IMMUNIZATION CHECKLIST

Why is this important?
Immunization is one of the most cost-effective of all health interventions. It prevents debilitating illness and disability, and saves millions of lives every year. More than 8.7 million children’s lives can be saved in the next 10 years if currently available and reasonably anticipated new vaccines are safely and effectively delivered to all children in need.

The challenge lies in getting high quality vaccines to the right child at the right time. With the addition of new vaccines, delivery schedules have become increasingly complex and many countries face severe challenges in delivering vaccines safely and effectively to all of their target populations. These challenges equate to 19.3 million infants who are not fully immunized (in 2010) and 1.5 million deaths from vaccine-preventable diseases in children.

There is evidence that the quality and specifically the safety of vaccine delivery can have profound negative implications for vaccination programmes much beyond those who are tragically affected by a programmatic error that may occur during a vaccination session.

Illustrative example 1:
The deaths of four children following measles vaccination due to reconstitution error recently in the state of Tamil Nadu, India illustrate the far reaching ramifications of unsafe and poor quality care delivered during vaccination sessions. These deaths were unrelated to the quality the vaccine, but were caused by provider and system error in re-constituting the vaccines, which led to the recall of several million doses of measles vaccine and the State EPI programme interrupted for several months.

In this example, there was a missed opportunity to provide the health worker or vaccinator with a reminder on the proper reconstitution of the vaccine with the correct diluent. Such a reminder during the set-up of the immunization session could well have saved lives and avoided serious negative repercussions on the entire immunization system.

Illustrative example 2:
A study of vaccine potency and efficacy in Nigeria found only 1 of 14 vials used for measles vaccination had a minimum virus titer as recommended by WHO, potentially leading to inadequate seroconversion and subsequent vaccine failure. This usually has to do with cold chain management at lower levels.1

This example shows how vaccine effectiveness is severely impacted by poor handling of vaccines by health workers. A checklist stressing proper vaccine handling and cold chain utilization could ensure the vaccine leads to desired outcomes for the clients.

The solution
Building on the success of previous checklist programme solutions in health care, this task force believes that an immunization checklist targeted at the health worker and combined with an m-Health application for the caregiver or vaccinee could improve the quality and safety of vaccine delivery worldwide. The use of this tool will not only contribute to improving the quality and safety of vaccination services, but has the potential to increase vaccine schedule.
completion, vaccine effectiveness, and decrease unsafe injection practices which threaten health care workers and patients. These improvements combined could thus reduce threats to vaccination programmes from adverse events following immunization (AEFI) and lead to improved consumer confidence in the health care system.

**What already exists: Strengths and Limitations**
An array of materials exist to improve the delivery of vaccinations and mostly targeting health workers. There are several tools at the global level, which have been adapted by countries, such as vaccination handbooks for health care workers, sets of FAQs, pocket-guides, and posters. These materials are critically important and used during the training of health care workers, and as compendia for front-line health care workers. No comprehensive tool exists, however, that outlines the most critical and most likely to be overlooked tasks that must be performed to safely administer a vaccine.

**How an Immunization Checklist might Work:**
A vaccination checklist would be embedded in a programme of quality and patient safety for both the health worker and the client. At the programme's core would be the vaccination checklist, but the checklist programme would include m-Health SMS reminders for the child's caregiver or vaccinee and a checklist implementation programme for the health worker. The m-Health component of the system could also provide information on vaccines given, alerts on adverse events and linkages to the health facility or community health worker if adverse events should occur. Use of a checklist in the vaccination sessions may be combined with SMS reminders on when subsequent vaccinations would need to be given and to provide additional broader disease prevention messages based on electronic databases which would link local immunization registries with country vaccination schedules.

Poor experience with health care services can influence clients to stay away from health service points, resulting in missed opportunities for vaccination. Health care workers have been described as patronizing, or openly criticizing clients in public settings thus creating adverse attitudes towards the health care system. The immunization checklist with proposed accompanying m-Health tools could be used as a mechanism to markedly improve the client–provider interactions, and to obtain client feedback on service quality, with the aim to (re)establishing community confidence in the health care system.

**Pause points**
The checklist would be designed for use during three phases of an immunization session:
- Setting up the immunization session
- Conducting the immunization session
- Concluding and following up on the immunization session

**Checklist items and design**
The checklist could be envisaged as a concise one-page laminated sheet to be staged prominently in the vaccination room or else be provided as a paper checklist to be ticked off prior, during and after an immunization session. Local adaptation and pilot testing of the draft checklist programme in countries will ensure the best use of the checklist for specific settings.

**Development and Evaluation:**
To begin drafting a vaccination checklist, A WHO working group was established in January 2012. A set of 32 possible items for a comprehensive checklist was prepared on the basis the WHO policy document *Immunization in Practice:* ([http://www.who.int/vaccines-documents/DoxTrng/h4iip.htm](http://www.who.int/vaccines-documents/DoxTrng/h4iip.htm)). EPI managers from 29 African countries were then asked to report on the most common and most critical errors committed during an immunization session. The initial expanded checklist was then revised with this addition preliminary qualitative data to presently 18 remaining items. This is only the first step, however, in
developing a robust checklist programme. A systematic literature review looking at the most common medical errors in vaccine delivery would be the next step as discussed below. This would be followed by consultation with stakeholders and experts from around the world as well as usability testing before a formal pilot evaluation. In the usability testing phase of the development, formative research around the m-Health SMS messages and perhaps putting the checklist itself on a mobile phone would be examined.

**Evaluation**
The checklist will be evaluated based on qualitative and quantitative feedback on its practical use in countries. Previous experience in developing and pilot testing checklists has revealed that it is helpful to have a combination of observational data as well as chart review, where possible, to assess the impact of the checklist programme on programmatic errors of both omission and commission. With the inclusion of SMS reminders for clients in the checklist programme, the evaluation would also include an assessment of health seeking behavior as well as an assessment of the quality of the vaccination session as determined by the caregiver’s or vaccinees themselves.

**Challenges**
There are two central assumptions to the concept of a vaccination checklist programme, which includes a comprehensive but checklist-based quality and safety improvement and SMS reminders for clients aimed at increasing uptake for a safe and effective vaccination programme. The first is that health-care workers administering vaccinations will find the checklist approach useful in their work and thus use the tool and the second is that vaccinees and family members can be empowered with reminders to utilize the vaccination sessions provided. The previous work on checklists in health-care suggests that a checklist-based approach embedded in a behavior change programme can encourage health workers to use checklists. Overcoming the second challenge of the added value that m-Health components may bring to the system will be explored in the formative testing phase of the development process but work in other areas, such as HIV, suggest that there is potential for patient empowerment in other areas of public health as well.

### Immunization Checklist: Recommended Ways Forward

1. Conduct a literature review on key issues around vaccine administration and prepare comprehensive background document.
2. Conduct usability testing of the immunization checklist in 10 to 15 sites.
3. Conduct a formal pilot evaluation in 2 to 3 countries with some countries in South-East Asia already having shown great interest.
4. Present findings and documentation to the WHO ‘Immunization Practices Advisory Committee’ (IPAC) in its next meeting in October 2012 for discussion, comments and final endorsement.
5. Review the potential for setting up databases to link local immunization registries with vaccination schedules and m-Health SMS messages to health care workers, clients and caregiver.

Contact:
Dr. Carsten Mantel, WHO Dept. for Immunization, Vaccines and Biologicals; email: mantelc@who.int; Tel: +41 22 79 13830