

## Safety of mass immunization campaigns

### To ensure safety during mass immunization campaigns with injectable vaccines

Mass immunization campaigns pose specific safety challenges, due to their objective of immunizing large populations over a short period of time and often being conducted outside the normal healthcare setting. Two of the most notable challenges are injection safety and adverse events following immunization (AEFI). Firstly, with respect to injection safety, the large number of injections to be administered and the large volume of waste generated pose added strains on the system. This increases the probability that breaches in safety may occur. Secondly, with respect to AEFI, there might be the perception of increased rates of AEFI. Reasons for this include the large number of doses being given over a short period of time and the administration of vaccine to a wider, usually older, age group.

If not prevented or managed properly, these safety issues can result in transmission of infections, impaired public and donor confidence in the campaign, and ultimately, reduced coverage and public health impact. However, one can avoid such problems by considering safety issues from the start of the campaign. Components to ensure safety include:

1. Assessing the existing injection safety situation
2. Preparing a detailed campaign plan which addresses key issues identified by the assessment.
3. Implementing the plan.
4. Monitoring the results.

Managers also need to ensure that they have a simple and timely monitoring system for adverse events for campaigns. Such a system not only supports the ongoing campaign, but also provides opportunities to identify key immunization and injection safety issues. These issues should then be addressed in routine immunization activities and included in a longer term immunization safety plan.

The main elements in ensuring immunization safety during a mass campaign are:

- An assured source of safe vaccines, safe injection supplies and other materials.
- Measures to ensure safety of vaccine administration.
- Measures to ensure safe sharps waste management.
- A system for AEFI monitoring and management.
- An advocacy and safety awareness strategy for the public and health staff.
- A budget to ensure funding of all planned components.

### Checklist

#### Detailed campaign plans must

- Identify all key players and partners
- Plan, budget for and order adequate supplies of all necessary items
- Assess the current injection safety situation
- Include a detailed budget with costs of all safety components
- Plan for staff training and media messages
- Include safety in the campaign from the start
- Monitor, document and disseminate results
- Evaluate and identify lessons learned

#### Safe vaccine administration

- Use WHO/UNICEF pre-qualified or nationally approved vaccine and injection material
- Bundled distribution of vaccine and diluent with reconstitution syringes, auto-disable (AD) syringes and sharps boxes to the immunization sites
- Emphasize need for sterile technique, correct reconstitution and safe administration
- Train healthcare workers in proper techniques
- Ensure traceability of vaccine by manufacturer and lot number

#### Sharps waste management

- Assess local regulations and possibilities for sharps treatment and disposal
- Identify practical, simple solutions for waste collection and disposal
- Ensure availability of sharps waste disposal facilities, adequate safety boxes.
- Plan transportation, storage and disposal procedures before the campaign begins
- Provide clear instructions and guidelines for health staff on disposal
- Monitor disposal on a daily basis

#### AEFI management and monitoring

- Assess or set up AEFI monitoring system
- Develop rapid reporting channels
- Decide which AEFI are to be reported and which contraindications to observe
- Train health care workers to investigate and manage AEFI and respond to rumours
- Explain to key people involved in the campaign why the campaign may result in the perception of increased rates of AEFI.
- Plan and transmit media messages on the campaign which address locally perceived safety concerns.
- Form an AEFI review committee
- Keep alert for "issues" and rumours

### Words of advice

- Campaign policies and strategies should be identified well in advance of the campaign.
- Practical, country-specific solutions for sharps waste management should be identified and planned well in advance.
- All supplies and materials should be ordered at least six months before the campaign.
- Roles and responsibilities for the campaign should be clearly stated from the start and should include deadlines for completing all tasks.
- All players and partners (including nongovernmental organizations, medical and nursing associations, religious groups, etc.) should be contacted to help disseminate safety awareness messages.
- Regular monitoring throughout the campaign, followed by a final evaluation should be conducted so as to identify successes, problems and lessons learned. The findings should then be disseminated to all partners.

### Key elements

<b>Planning for mass campaigns, including safety components:</b> <ul style="list-style-type: none"> <li>• Identify the different key players and clearly assign activities, roles and responsibilities to each player.</li> <li>• Ensure that campaign advocacy messages include safety issues.</li> <li>• Conduct an assessment of current injection safety practices to assess the situation and identify the needs and challenges for the forthcoming campaign. The standard WHO tool for the assessment of injection safety practices might be considered for this.</li> <li>• Include the following safety components in immunization mass campaigns:</li> </ul>	<ol style="list-style-type: none"> <li>1. A detailed budget with identified funding sources;</li> <li>2. A micro-plan for distributing vaccines, diluents, injection and reconstitution materials, and safety boxes;</li> <li>3. A plan for training on safe injections and AEFI monitoring;</li> <li>4. A comprehensive waste disposal plan;</li> <li>5. The information flow on AEFI;</li> <li>6. A crisis management plan with communication strategies to prevent rumours from endangering the campaign.</li> </ol> <ul style="list-style-type: none"> <li>• Prepare "Questions and Answers" for the media on the background for the campaign and the potential for AEFI.</li> </ul>	<ul style="list-style-type: none"> <li>• Decide on a protocol for treatment of anaphylaxis, and provide the necessary training, drugs and equipment.</li> <li>• Review contraindications to vaccination (e.g. AIDS) and implications for the campaign; train staff accordingly.</li> <li>• Plan to monitor activities, successes and problems through routine reporting by all vaccination sites.</li> <li>• Plan from the start to undertake a final evaluation and use this to develop a long-term plan of action to address the problems and issues that have been identified. Disseminate lessons learned so that others can learn from the experience.</li> </ul>
<b>Vaccine administration</b>	<b>Sharps waste management</b>	<b>AEFI monitoring</b>
<ul style="list-style-type: none"> <li>• Procure vaccines, AD syringes and safety boxes (and reconstitution syringes if necessary), from pre-qualified WHO/UNICEF or national regulatory authority-approved sources.</li> <li>• Ensure that quantities of all supplies match and that all distribution is bundled. Plan logistics carefully to ensure availability of all supplies at all vaccination posts.</li> <li>• Place orders well in advance (at least six months) before the start of the campaign.</li> <li>• Raise health care worker awareness on the need for safety throughout the campaign</li> <li>• Needles should never be recapped but must be placed into an approved safety box or puncture-resistant container immediately, and disposed of safely as soon as possible after use.</li> <li>• The training of staff at each level must include reconstitution of freeze-dried vaccine (use only the diluent supplied with the vaccine, use whole amount of diluent), the use of AD syringes and of the need for proper disposal in a safety box.</li> </ul>	<ul style="list-style-type: none"> <li>• The safe disposal of used injection equipment is one of the most important issues in assuring injection safety. There is no single, universally accepted method, but a locally acceptable solution needs to be identified and agreed upon with all partners before the campaign.</li> <li>• Assess local possibilities of sharps treatment and disposal (e.g. identify functioning incinerators, sites for burning, re-cycling, safe burial, etc.).</li> <li>• Construct incinerators where needed, or find temporary treatment sites.</li> <li>• Plan for transportation, storage and treatment of sharps waste. Safety boxes should be numbered so as to verify their return to the destruction point.</li> <li>• Identify practical, simple solutions that can be implemented during the campaign. Use the waste disposal plan and system developed for routine sharps waste management in the future. (Possibilities include incineration, burning, recycling, safe burial.)</li> <li>• Prepare clear instructions and guidelines for health staff on sharps disposal and waste management.</li> <li>• Instruct personnel on practices recommended for the campaign and monitor the compliance on a daily basis.</li> </ul>	<ul style="list-style-type: none"> <li>• Institute a simple surveillance system for adverse events, if one does not exist already, with case definitions, a reporting form and instructions on how and where to report.</li> <li>• Monitor the distribution and use of all vaccine lots.</li> <li>• Ensure routine reporting and managing of AEFI at vaccination sites/clinics through training staff at all points where AEFI might occur, points for acute AEFI and points for delayed AEFI.</li> <li>• Maintain monitoring for at least four weeks after the campaign and introduce as a permanent system wherever possible.</li> <li>• Estimate the expected rates of AEFI for the vaccine(s) to be used, and the differences in background rates of diseases in target age groups involved in the campaign. Use these baseline figures to compare with actual rates occurring in the campaign.</li> <li>• Identify a focal point and form a committee to receive and review reports of AEFI during the campaign.</li> <li>• Ensure rapid response to AEFI with the necessary investigation and correction of potential programmatic errors.</li> <li>• Be sensitive to rumours that might arise about AEFI and follow them up actively.</li> </ul>

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This document is available on the Internet at: <http://www.who.int/vaccines-documents>

Additional information on immunization safety can be obtained on the Internet at <http://www.who.int/vaccines>

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