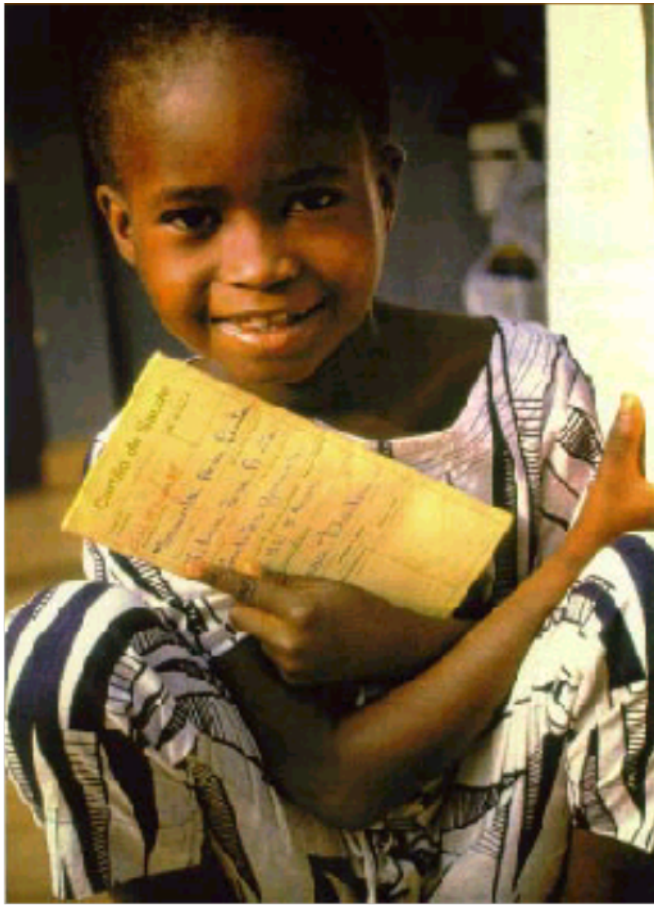
Why are we reviewing the evidence on Hib vaccine & what are the questions for SAGE today?



J Abramson

SAGE Member

WHY A REVIEW OF IMMUNIZATION SCHEDULES?

WHY are we working on this?

"SAGE recognized the importance and timeliness of reviewing the scientific and operational basis for the choice of the optimal schedule for childhood immunization. More than 20 years have passed since the "EPI schedule" of 6, 10 and 14 weeks for DTP-OPV and 9 months for measles vaccine was introduced, and more information has accrued, together with the development of improved techniques for assessing immune responses. There was recognition that immunization schedules in use today vary greatly around the world, and it is unlikely that a single, uniform immunization schedule would suit all countries. ***WHO should aim to provide countries*** *with advice on the parameters to be considered when they select a schedule*. There was ***unanimous support for a new review of the evidence*** *base*, and agreement that changes in schedule are not appropriate without strong evidence to demonstrate benefit. *It has also been stressed that it is* ***difficult to design ONE schedule for ALL*** *countries* as there are differences in epidemiology, health infrastructure and resources. In developed countries these discussions take place at national level based on local data however, low resource countries often rely on decisions made by others".

WER, January 2006

SAGE discussions relevant to immunization schedules

Date	Topic	Main recommendation
Nov 2005	Optimizing immunization schedules	Review of the primary schedule, boosters and adolescent vaccination should be undertaken.
April 2006	Update on optimization of immunization schedules and discussions on tetanus immunization	A 5-dose childhood immunization schedule of TT containing vaccine SAGE subgroup to work on the use of innovative strategies to maximize the benefits of conjugate vaccines
April 2008	Immunization schedules	Development and dissemination of a consolidated table of current recommendations
Oct 2009	Immunization schedules	Process of reviewing schedule should incorporate the best context-specific data on disease, impact assessment, Cost Effectiveness Analysis, experts judgment and applicability to local health systems
Nov 2010	Immunization schedules	SAGE requested a critical appraisal of alternative schedules for pneumococcal conjugate vaccine, rotavirus vaccine and Hib vaccine in 2011.
Nov 2011	Optimizing PCV schedules	Both the 3p+0 and 2p+1 schedules are acceptable for use in different scenarios.
April 2012	Rotavirus immunization schedules	Vaccination at 6 weeks or soon thereafter. Removal of age restrictions for when the first and last dose of RV vaccine can be given.
Nov 2012	Hib immunization schedules	a revised summary of the evidence, including a critical appraisal of the evidence with GRADE tables

SAGE November 2010

http://www.who.int/wer/2011/wer8601_02.pdf

SAGE recognized that:

- optimizing schedules for new vaccines **could reduce cost and streamline their integration** with other vaccines,

- several countries are introducing vaccines **using schedules that differ from WHO recommendations.**

- the proposed **approach should inform** schedule optimization.

SAGE November 2010

http://www.who.int/wer/2011/wer8601_02.pdf

SAGE also recommended that:

- the project should be completed **promptly**
- **information-sharing** is critical and that a web site could facilitate this
- WHO should provide **support to country-level policy-makers** on the use of analyses generated in this project
- a critical appraisal of alternative schedules for **pneumococcal conjugate vaccine, rotavirus vaccine and Hib vaccine in 2011**.

Optimizing Immunization Schedules

WHAT evidence should be considered?

DISEASE
Epidemiology and clinical characteristics

ECONOMICS & AFFORDABILITY
Costs, cost effectiveness
Opportunity costs

VACCINE
Effectiveness & Safety
Availability
Regulatory issues

OPERATIONAL & HELTH SYSTEMS
Cold chain & logistics
Health systems opportunities
Acceptability
Challenges for implementation

Progress to date

Vaccine	Epidemiology	Systematic review	Operational considerations	ICEA
PCV	U of Melbourne/ LSHTM	Dosing Landscape: GAVI	LSHTM	LSHTM/PROVAC
Rota	LSHTM	Vaccine Reviews Risk benefit CDC / PATH	LSHTM	LSHTM/CDC/ PROVAC
Hib	CDC/LSHTM	U of Berne / J Watt/LSHTM	LSHTM	LSHTM
Hep B	WHO consultant/ IARC	Enhanced reviews	WHO/IVB	**Planned** LSHTM/WHO-IVB
DTP	**Planned**	Haute Ecole de Sante Publique, France	WHO/IVB	**Planned**

* Systematic reviews include data from both RCTs and observational studies

Univ of Bern; LSHTM: London School of Hygiene & Tropical Medicine
CDC: Centers for Disease Control & Prevention, USA;

Maximize the impact of the Hib immunization programme in reducing morbidity and mortality due to Hib disease

Today's Questions

What are the optimal schedules for Hib vaccines for children living in different epidemiological settings?

1. **How many primary doses, and is there a need for a booster?**
   - Interval between doses?
   - Duration of protection?

2. **Does the type of vaccine influence the choice of schedule?**
   - Effect of type of Hib vaccine conjugate on effectiveness
   - Effect of wP and aP on Hib vaccine effectiveness
   - Effect of vaccine presentation (monovalent or combined)