but the long term benefit in this age group is unknown.
- A single dose of an adjuvanted influenza vaccine is more efficacious compared to an unadjuvanted vaccine, and there is some evidence that a single dose of adjuvant may even be sufficient for priming, long term benefit possible (only backed by Vesikari data[7] to date)
- Although there are no data available for LAIVs in this age group, a high risk scenario may justify use of LAIVs in the very young depending on the risk-benefit risk ratio.

Discussion/Implications for Recommendations

- Although available data suggest LAIV provides increased protection for children, indicating a preference of certain licensed products in the recommendations is challenging, particularly since LAIV is not widely available. However, should not ignore the benefits altogether; rather, address improved protection in the recommendation without being prescriptive. Text suggesting preference where both products are available ("…if you have both products, LAIV in younger, TIV in older…") would capture differences in vaccine performance, but creates logistical issues.
- Single vaccination with double-dose monovalent H1N1pdm vaccine in the <3 year age group does not show an improved immune response[8], which could be addressed in "future developments" section of the position paper. Also, since this paper will be in place for several years, we want to include provisions for additional products, such as adjuvanted vaccines and LAIV, which may soon

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[3] Skowronski et al, BMJ. 2011 Feb 3;342:c7297.
[4] Wichmann et al, Euro Surveill. 2010 May 6;15(18).
[5] Valenciano et al, PLoS Med. 2011 Jan;8(1):e1000388.
[6] Griffin et al, PLoS One. 2011;6(8):e23085.
[7] Vesikari et al, N Engl J Med. 2011 Oct 13;365(15):1406-16.
[8] Frey S et al, presented at 48th Annual Meeting of IDSA 2010

become more available. Producers are now setting up large efficacy trials, and this is an opportunity to motivate targeting key age groups in clinical trials where there are data gaps (<2, >49).

- Co-administration of influenza has been investigated with 20 other vaccines. Safety and immunogenicity of co-administration could be a possible grading table.

8. Progress on the preparation of background paper (Katie Lafond)

The purpose of this document is to summarize the available data in support position paper and recommendations. Its structure is based on the conceptual matrix, with an introduction including context and previous recommendations, influenza epidemiology, types of vaccines and overall vaccine safety, as well as a final section with cross-cutting issues and recommendations. To date, the bulk of the document has been drafted, with the exception of the cross-cutting issues, and the latest version of the recommendations and any grading that will be included. The working group reviewed and modified the key points, knowledge gaps, and special considerations for each target group.

- Additional suggestions for the background document included:
  - Need to concentrate on the key studies that provide firm evidence base, rather than listing all studies; one way to draw attention to key studies is through tables.
  - Order of the target populations: currently taken from matrix – what is best order?
  - "Children" currently includes up to 18 years. Need to redirect this section to either exclude older ages or refocus emphasis on children under 5 years. Also needed is a section on the need for two doses in the general part of the text.
  - Additional text in the elderly section is needed to account for non-respiratory disease attributable to influenza, as well as co-infection as a special issue for elderly.
  - "Risk groups": refers to underlying medical conditions, so will need a table listing what conditions are considered part of this group, listed alphabetically/not prioritized (Tony). To recommend risk groups, we need to reference the evidence base for increased severity in these populations, and also acknowledge the range of risk within each group. Focus should be on those risk groups that are also logical operational targets.
  - Healthcare workers: data are limited on indirect effects of vaccinating this population, although staff absenteeism also has an impact on patient health outcomes. However, they are operationally easy to access, as a group. Differentiating HCW in long-term vs. acute care setting may not have any policy or program implications. Will mention this in the document.
  - Cost-effectiveness and safety sections are currently listed as part of the general text. Will keep it that way, but add special safety considerations as applicable to individual target groups.
  - Cross-cutting issues should include section on surveillance/vaccine monitoring, may not need policy/communication sections.
  - Need for a glossary of terms (defining terms including LAIV, TIV/QIV, Adjuvanted vaccine, "young children", efficacy/effectiveness).
  - Additional text to address vaccine performance over time in same individual sequentially/by age group, to have some data on revaccination and duration of vaccine protection. (Yearly immunization remains recommended, based on last discussions.)
- **Next steps**: Katie will circulate a next version, reflecting modified key points discussed today. John Tam will extract references for the grading tables. All members of the working group should send feedback on all sections, but with specific point people assigned to focus on each of the sections:
  - Healthcare workers: Jon Abramson
  - Pregnancy: Jan Englund
  - Elderly: Randeep Guleria

- Children: Joe Bresee
- High-risk groups: Tony Mounts/Barry Schoub (HIV)
- Operational Issues: Liz Miller/Michael Pfleiderer
- Document review: JHU (collaborating center)

9. Discussion/draft recommendations for SAGE April meeting

Draft text of the recommendations was presented to the WG for revision. This included introductory text to acknowledge the historical context of the recommendations and the realignment of focus to LMIC-based burden, and to clarify that existing programs are not "wrong." The current list raises pregnant women to first on the list, and the rest are not listed in order of priority.

Specific questions to SAGE were identified for several of the target groups:

- Children: should there be a preference for LAIV?
- HCW: should mandatory vaccination be recommended or mentioned?

Global criteria for prioritization were listed as: disease severity, vaccine performance, accessibility, and evidence of indirect/secondary protection, and these were scored for each target group.

Country-level considerations for determining target group prioritization:

- Contribution of risk group to the overall influenza disease burden in population, e.g., population demographics, prevalence of HIV infection in adults
- Disease severity within individual risk group
- Direct and indirect vaccine effectiveness
- Feasibility of delivery
- Cost-effectiveness and opportunity cost

The statements identified for grading were as follows:

- Vaccine efficacy in protecting pregnant woman against disease (could be combined with healthy adults)
- Efficacy of vaccinating pregnant women in protecting neonates <6 months
- Vaccine safety in pregnant women
- Efficacy of TIV in <2 year and 2-5 year age groups
- Overall and relative efficacy of LAIV (vs. TIV) in 2-5 year age group
- Indirect protection in healthcare/long-term care settings (VE in HCW could also cross-reference to a grading table for healthy adults)
- Vaccine efficacy in elderly

Next step for the recommendations: Art Reingold will continue work on the wording of the slides.

Appendix 1 Agenda

WORLD HEALTH ORGANIZATION

4th MEETING OF THE SAGE WORKING GROUP ON INFLUENZA VACCINES AND IMMUNIZATION

14 to15 February 2012
WHO Geneva - HQ

PROPOSED DRAFT AGENDA

Day 1, Tuesday 14 February 2012, Room M105

Chair: Liz Miller
Rapporteur: Kathryn Lafond

13:30 - 13:50	Welcome and objectives of meeting	*Joachim Hombach* *Chair*
13:50 - 14:00	Minutes of the 3rd meeting and action points	*John Tam*
	Seasonal Influenza Vaccine for Infants Less Than 2 years old infants	
14:00 - 14:20	Seasonal influenza disease burden: recap and additional information	*Tony Mounts*
14:20 - 14:50	Influenza vaccines for children less than 2 years of age: immunogenicity considerations	*Janet Englund*
14:50 - 15:10	Vaccine efficacy, effectiveness and cost-effectiveness: recap and additional information	*Joseph Bresee*
15:10 - 15:30	Influenza vaccine safety in children < 2 years old	*David Wood*
15:30 - 16:00	***Refreshment Break***	
16:00 - 16:30	Comparative vaccine efficacy and effectiveness: TIV vs. adjuvanted vaccines vs. LAIV	*Martin Friede*
16:30 - 17:00	Experience from (H1N1)pdm vaccines	*Michael Pfleiderer*
17:00 - 17:30	Discussion on recommendations for seasonal vaccine for < 2 years old	
17:30 - 19:30	***Cocktail***	

Day 2, Wednesday, 15 February 2011, Room M-105

	Seasonal Influenza Vaccine for Infants Less Than 2 years old infants (cont.)	
09:30 - 10:30	Discussion topics: - Vaccine delivery - EPI? or other programs? - Knowledge gaps - research issues	*Led: Chair*
10:30 - 11:00	***Refreshment Break***	
11:00 - 11:30	Progress on the preparation of background paper	*Kathryn Lafond*
11:00 - 12:30	Discussion on the background paper	*Led: Chair*
12:30 - 13:30	***Lunch Break***	
	Other businesses, action items and next steps	
13:30 - 15:00	Other necessary discussions for the background paper - Prioritization (target groups, vaccine types etc.) - coverage goals (specific risk groups) - definition of risk groups - (Tony Mount)	*Led: Chair*
15:00 - 15:30	***Refreshment Break***	
15:30 - 16:30	Preparation for report to SAGE April meeting	*Led: Chair*
16:30 - 17:00	Summary of action points and next steps	*Chair*

Appendix 2 List of participants

World Health Organization

4th MEETING OF THE SAGE WORKING GROUP ON INFLUENZA VACCINES AND IMMUNIZATION

14-15 February 2012

WHO Geneva - HQ - room M-105

LIST OF PARTICIPANTS

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