WHO Recommendations for Routine Immunization:

A User's Guide to the Summary Tables

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Preface

In order to assist programme managers develop optimal immunization schedules, in 2008 WHO compiled key information on its current routine immunization recommendations into three summary tables. These tables are updated periodically to incorporate new recommendations. The most recent version of the tables can be found at: http://www.who.int/immunization/ policy/immunization_tables/en/index.html.

By consolidating its many recommendations into three tables, WHO hopes to provide easy access to its policy advice. Such a tool was needed for many reasons, primarily the increasing complexity of immunization schedules and the perceived need to support national immunization programmes to critically examine, and possibly modify, their schedules.

This short guide has been developed as a companion piece to help orientate users of the summary tables of WHO's recommendations for routine immunization.

Because the review and revision of national vaccination schedules is likely to occur within the context of introducing new vaccines, readers are also encouraged to consult the 2005 WHO publication, *Vaccine Introduction Guidelines*. *Adding a vaccine to a national immunization programme: decision and implementation*. It is available at: http://whqlibdoc.whoint/hq/2005/WHO_IVB_05.18.pdf¹

What are the purposes of this guide?

- To raise awareness that the full spectrum of WHO recommendations for routine immunization are available in three summary tables.
- To explain how the summary tables can be used at country level to review and possibly modify a national immunization schedule so that it has greater impact and efficiency.
- To highlight practical and operational issues that country decision-makers should consider when making a change to the national immunization schedule.

Who should use this guide?

- National immunization officials and key policy-makers, chairs and members of national advisory commitees on immunization, and partner organizations, including industry.
- Regional and country-level WHO and UNICEF immunization advisers.

When do you need this guide?

- When reviewing and considering the revision of a national immunization schedule.
- When orienting regional technical advisory groups and national immunization managers to WHO recommendations for routine immunization.

How can you use this guide to inform decision making?

- To learn if the current WHO recommendations for routine immunization are being fully implemented in your country or not.
- To identify disparities between the WHO recommendations and national immunization schedules.
- To stimulate and contribute to critical thinking and careful decision-making on issues related to revising national immunization schedules.

¹ This document is currently being updated and will be available before the end of 2012.

I. Background and Purpose of the Summary Tables of WHO Recommendations for Routine Immunization

The first immunization schedule ever published by WHO was in 1961 as part of a report of the technical discussions that took place at the 13th Wolrd Health Assembly (Figure 1). It is interesting to look back and see that in those early days due consideration was given to vaccinating those beyond the first year of life.

It was not until 1977, after the Expanded Programme on Immunization (EPI) was launched, that WHO published the more "traditional" EPI schedule focusing on children under 1 year of age only (Figure 2). Over the years this schedule evolved: smallpox vaccination was no longer needed, and by 1984 the EPI schedule consisted of the six standard antigens: BCG, DTP, OPV, and measles. In 1995, an EPI policy paper published an updated schedule that added yellow fever vaccination for selected countries at risk, and hepatitis B vaccine for all.

Since 1995, the pace of change has accelerated and WHO has published over 20 position papers with its vaccination recommendations.

To help, WHO has consolidated and electronically published its routine immunization recommendations in three summary tables. Table 1 summarizes the vaccines that are recommended across all age groups (children, adolescents, and adults), while Table 2 focuses in more depth on vaccination of children. Table 3 provides the recommendations for interrupted or delayed vaccination.

These tables were developed in response to the increasing complexity of immunization schedules and the need to support national immunization officials to critically examine, and possibly modify, their schedules. By consolidating the multiple recommendations into three tables, WHO hoped to provide:

- a convenient format to access all of WHO's current recommendations on routine immunization;
- a tool to help policy-makers communicate the need to consider adding vaccines and the corresponding age groups; and
- a flexible framework for countries to use in developing their own schedules according to their programmatic, epidemiologic and policy considerations.

The target audience for the consolidated recommendations are national immunization officials and key decision-makers, chairs and members of national advisory committees on immunization, and partner organizations, including industry. The tables are intended primarily to aid decisions at the national level that will benefit immunization programme impact and efficiency. They are not intended for distribution to or direct use by vaccinators. The recommendations summarized in the tables focus on *routine service delivery* and therefore, do not include non-routine immunization for outbreak response, supplementary immunization activities, post-exposure prophylaxis, and travel.²

The summary tables can serve as a driving force and reference tool to help review and improve schedules in keeping with the Global Immunization Vision and Strategy (GIVS), which promotes immunizing more persons across wider age groups. Many countries are appropriately adding new vaccines, but their schedules may lag behind in providing the adequate number of doses or booster doses for traditional vaccines and give little consideration to older age groups.

² WHO's vaccine recommendations for travels are published in Chapter 6 of International Travel and Health 2012 (WHO) (www.who.intith/en/)

Figure 1:

1961 - 1st Schedule Published by WHO

(Report of the technical discussion at the Thirteenth WHA)

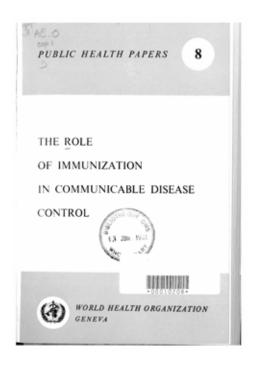


TABLE 2. SUGGESTED SCHEDULE OF IMMUNIZATION IN AREAS WITH INADEQUATE MEDICAL SERVICES; TO BE MODIFIED AS REQUIRED TO SUIT LOCAL CONDITIONS

| Age | Vaccination | Visit |
|---------------------------------------|--|----------------------|
| 0-4 weeks | (1) BCG vaccination | Ist |
| 3-9 months | (2) Smallpox vaccination (3) Diphtheria-pertussis-tetanus (triple vaccine with alum): 2 doses at an interval of one month The first injection could be given at the time of smallpox vaccination. Smallpox vaccination is verified at the second visit. Failures of smallpox vaccination are revaccinated. | 3rd |
| School entry or soon thereafter | Diphtheria/tetanus booster (plain or with alum TAB vaccination (where necessary): 2 doses a an interval of one month Smallpox revaccination: at the time of second TAB injection | t 4th |
| 10-14 years | BCG revaccination (in tuberculin-negative reactor Smallpox revaccination TAB booster | s) 6th and 7th |

Figure 2:

Expanded Programme on Immunization 1977 - EPI Fiel Manual

| Age in months | Scar | Vaccinations given at one time |
|---------------|------------------|--|
| 3 ~ 5 | None | lst DPT, 1st Polio, BCG |
| 6 - 8 | With BCG scar | 2nd DPT, 2nd Polio |
| 6 - 8 | Without BCG scar | lst DPT, 1st Polio, BCG |
| 9 -11 | With BCG scar | 2nd or 3rd DPT, 2nd or 3rd Polio, Measles, Smallpox |
| 9 -11 | Without BCG scar | lst DPT, lst Polio, Measles, Smallpox |

II. How to Read the Summary Tables

The summary tables contain a lot of information that may seem overwhelming at first glance. However, the tables follow a logical format and with a little practice one can soon become familiar with the systematic way in which the recommendations for every antigen are presented.

Before proceeding to read this section, it is suggested that you print a hard copy of each of the tables from the WHO web site (http://www.who.int/immunization/policy/immunization_tables/en/index.html).

Table 1: Recommended Routine Immunization - Summary of WHO Position Papers

Table 1 summarizes all of the routine vaccinations recommended by WHO for all age groups. The first column lists the antigens. Moving down the column, different shades of grey differentiate the scope or type of the recommendation. There are four types of recommendations:

- (i) recommended for all (universal or worldwide);
- (ii) recommended in the particular geographical areas where the disease is present;
- (iii) recommended for some high-risk populations; and
- (iv) recommended for immunization programmes with certain characteristics (e.g. a minimum coverage level).

Each individual antigen has a footnote that provides a reference to the relevant WHO Position Paper and brief bullet points with crucial, detailed information about the specific recommendation.

The middle three columns of the table contain recommendations by age group across the life cycle, as follows — children, adolescents, and adults. The final, far-right column, labelled "Considerations," draws attention to specific vaccine issues that are further elaborated in the footnotes.

For each age category the recommendations themselves are contained in the cells that include the following information:

- The number of recommended doses for the primary series;
- The target population if recommended only for a particular sub-group (e.g. girls, pregnant women);
- The number and timing of booster doses, if required.

For example, for DTP, a three-dose primary DTP series is recommended, with a booster for children at 1-6 years of age and a Td booster for adolescents (completing the 5 doses of tetanus toxoid recommended in childhood); and again a booster of Td in early adulthood or pregnancy (to assure long-lasting, possibly life-long protection against tetanus).

Some diseases, such as Japanese encephalitis (JE), have several types of vaccine available. The information on the different types is included in separate cells, as long as WHO recommends the use of that particular type of vaccine; in the case of JE, this includes both the live-attenuated and the mouse brain-derived vaccine (both of which WHO recommends). WHO does not recommend the use of a third type, cell-cultured-based inactivated JE vaccine, so this is not included in the summary table but is explained in the footnotes.

A note at the bottom of Table 1 provides the web address to obtain the most recent version of the table and position papers. There is also a reminder stating that this table is for use in developing a schedule and is not designed to be directly used by health care workers who administer vaccinations.

Table 2: Recommended Routine Immunizations for Children: Summary of WHO Position Papers

Table 2 is similar to Table 1 but focuses on routine immunization recommendations for children only. It provides more detailed information on the recommended timing of childhood vaccinations including:

- The optimal age of first dose (including minimum and maximum ages);
- The number of doses in the primary series;
- · The minimum and maximum intervals between doses;
- · The timing and number of booster doses, if required.

As in Table 1, the antigens are listed in the left-hand column of Table 2 and grouped according to the four types of recommendations (i.e. recommended for all children; recommended for children residing in certain regions; recommended for children in high-risk populations; and recommended for children receiving vaccination

Table 1:from immunization programmes with certain characteristics). Each antigen has a footnote that provides the reference for the relevant WHO Position Paper and a summary of important information on the specific recommendation.

The second column shows the recommended age for the 1st dose, with minimum and maximum ages, if applicable. The next column shows the number of doses in the primary series, and the next three columns display the recommended intervals between 1st and 2nd, 2nd and 3rd, and 3rd and 4th doses, with applicable minimums. The next column gives booster-dose schedules. If the booster schedule is unclear and currently under investigation, the user is referred to a footnote for information on the possible options.

As in Table 1, the final column of Table 2, entitled "Considerations," flags important issues such as choosing between types of vaccine, the number of doses required for children over 1 year of age, definitions of high-risk populations, and combination-vaccine issues (e.g. DTP and MMR).

At the bottom of Table 2 is the web address for the latest version of the table and WHO position papers, along with a reminder that the table is not intended for direct use by those giving vaccinations.

Table 3: Recommendations for Interrupted or Delayed Routine Immunization – Summary of WHO Position Papers Inevitably, children and individuals come late for their vaccinations or for whatever reason, are unable to adhere to the usual schedule. These irregular situations can be challenging for health workers who may not know what to do. If a child starts a vaccination series late, how many doses should be given? If a vaccination series is interrupted, does it need to be restarted or can it simply be resumed without repeating the last dose?

To help countries develop clear policy guidance, Table 3 summarizes WHO's recommendations for interrupted or delayed vaccination. For some of the antigens, the advice provided in Table 3 is based on expert opinion because the corresponding WHO Position Paper does not yet address these situations. When the Position Paper is next revised this guidance will be included.

In the same order as Tables 1 and 2, the antigens are listed in the first column of Table 3 and grouped according to the type of recommendation. For easy reference, the recommended age of first dose is provided in the second column, and the number of doses in the primary series with the minimum interval between doses (indicated in brackets) in the third column.

Column 4 "Interrupted Primary Series" provides the guidance on what to do when the series of vaccine doses to a child or individual has been started but is then interrupted. In most cases the instruction is to resume vaccination without repeating the previous dose. However, for a few antigens the series may need to be restarted depending on the length of the interruption.

Columns 5 and 6 contain guidance on what to do when the start of vaccination is delayed. For some antigens the number of doses and intervals differ by age -- under 12 months of age (Column 5) or older than 1 year (Column 6). Finally, column 7 summarizes the booster recommendations. The web address for the latest version and detailed footnotes for each antigen are provided at the bottom of Table 3.

Recommended: number and timing of doses

Target population

elaborated in footnotes Specific issues further

Table 1: Recommended Routine Immunization - Summary of WHO Position Papers

| | Antigen | | Children (see Table 2 for details) | Adolescents | Adults | Considerations (see footnotes for details) |
|---|--|------------------------------|---|--|---|---|
| | Recommendations for all | 1 | | | | |
| | Be61 | | 1 dose | | | Exceptions HIV |
| | Hepatitis B² | ees) | 3-4 doses (see footnote for schedule options) | 3 dose (for high-risk groups (see fo | 3 dose (for high-risk groups if not previously immunized) (see foamote) | Birth dose Premature and low birth weight Co-administration and combination vaccine Definition high-risk |
| _ | Polio ³ | | 3 doses, with DTP | | | OPV birth dose Transmission and importation risk criteria Type of vaccine |
| _ | DTP⁴ | 3 dose | Booster (DTP) 1-6 years of age | Booster (Td) (see footneote) | Booster (Td) in early adulthoos or pregnancy | Delayed/interrupted schedule Combination vaccine |
| | Haemophilus influenzae type b [§] | | 3 doses, with DTP | | | Single dose if 12-24 months of age Delayed/interrupted schedule Co-administration and combination vaccine |
| | Pneumococcal (Conjugate) ⁶ | | 3 doses, with DTP | | | Single dose if >12 months of age Delayed/interrupted Co-administration |
| | Rotavirus 7 | Rotas 4 | Rotas Feg vaccine: 3 doses with DTP | | | Maximum age limits for starting/completing vaccination; Rotarix with DTP1 and DTP2. |
| _ | Measles ⁸ | | 2 doses | | | Combination vaccine; HIV early vaccination |
| | #AdH | | | 3 doses (girls) | | Vaccination of males for prevention of cervical cancer is not recommended at this time |
| _ | Recommendations for certain regions | rtain regions | | | | |
| | Japanese Encephalitis ¹⁰ | Live a Mouse I Booster | Live attenuated vaccines: 1 dose Booster after 1 year Mouse brain-derived vaccine: 2 doses Booster after 1 year, then every 3 years | Mouse brain-derived vaccine: booster every 3 years of age | | Vaccine options |
| _ | Yellow Fever 11 | | 1 dose, with measles | | | Co-administration |
| _ | Recommendations for some high-risk populations | me high-risk po | opulations) | | | |
| | Typhoid*2 | | VI polysacch | // polysaccharide vaccine: 1 dose; Ty21a live oral vaccine: 3-4 doses Booster dose 3-7 years after primary series | 3: 3-4 doses | Definition of high-risk Vaccine options |
| | Cholera ¹³ | Duk | oral (WC-rBS): 3 doses ≥ 2-5 yrs, t Shanchol & | Dukoral (WC-rBS): 3 doses ≥ 2-5 yrs, booster every 6 months; 2 doses adults/children > 6 yrs, booster dose every 2"⁴ year Shanchol & mORCVAX: 2 doses ≥ 1 yrs, booster dose after 2 years | ren > 6 yrs, booster dose every 2 nd year fter 2 years | Minimum age Definition of high-risk |
| | Meningococcal 14 (polysaccharide) | | | 1 dose | | Definition of high-risk Conjugale vaccine |
| | Hepatits A ¹⁵ | | | 2 doses | | Definition of high-risk |
| | Rables 16 | | | 3 doses | | Definition of high-risk & booster |
| | Recommendations for imp | munization pro | Recommendations for immunization programmes with certain charateristics | | | |
| | Mumps 7 | | 2 doses, with measles | | | Coverage criteria > 80% Combination vaccine |
| | Rubella ¹⁸ | | 1 dose (see footnote) | 1 dose (alternative strategy adolesos | 1 dose (alternative strategy adolescent girls & child bearing age woman) (see footnote) | Coverage criteria > 80% Combination vaccine |
| / | Influenza ¹⁹ (Inactivated) | First vac | First vaccine use: 2 doses. Revaccinate annually: 1 dose only (see footnote) | 1 dose from 9 year of ac | 1 dose from 9 year of age. Revaccinate annually (see footnote) | Priority tragets Definition of high-risk Lower dosage for children |

recommendation

Type of

for latest version web site of table

Refer to http://www.wha.int/immunization/documents/positionpapers/ for modit recent version of this table and position papers.

Refer to http://www.wha.int/immunization/documents/positionpapers/ for modit recent version of this table surmentation is the selegated to asset the development of country specific schedules should be based on local epidemiologic, programment resource and policy considerations. While are unversally recommended some of hidden may have contrandications to particular vecicies.

III. Let Everyone Know: Raising awareness of the WHO recommendations for routine immunization summary tables

By consolidating its many immunization recommendations into three tables, WHO hopes to provide easy access to its policy advice. However, the summary tables will only help those who know that they exist and where to find them. As the tables are a "living document" that will be revised and updated periodically, they must be disseminated on a regular basis to those who should use them.

It is important to note that the WHO immunization recommendations are not new, but are rather a compilation of existing WHO recommendations in a new table format. All the recommendations come from WHO Position Papers that are published in the Weekly Epidemiological Record (WER).

The intended target audience for the summary tables spans a wide range of users from national immunization programme managers and key decision makers, chairs of national and regional immunization advisory committees, partner organizations, including donors and industry.

Although not an exhaustive list, below are some of the ways that WHO would like to see the summary tables used and disseminated.

1. EPI Managers' Meetings: Each year EPI managers should be reminded (or informed, if they are new) about the summary tables, this guide, and any new WHO policy recommendations that have been issued since the last meeting. Ideally, this topic should be a "standing" agenda item of every EPI managers' meeting, and a printed hard copy of the tables and this guide should be placed in the folders (or CD-ROM) of participants (making sure to emphasize that these are updated periodically, so the latest version should always be downloaded from the WHO web site).

Time should be provided to review the tables and the basic content of this orientation guide. WHO is planning to provide a PowerPoint presentation to regional staff to assist with the introduction of the tables, and country managers can bring back copies to use in orienting in-country colleagues.

For those interested, a working group exercise in which EPI

managers compare the WHO summary tables with their own current national schedules and discuss the reasons for differences can be organized. Feedback reports from the working groups could highlight the opportunities for adopting the WHO recommendations that are missing from their national programmes, as well as constraints.

EPI managers should be encouraged to share the summary tables of WHO's recommendations with their National Advisory Committees and Inter-Agency Coordinating Committee's (ICC's).

- 2. Regional Advisory and Technical Committees: To promote coordination and feedback between global and regional policy processes, regional offices should brief all of their regional advisory and technical groups on the content and purpose of the consolidated summary tables. The tables can serve as a quick and comprehensive reference resource at meetings where new regional immunization policy is being considered.
- 3. Global Meetings: Large events with participants from all regions of the world, such as the Global Immunization Meeting (GIM) or the GAVI Partners' Meeting are excellent occasions to increase the awareness that WHO's routine immunizaton recommendations are now available in an easy-to-use summary table format. All levels of staff (country, regional, or headquarters) of all the agencies involved with strengthening immunization programmes (i.e. UNICEF, WHO, NGO's and other partners) should be knowledgeable about the tables and where to find the latest version.
- 4. Donors and Resource Mobilization Efforts: In discussions with donors it is always useful to explain the broader context of any proposal or activity for which you are seeking funding support. Sharing the summary tables with donors enables them to see the full breadth of vaccination that needs to be financed. This helps respond to the misconception of some that EPI is a "vertical" programme. It also can be used to point out where there are "gaps" in funding support; for example, one donor may be willing to fund the primary series of DTP vaccination without understanding that

later booster doses are necessary, and in fact recommended by WHO, to protect children over the long term.

5. Other Health Programmes: The general success and high coverage that EPI has been able to achieve is the envy of many other programmes. Not surprisingly, there is great interest in using immunization contacts to deliver other health interventions. The summary tables should be shared with other health programmes (such as malaria, HIV/AIDs, nutrition, adolescent health, etc.) to improve their knowledge of the full spectrum of recommended vaccinations.

With better understanding of the target groups and timing of vaccination, opportunities to integrate services can be proposed and explored. This may result in the rationalization of services and resource savings (for example, if it is discovered that EPI and another programme are independently reaching the same target group at the same time). Or in another scenario, EPI may benefit by gaining a new contact if another programme is planning to schedule the delivery of its intervention at a time when a vaccination is not currently scheduled but would improve the impact of the programme if it was. For example, a nutrition programme may plan to give vitamin A supplementation or a deworming treatment at 18 months of age. For certain immunization programmes this could be an ideal contact to introduce a 2nd routine dose of measles vaccine.

6. Duty Travel and Field Visits: Because of the fast pace of change and increasing number of antigens available, it is difficult to remember in detail all of the WHO recommendations. Why not make it a habit to take a copy of the latest summary tables with you on all your trips? You never know when you will be asked a question about the WHO recommendation for an antigen that is not your speciality. The summary tables provide you with all the information you need to advise confidently and correctly.

IV. A Tool For Action: Using the summary tables at country level to review the national immunization schedule

A primary purpose of the summary tables is to serve as a tool for reviewing, and possibly modifying, national immunization schedules. Undertaking a comprehensive review of a national immunization schedule does not necessarily mean that the schedule will change. National immunization schedules have been developed over long periods of time and often shaped by factors that are unique to a particular country programme. However, the periodic review of the national immunization schedule is an important process:

- To learn if the current WHO recommendations for routine immunization are being fully implemented in your country or not (Is the national schedule effective and efficient? Is the schedule achieving optimal impact?).
- To identify disparities between the WHO recommendations and the national immunization schedule (Are too few or too many doses being given? Does the schedule extend to older age groups and protect sufficiently beyond infancy?).
- To stimulate and contribute to critical thinking and careful decision-making on issues related to revising national immunization schedules (Does the schedule need to be changed, or is it good as it is? What are the opportunities and constraints to changing the schedule?).

The process to review a national immunization schedule can be quick and informal, or in-depth and official. What is important is that a regular practice of reviewing the schedule is established. How the review is carried out will depend very much on what opportunities are available each year. For example, the following are suggested:

- Once a year, the EPI Manager and Team should review the national immunization schedule during their annual workplanning process.
- Every 3-5 years, the national immunization schedule should be reviewed as part of the preparation of the comprehensive Multi-Year Plan (cMYP).
- Whenever a National EPI Review takes place, an assessment of the immunization schedule should be included.

In this way, using the summary tables as an aid ensures that national programmes stay abreast of and regularly consider global recommendations for routine immunization.

The suggestion to modify a national schedule might come from different sources, such as the national immunization programme itself, country decision-makers, international organizations, the academic community or private sector. Some typical reasons to consider changing a national vaccination schedule include:

- The planned introduction of a new vaccine(s).
- Switching to a combination vaccine either to add antigens or reduce the number of contacts/injections.
- A national EPI review has recommended changes to the national schedule.
- Discussions with other child health programme officials have led to an agreement to change the schedule in order to benefit both immunization coverage and other interventions.
- Coverage or drop-out rates are so troubling that the national immunization programme has decided to explore whether modifying the schedule can help address these problems.
- National immunization programme leadership desires to verify that the national schedule follows global recommendations, or if not, that the differences are clearly justified by the particular country circumstances.

Although each country has its own mechanisms for an informed decision-making process, it is important to ensure that all interested parties are consulted and the implications of all reasonable options are discussed. Changes in the national schedule carry numerous resource and managerial implications for every component of the immunization programme, so decisions to make a change should not be taken lightly.

Many countries already have one or more advisory committees that are mandated to provide technical and programmatic advice to the national immunization programme. Countries that do not should consider establishing such a committee. The committee members are usually selected from the scientific community, immunization partners and programme implementors. ³

The process of reviewing the national immunization schedule should provide the opportunity for the immunization policy makers and programme implementers, other key MOH officials, and technical staff from immunization partners to thoroughly review both epidemiological and practical/operational considerations.

³ For more information see: Duclos, P. "National Immunization Technical Advisory Groups (NITAGs): Guidance for their establishment and strengthening." Vaccine, Vol.28, Supplement 1, 19 April 2010, pp. A18-25.

V. Things to Consider: Practical and operational issues when changing a national immunization schedule

There are many practical and operational issues to consider when deciding if and how to modify a national immunization schedule to add antigens, expand target groups, or adjust the timing of doses. There is tremendous variation among countries in vaccine-preventable disease patterns and programme strategies, strengths, and weaknesses. Clearly not all of the issues and actions proposed here will be relevant to every country. The focus, in general, is on immunization programmes in the most challenging country situations, where the review and revision of the immunization schedule requires careful planning.

► Adding a new immunization contact to the schedule

The decision to add an additional vaccination contact has many *cost implications* for an immunization programme (vaccine, supplies, waste disposal, forms, records, job aids, educational materials, training, staff time, transportation costs for outreach...), as well as non-monetary costs to caregivers in time and effort. A change that is well planned and managed may be acceptable to both the programme and the public, but such issues need to be discussed and resolved.

TIPS

- Before proposing a new contact, national decisionmakers should gather and analyze immunization coverage data as well as cost data.
- Prepare a cost projection for a new contact(s).
- Discuss costs and benefits and how system performance can be maintained or even improved in the process of changing the schedule.
- Consider issues of acceptability to health workers and the public.

In most instances, strong immunization programmes with good access, timely vaccination and high coverage can accommodate a new immunization contact easily. However, in those countries where programmes are weak and many children receive no vaccinations (are unreached), are not vaccinated on time or are incompletely vaccinated (drop outs), adding a new contact is unlikely to be successful if not accompanied by efforts to improve access and/or communication and mobilization. While being more

challenging for these countries, adding a new immunization contact can provide opportunities to revitalize and boost immunization services overall – if the needed financial and human resources are made available.

► Adding a birth dose to the schedule

The current coverage level for BCG is a good indicator of an immunization programme's ability to reach newborns. Besides being related to institutional births and access, coverage of birth doses is also affected by the cultural practice of postpartum isolation of mothers and babies, which may lead them to stay at home for a month or longer in some places.

In countries where the percentage of institutional births is low, adding a birth dose to the immunization schedule will be difficult unless a significant percentage of home births are attended by a trained midwife or traditional birth attendant. In these cases, they may be able to administer the vaccine (e.g., hepatitis B), by syringe or compact auto-disable injection devices, such as the pre-filled Uniject®. Exploring this option is even more attractive if, at the same time, other services could also be provided such as delivering the child's health book, the mother's postpartum vitamin A dose, and basic education and motivation about the immunization schedule. Use of vaccine by village-based midwives, out of the cold chain, is likely to require revision of policies and operational guidelines, training, supervision, monitoring, etc.

TIPS

- Analyze DHS and/or Multi-Indicator Cluster Survey (MICS) data to calculate the percentage of births delivered at home.
- Assess whether and how most newborns can be systematically reached.
- Review current policies for out-of-the cold chain vaccine use, and community-based administration of vaccination.
- Investigate the availability and cost of alternative birthdose vaccine presentations (e.g. Uniject).

Reaching school-age children and adolescents as a new target group

The easiest way to reach school-age children is in school, but the effectiveness of this strategy varies by level of school enrollment. Even where school attendance is very high for both boys and girls, there are important costs to consider (transport, additional human resources, etc.). In some countries existing school health programmes have not only reached many children with tetanus immunization and various boosters, but also with deworming, trachoma and schistosomiasis treatment, iron tablets, school feeding, and other interventions. Elsewhere there may be no history of school-based health programme delivery. However, it is worth noting that although too many children, particularly in rural areas, drop out of school at young ages, in some countries it is not unusual for children to remain in primary school into their late adolescence.

TIPS

- Work with education officials to understand the school attendance patterns in the country.
- Consider strategies for reaching the enrolled, enrolled but absent students, as well as children not enrolled in school.
- Estimate the costs and human resources required for a school-based programme.
- Consider alternative and possible cheaper strategies for encouraging youth to visit exisiting health service locations
- Consult with youth to learn about their interests that might be conveniently linked with vaccination – HIV/ AIDS and family planning education, job skills, social contact, etc.

► Increasing the number of injections during the same visit

Adding a new vaccination to the schedule can increase the number of injections that a child receives during one visit. This sometimes raises concerns for health workers and caregivers alike. Health officials contemplating modifying the schedule in a way that would add vaccinations on the same visit should consider the acceptability of the change to both staff and the public.

WHO's general advice is that during any vaccination contact it is appropriate to give whatever vaccinations the child is eligible for (by age and vaccination history), as long as each injection can be safely given in a different but appropriate site on the child's body.

TIPS

- Review the recommended and acceptable injection sites for antigens proposed to be co-administered at the same contact and for multiple antigens given when children have become delayed in their vaccinations.
- Use this information to provide guidance to vaccinators about multiple vaccinations and their recommended injection sites.
- Investigate health worker practices by analyzing vaccination registers and health records. Recent population-based coverage surveys can also be used to determine if children are vaccinated on the same visit with all age-eligible vaccines (or if some are being withheld).
- If there are significant missed opportunities to give multiple antigens on the same visit, interview some health providers and caregivers to understand the reasons.

► Increased complexity of immunization schedules

With the addition of one or more new antigens, country schedules can rapidly become more complicated. A revised vaccination schedule may be more challenging for a health worker to follow, and appropriate training to support their decision-making skills should be provided.

Health workers generally have no problem following a vaccination schedule as long as children are brought in at the right time/age. But this is rarely the case, so health workers are forced to make somewhat complex decisions regarding which vaccinations should be given to a particular child. This will be based on the child's age, vaccination history, and the national policy on contraindications to vaccination, but also sometimes the fears (e.g. vaccinating a sick child) and misconceptions (e.g. restarting DTP vaccination because "too much time has passed" since the last dose 1) of the health worker are factors also.

¹ This does not harm the child but may result in unnecessary visits and vaccinations.

TIPS

- Assess whether health workers follow the immunization schedule correctly or if "incorrect" decisions are common.
- Address the underlying problems related to health workers' misunderstanding, perceptions, and fears pertaining to vaccination.
- Provide training and job aids (see Annex 1 for examples) to help health workers improve decisionmaking.
- Ensure that supportive supervision addresses existing problems and prevent new ones resulting from any modifications to the immunization schedule.

► Implications of a change in the vaccination schedule for the immunization delivery system

A change in the vaccination schedule is likely to have repercussions throughout the immunization programme. These issues are well covered in the WHO publication *Vaccine Introduction Guidelines*. The key is to anticipate, plan for, and address these issues effectively:

- Updating the immunization multi-year plan
- · Updating the current annual plan and budget
- · Vaccine formulation and presentation
- Phase or countrywide introduction
- · Procuring the vaccine and safe injection supplies
- Delivery strategy
- Cold chain readiness and vaccine management
- · Immunization safety
- Staff training and supervision
- · Advocacy, social mobilization, and communication
- Supportive supervision
- Information systems

TIPS

 Recording and reporting: Unless the immunization or child health card was designed with spaces to accommodate additional antigens, it will need to be redesigned, printed, and distributed. In addition, recording forms and registers and reporting formats will also need to be revised. If school-age and older children are a new target group, then an entire vaccination information system will need to be developed for them.

- Capacity building: At a minimum, a change in the vaccination schedule requires an orientation of all vaccination personnel, and ideally training in both the technical aspects and in effectively responding to the public's questions and concerns. This may also be an excellent opportunity to address inadequate understanding and sub-standard practices that have persisted for some time.
- Public education: If families are to participate fully in immunization activities, then they need an explanation of any change to the vaccination schedule. Technical staff and communication experts need to work together to agree on key messages. Extremely technical explanations are not necessary and may be counterproductive. What is needed is a basic explanation of the change and how it should be beneficial for families and children in general, as well as anything different that families need to do, such as come for a new vaccination contact. It is important to explain that while some new antigens (such as Hib, pneumococcal, and rotavirus) are recommended and beneficial, they protect against some but not all cases of pneumonia and diarrhoea.
- Cold chain readiness and vaccine management:
 Whenever revisions to the vaccination schedule
 are considered, national programme officials must
 anticipate the impact on the cold chain, frequency of
 re-supply, and transport required at each level. Some
 newer vaccines require much greater storage volume
 per dose and add large quantities of medical waste
 that need to be safely disposed.

If there are existing weaknesses in the immunization programme that need to be addressed, then a change in the schedule can be viewed as an appropriate opportunity to make some overdue improvements. Regardless, these actions involve significant expense and effort that needs to be carefully planned.

► Effect on session size and frequency of services

National immunization programmes normally recommend that every health facility with a refrigerator offer immunization every work day. But the reality is that in many countries, some or most facilities with refrigerators offer immunization services only one or two days per week. There are many reasons for this: not enough vaccine (or fear of shortages); not implementing the multi-dose vial policy (MDVP); or insufficient and overworked staff.

Regardless of the causes, a change to the immunization schedule, particularly one that adds new contacts and target groups, is likely to have an impact on the number of individuals seeking vaccination. Overcrowding and increased waiting times can discourage clients from attending sessions and can impact negatively on vaccination coverage levels. The adequacy of the number and frequency of vaccination sessions held must be assessed before changes to the immunization schedule are implemented.

TIPS

- Assess the efficiency and effectiveness of vaccination services in the field, including the current situation regarding daily vaccination, overcrowding, and waiting times.
- If there are problems, analyse the causes and anticipate the additional effect of making a change to the immunization schedule (will it improve or exacerbate the situation).
- Identify what corrective action is needed to resolve the problems (e.g. adding staff to some facilities, increasing the frequency of fixed or outreach sessions, etc.).

► Opportunities for other non-vaccine interventions

Whenever a revision to the immunization schedule is being considered it makes sense to explore whether there is an opportunity to integrate with the scheduled contacts for other health interventions. Combining efforts can reduce costs, and in many instances a package of services that is attractive to the public will improve demand for and coverage of services.

TIPS

- When considering a revision of the immunization schedule consult with colleagues from other programmes to determine whether there is any potential synergies in the timing of contacts for delivering services.
- Analyse the overlap of target groups; periodicity
 of interventions; logistical requirements, including
 additional staff (and tradeoffs in staff time); medicine
 and supplies; record keeping and monitoring; and cost/
 benefits. Discuss with health workers and communities
 the acceptability of providing "packages" of services.
- Explore opportunities for cost-sharing budgets.

VI. Conclusion

When contemplating making changes to a national schedule, decision-makers will need to weigh various epidemiological information with practical knowledge about the capabilities of the immunization programme and vaccinators.

The summary tables provide the latest WHO policy advice and lay out the parameters for developing optimal immunization schedules. Inherent in the WHO recommendations is a degree of flexibility and a recognition that there is not a "one size fits all" immunization schedule.

National immunization schedules are shaped by many factors, including disease epidemiology, available financial resources, and socio-political and cultural issues. Revising a national vaccination schedule requires a deliberate revisiting of programme readiness, which may well require:

- Expanding the cold chain and improving stock management and transport;
- · Expanding and improving waste management and disposal;
- Strengthening health providers' capability to administer all antigens correctly and increasing their willingness and ability to counsel mothers and provide new information on when to return for the next dose;
- Modifying the information system, including reporting of Adverse Events Following Immunization (AEFI) and diseases surveillance;
- · Providing new information to the public and media;
- Making inquiries and agreements to build confidence that the global vaccine market is healthy, that global supply is assured, and that the vaccine is affordable and easily incorporated.