Report on the

Intercountry workshop on immunization safety

Cairo, Egypt
14–16 December 2003
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1. INTRODUCTION

The World Health Organization (WHO) Regional Office for the Eastern Mediterranean (EMRO) organized an intercountry workshop on immunization safety in Cairo, Egypt, from 14 to 16 December 2003. The meeting was attended by Extended Programme on Immunization (EPI) managers and focal points for communicable diseases surveillance from all countries. It was also attended by WHO headquarters staff, WHO Mediterranean Centre for Vulnerability Reduction (WMC) staff, and EMRO staff, as well as staff from Naval Medical Research Unit 3 (NAMRU-3), Cairo.

The objectives of the meeting were to:

- review the current situation of immunization safety in the Eastern Mediterranean countries
- update the national focal points on the latest progress in immunization safety
- develop/review/update the national plans for improving immunization safety
- discuss the strategic approaches for developing/improving national infection control programmes, building on the successful experience of the injection safety programme.

The meeting was opened by Dr Zuhair Hallaj, Director, Communicable Diseases Control Division, who delivered a message from Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean. In his message, Dr Gezairy highlighted the fact that immunization was one of the most efficacious, cost-effective and safest of public health interventions, and has tremendous effect on saving millions of lives each year. He reminded the participants that immunization activities were expanding within and outside EPI, to meet the global target of elimination and eradication of some vaccine-preventable diseases, as well as the prevention and control of several others. With this expansion and with the increasing number of vaccine antigens available, ensuring and monitoring safety of all aspects of immunization (e.g. vaccine quality, vaccine storage and handling, vaccine administration and disposal of sharps) had become a real challenge. Unsafe injection procedures could transmit life-threatening infectious diseases that lead to a high burden of chronic illness, disability and death. The adverse events that might follow immunization could have a negative impact on health and on the programme itself.

Dr Gezairy highlighted the unsatisfactory situation of injection safety in the Eastern Mediterranean Region. There was a high risk to patients from non-sterile injections, a serious risk to health care workers from needlestick injuries, and a major risk to communities resulting from the unsafe disposal of sharps and infectious waste. Dr Gezairy outlined the main activities being undertaken by WHO to ensure immunization safety: WHO had established the Immunization Safety Priority Project (ISPP) and WHO headquarters hosted the secretariat of the Safe Injection Global Network (SIGN). Efforts were continuing in order to ensure optimum vaccine quality, to produce more combined vaccines to minimize number of injections and to produce safer injection equipment. The regional strategic plan for injection safety 2002–2005 had been developed and was being implemented. In addition, EMRO was supporting countries for assessment of safety of injection and in developing plans of action for improving injection safety, assisting countries eligible for Global Alliance for
Vaccines and Immunization (GAVI) funds in applying for GAVI support for immunization safety, and supporting phased introduction of auto-disable (AD) syringes including the proper disposal of used injection equipment and proper waste management practices.

Dr Gezairy commended the positive steps taken by several Eastern Mediterranean countries to ensure safety of immunization. Yet, he said, safety of immunization was not guaranteed for the majority of the populations in our Region. He added that immunization safety should be emphasized as a core component of any immunization programme whether routine EPI, catch-up campaigns or school-based programmes, in order to safe precious lives and health care resources.

The programme of the meeting, list of participants, outcome of group work and the case study are included as Annexes 1 to 4, respectively.

2. OVERVIEW ON IMMUNIZATION SAFETY

2.1 Global overview

Dr P. Duclos

In 1998, it was estimated that safety was not guaranteed for up to one third of injections related to immunizations worldwide. Safe technologies remained inaccessible to many countries and there were many reports of programmatic mistakes and adverse events being mishandled. In addition, anti-immunization lobbies and persistent rumours added to the potential loss of confidence in the immunization programme. The risk of transmission of blood-born pathogens through unsafe injections is real. In 2000, it was estimated that nearly 35% of new hepatitis B infections were attributed to unsafe injections each year. Although immunization-related injections represent a small proportion of all injections and are generally better controlled than injections provided in the curative sector, the safety of immunization-related injections has to be guaranteed.

Indeed, for a preventive intervention administered to healthy individuals and infants, one can tolerate no compromise in safety. Despite much progress being achieved, there are still many unfortunate examples of mishaps including unsafe injections or improper reconstitution of vaccines. To guarantee immunization safety, countries must only use vaccines of ensured quality. They need to prevent reuse of needles and syringes through the exclusive use of AD syringes, and they need to ensure proper disposal of immunization waste and appropriate waste management. It is of the utmost importance to ensure that staff members are trained on and follow policies for vaccine reconstitution and use of multi-dose vials. It is also essential to implement an effective monitoring and management system for adverse events following immunization (AEFI), including appropriate handling of safety issues and rumours.

A standard injection safety assessment tool has been developed using representative sampling to assess the safety of injection practices in health facilities and to serve as the basis of a national plan to help drive change, where needed. Representative injection safety
assessments, as recommended by WHO, have now been conducted in over 60 countries. They highlight that waste disposal and management is commonly problematic in developing countries. These assessments indicated, for example, the presence of sharps around the health facilities in 49% of cases in the Eastern Mediterranean Region versus 9% in the European Region. To date, the GAVI-Vaccine Fund for injection safety support has committed a total in excess US$ 85 million to 58 eligible countries.

WHO is monitoring progress in immunization safety by combining different sources of information including the WHO/United Nations International Children’s Emergency Fund (UNICEF) joint reporting form, UNICEF country reports, UNICEF supply division procurement data and data from injection safety assessments, as well as GAVI-related data such as annual reports and ad-term reviews. As a result, much progress has been achieved with 56% of developing countries having introduced AD syringes by the end of 2002. In the WHO African Region progress has been even faster with 76% of countries using AD syringes, versus only 38% in 2000.

With respect to the monitoring of AEFI, only 44% of the global population was monitored by a documented surveillance system and only 5% of the population living in countries were procuring vaccines through the UN system. As a result of reviewing the situation at its June 2003 meeting, the Steering Committee of the ISPP of WHO has made a number of recommendations for the strengthening of AEFI monitoring and management, including:

- countries supplying vaccines through UNICEF should implement a monitoring system
- countries should assign long-term funding to national regulatory authorities
- countries should assign focal point for AEFI
- countries should assess AEFI monitoring and management capacity
- countries should put in place mechanisms for review of AEFI
- countries should have a communication strategy for management of AEFI. The Steering Committee also wanted WHO and the GAVI secretariat to make countries aware of potential to use Vaccine Fund for strengthening National Regulatory Authorities (NRAs).

A new WHO immunization safety website http://www.who.int/immunization_safety/en is now active. The purpose of the website is to provide easy access to up-to-date factual information, global policies, best practices and resource documents, including training and documentation material in the area of immunization safety, in different official WHO languages.

The Global Advisory Committee on Vaccine Safety (GACVS) was established by WHO in 1999 to act as a scientific and clinical advisory body that aims to provide a reliable and independent assessment of vaccine safety issues. During the last two years, GACVS has reviewed a number of issues including:

- safety of thiomersal-containing vaccines
- alleged association between hepatitis B vaccination and childhood leukaemia
• alleged association between hepatitis B vaccination and multiple sclerosis
• aluminium-containing vaccines and macrophagic myofasciitis
• immunization and autoimmune diseases
• safety of bacille Calmette–Guérin (BCG) vaccine in immuno-compromised persons
• safety of yellow fever vaccine
• safety of mumps vaccines.

The GACVS website can be accessed at website http://www.who.int/vaccine_safety/en. It contains all GACVS statements and supporting information.

Despite the huge progress achieved in the area of safety, some of the remaining challenges include the:

• issue of waste management
• need to address the problem of resources and conflicting priorities
• need for a stronger advocacy and to address some remaining prejudice against AEFI monitoring
• need to explore integration of immunization safety-related activities within other surveillance and health systems
• need to build on immunization safety, to improve injection safety and larger and wider infection control.

2.2 Regional situation

Dr S. Youssouf

The main injection safety goals in the Region are to ensure the safety of all immunization injections and to extend successful injection safety strategies and activities to other parts of health care services.

Assessment of injection safety was conducted in 13 of the Eastern Mediterranean countries. The results showed that 26% of the countries practise unsafe injection within immunization services and 89% practise unsafe therapeutic injections.

Assessment of NRAs was conducted in Egypt, Islamic Republic of Iran, Pakistan and Tunisia. Some progress has materialized in Egypt, Islamic Republic of Iran and Tunisia but Pakistan needs further strengthening.

3. ENSURING SAFETY OF INJECTIONS

3.1 Injection equipment

Dr P. Duclos

The syringe currently preferred by WHO for immunization is the AD syringe. A joint WHO/UNICEF/United Nations Population Fund (UNFPA) statement on the safety of all injections related to immunization has been developed recommending the sole use of AD
syringes in national immunization programmes by the end of 2003. The statement has now been endorsed by over 15 major organizations including the World Medical Association, the International Council of Nurses, the International Paediatric Association and the World Bank.

Overall, the AD syringe contributes to decreased blood-borne pathogen transmission between patients by preventing the reuse and resale practices which exist in some developing countries. However, AD syringes lack needle protection and neither eliminate the hazards of needlestick injuries for the health care provider nor those relating to sharps waste in the environment. Technology transfer for the local production of AD syringes is in progress in a number of countries, and there are now 10 approved AD syringe manufacturers, some of them with production sites in developing countries. Availability of AD syringes is no longer an issue. The cost of an AD syringe has been decreasing over the years, and is now less than US$ 0.06 for international producers. Locally produced AD syringes are now available for purchase at an even lower price. Over the last few years, the proportion of AD syringes used in the context of immunization services has been growing fast with nearly 500 million AD syringes distributed by UNICEF in 2003. New WHO prequalification procedures for single-use injection devices are being finalized which will be similar to the vaccine prequalification process. The UNJECT pre-filled device is also a type of AD equipment in the respect that it cannot be reused. It is currently only available for tetanus toxoid and hepatitis B vaccination and in limited quantities.

A document, Best infection control practices for skin-piercing, intradermal, subcutaneous and intramuscular needle injections, has been produced (Bulletin of the WHO, 2003). It includes recommendations on the use of sterile injection equipment, preventing contamination of equipment and medication, preventing needlestick injuries and preventing access to used needles. The WHO guidelines First do no harm: introducing auto-disable syringes and ensuring injection safety within immunization systems of developing countries (WHO, 2002) have been developed to highlight the key steps for achieving successful introduction of AD syringes and for ensuring safety.

In the longer term, technological advances such as needle-free delivery devices and new kinds of vaccine formulations have the potential to greatly improve injection safety. Recognizing both the immense value that a multi-dose, multi-use fluid path jet injector might have for rapid mass immunization purposes and the safety concerns attached to the existing models, an important effort is under way to develop and clinically evaluate the new generation of contamination-free jet injection devices. Although the design is greatly improved over previous models, no jet injector is yet to be recommended for use as their safety has not been demonstrated.

3.2 Waste management

Dr P. Duclos

Poor management of health care waste exposes health care workers, waste handlers and the community to infections, injuries and toxic chemicals (including the release of air pollutants, dioxins, furans, mercury and other heavy metals). Improper disposal creates
opportunities for the reuse of contaminated medical equipment. Poor waste disposal practices also damage the environment.

Although there is no one-size-fits-all solution when it comes to waste management, solutions exist for many situations and the non-availability of technologies is often not a technical problem. Rather it is a matter of allocated resources, regulatory compliance or social acceptance. Environmental concerns and bans on burning represent a major issue in some countries. A number of technical options are available, which have various strengths and weaknesses (summarized in Table 1). Although some are more preferable than others, none is without any disadvantage. Much work is currently undergoing with respect to the testing of needle cutters and destroyers. Although various models are available, before they can be recommended as part of the best injection practices it must be demonstrated that they do not result in blood splashing and that their use in the field is practical.

With respect to incinerators, several models exist. In practice, De Montfort and other small-scale incinerators at small hospitals run for 2–4 hours per week and the amount of dioxin and furans released by a De Montfort incinerator would be less than that produced by small incinerators meeting the United States of America or Japanese standards that run for 40 hours a week. European standards, however, would be difficult to meet. Incinerators need proper maintenance and operation, as do other options.

Table 1. Waste treatment: comparison between options

<table>
<thead>
<tr>
<th>Technical option</th>
<th>Strength</th>
<th>Weakness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste burial</td>
<td>Low-tech</td>
<td>Space availability</td>
</tr>
<tr>
<td>Encapsulation</td>
<td>No needle reuse</td>
<td>Space availability</td>
</tr>
<tr>
<td>&lt;800 °C incineration</td>
<td>Waste reduction</td>
<td>Pollutant emissions</td>
</tr>
<tr>
<td>&gt;800 °C incineration</td>
<td>Waste reduction</td>
<td>Pollutant emissions (low)</td>
</tr>
<tr>
<td>Autoclave</td>
<td>Waste disinfection</td>
<td>Maintenance and electricity</td>
</tr>
<tr>
<td>Microwave</td>
<td>Waste disinfection</td>
<td>Maintenance and electricity</td>
</tr>
<tr>
<td>Shredding</td>
<td>Waste reduction</td>
<td>Maintenance and electricity</td>
</tr>
<tr>
<td>Chemical</td>
<td>Cheap and available</td>
<td>Handling, dose, environment</td>
</tr>
<tr>
<td>Landfill</td>
<td>Take waste away</td>
<td>Requires disinfectants</td>
</tr>
</tbody>
</table>

Another option for waste disposal that is being refined is that of melting the syringes in ovens, including domestic ovens, resulting in a plastic cake with embedded needles.

It is also important to consider options including a system of sharp collections in the field with central management of waste, and that a country may be better served by a menu of options that may vary in different settings.

More information on policies and various tools can be accessed at the following website: [http://www.healthcarewaste.org](http://www.healthcarewaste.org). This site also provides access to a database of waste treatment options that is being reworked into a more practical concept including a large
number of parameters (such as legislation, cost analysis, etc.) to assist countries in making their decision.

Health care waste management requires:

- A policy, including the designation of responsible authority;

- A comprehensive system of health care waste management including the assignment of responsibilities and allocation of necessary resources (depending on the method used and the number of syringes to be processed, the cost of waste management may vary from 20%–100% of that of syringes and needles);

- Raising awareness on the risks and training;

- The proper selection of options with due consideration to environmental friendliness and workers’ safety. Mass vaccination campaigns do not cause a new problem but they merely exacerbate existing chronic problems by generating large quantities of sharps waste over a short period of time.

Although there are no perfect waste management systems for immunization-related sharps, there are many options that can be adjusted to the local situation, taking into consideration the environmental regulations and other health care waste management methods. For the success of the strategy, it is essential that responsibilities be assigned, local solutions considered and long-term planning implemented.

3.3 Communication for behavioural impact strategy (COMBI)

*Dr S. Khamassi*

There are many planning models for social mobilization and communication. Since 2000, the WHO social mobilization and training unit, now based in Tunis, has been applying an approach known as communication for behavioural impact (COMBI) in the design and implementation of behaviourally focused social mobilization and communication plans for the adoption of healthy behaviours.

COMBI integrated action areas are:

- administrative mobilization/public relation/advocacy
- community mobilization
- sustained and appropriate advertising and promotion
- personal selling/interpersonal communication/counselling
- point of service promotion.
4. ASSESSMENT, MONITORING, EVALUATION AND SUPERVISION OF IMMUNIZATION SAFETY

4.1 Monitoring, evaluation and supervision

Dr E. Mohsni

The comprehensive plan of action for ensuring immunization safety should include:

- conducting an injection safety assessment
- developing an injection safety policy, strategy and annual work plan
- establishing reliable estimates of equipment requirements, minimum stock levels and effective supply and distribution systems
- securing the required financial resources for all the components of the plan, including safe disposal of used equipment
- planning for the safe disposal of used injection equipment through the progressive introduction of appropriate waste management options
- training for health workers and managers on safe injection and disposal procedures
- providing adequate supplies and disposal facilities at all levels
- developing appropriate advocacy strategies targeting decision-makers, health workers (including the private sector) and the general population
- promoting injection safety activities in all areas of the health care system
- setting-up monitoring and supervision procedures to ensure correct practices by health workers.

*Tool C for the assessment of injection safety* (WHO, 2001) is a document developed in collaboration between SIGN, Basic Support for Institutionalizing Child Survival (BASICS) and WHO’s Departments of Vaccines and Biologicals and Blood Safety and Clinical Technology. It is also used to identify local issues, to design effective and efficient interventions, and to provide baseline information and indicators for monitoring and evaluating progress.

Supervision, monitoring and evaluation of injection safety are crucial to ensure safety of injections in all health care services. Supervision of injection safety in immunization services should be an integrated part of EPI. It should be well planned and conducted on a regular basis using appropriate checklists. WHO has developed *A guide to supervising injection providers* (WHO, 2004), which can be found on the following website: http://www.who.int/immunization_safety/publications/safe_injections/en/. The guide addresses the behavioural component of injection practices, i.e. those practices that can be changed by supervision. It highlights three basic steps for supervision of injection safety practices:

1. Observing injection practices to collect information, using supervisory checklists.

2. Evaluating the observed injection practices against the best practices to identify discrepancies and gaps.
3. Providing feedback to reinforce good practice and help correct poor practice.

Implementation of the above components of the national action plan should be closely monitored. It can be done through inclusion in the standard EPI reporting system, regular supervisory visits, and injection safety surveys to assess and evaluate progress. Appropriate indicators that relate to the national strategy, objectives and activities, and cover all aspects of and components of the national plan, should be developed. These indicators should include input indicators, process indicators, outcome indicators and indicators related to injection safety outside the immunization services.

4.2 Assessment of injection safety

*Dr C. Mantel*

Unsafe injection can pose a risk to the recipient as a result of re-use of syringes or needles and/or use of non-sterile equipment, risk to the health care worker as a result of inappropriate waste collection and risk to the community due to inappropriate waste disposal.

*Tool C for assessment of injection safety* is being widely used in order to describe injection practices in a standardized and representative way. Injection safety assessment using tool C helps in describing injection practices in a standardized and representative way. It helps to identify problems in injection practices and in identifying local solutions for effective and efficient intervention. It also aids in generating baseline information and indicators for monitoring progress.

The objectives of injection safety assessment are to:

- determine whether a facility where injections are given meets necessary requirements for staff competence, equipment, supplies, and waste disposal
- determine whether the injections are administered according to recommended best practices
- identify the unsafe practices that may lead to infections and that should be targeted by interventions
- estimate the proportion of healthcare facilities where injection practices are safe. The result of the assessment should lay the ground for developing the plan of action.

*Methodology of assessment using tool C*

The methodology for assessment of injection safety, using tool C, is standardized and representative. It allows for measuring and documenting progress and for comparison across countries. It is a simple, structured and flexible cross-sectional observational study that covers a 3-week period and can be adjusted to each country’s needs. It consists of two-stage cluster sampling with probability proportional to size of population, with eight districts randomly selected and 10 health care facilities visited in each district. This methodology guarantees that the sample is representative.
Data collection

A standardized method of data collection, using pilot-tested instruments, should be followed. Data collection should cover:

- observation of supplies, i.e. collecting data concerning type and number of syringes and needles, number of safety boxes, sharps containers and type of waste disposal
- observation of injections in both immunization and curative departments
- interview of health care workers, i.e. interviewing both injection providers and the supervisor of the centre.

Data analysis

The collected data is analysed using EpiInfo (Version 3 or Version 6.04). Calculation of means and proportions and 95% confidence intervals (binomial) is performed.

To date, tool C was used in conducting full, standardized assessment of the injection safety in 10 countries and partial assessments in three additional countries of the Region. These assessments revealed that there is a high risk to the injection recipients, coupled with a serious risk to health care workers and a major risk to the community.

The following table summarizes this risk, as of end 2002.

<table>
<thead>
<tr>
<th>Risk</th>
<th>Weighted proportion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk to recipients (EPI and curative):</td>
<td></td>
</tr>
<tr>
<td>• non-sterile injections</td>
<td>34</td>
</tr>
<tr>
<td>Risk to health care workers:</td>
<td></td>
</tr>
<tr>
<td>• sharps in open containers</td>
<td>71</td>
</tr>
<tr>
<td>• two-hands recapping</td>
<td>60</td>
</tr>
<tr>
<td>• needlestick injuries (admitted)</td>
<td>50</td>
</tr>
<tr>
<td>Risk to the community:</td>
<td></td>
</tr>
<tr>
<td>• unsafe sharps waste disposal</td>
<td>85</td>
</tr>
</tbody>
</table>

Discussion

There is the need for a tool to assess safety of clinics, in order to certify them as being acceptable with regard to injection safety. Scoring systems should be considered during the development of such a tool. The tool could probably become a useful supervisory checklist, suitable for the public and private sectors.

The need for having a reliable system, suitable indicators and capacity to monitor injection safety after the initial assessment activities were highlighted.
Lack of cooperation between private and public sector is one of the most important problems to be tackled. It is difficult to assess the injection safety situation in the private sector in many countries.

*Group work*

The topics and results of the group work are presented in Annex 3.

The following points were discussed after presentations of the group work.

*Waste management*

Infectious disease staff should become the focal point for waste management. Vaccination waste should be looked at as a part of hospital waste. Waste management is part of overall infection control and cannot be dealt with in isolation. The financial situation of the country may determine the degree of development of the waste management.

*Supervision, monitoring and evaluation*

- Zero reporting is important.
- EPI managers insisted that they can only supervise and be responsible for safety of immunization and they cannot be responsible for supervision of other sectors.
- The Regional Office’s view is to look at injection safety as a whole and not at immunization safety.
- The difference between immunization safety and injection safety is not very significant nor that large.
- Immunization safety is applicable only to healthy recipients whilst injection safety is relevant to both healthy and unhealthy recipients.
- For immunization safety there are AD syringes, but for curative injection there is no such tool.
- For curative sector, oral drugs can be encouraged, but for immunization this is not possible.
5. ENSURING SAFETY OF IMMUNIZATION AND MONITORING AEFI

5.1 Ensuring safety outside EPI routine activities

Dr. P. Duclos

Because they aim at immunizing large populations over a short period of time, mass immunization campaigns pose specific safety challenges. Firstly, with respect to AEFI, an apparent rise in the risk of adverse events may occur. Reasons for this apparent increase 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. Secondly, with respect to injection safety, the large volume of injections to be administered and the large volume of waste to be generated put added strain on the system, increasing the probability that breaches in safety will occur.

If not managed properly, these safety issues can result in damage to health, impaired public and donor confidence in the campaign and, ultimately, reduced coverage and public health impact. Campaigns represent a substantial financial investment, which could be wasted if the necessary coverage is not reached. Campaigns are also the focus of high visibility and scrutiny by the general public and the media. Adverse events that occur during campaigns and the impact of these events must be managed quickly and effectively to encourage good practice and promote public confidence in the programme.

However, EPI managers can take simple steps to ensure safety through a systematic approach including an initial assessment of the existing situation, plans for safety appropriately budgeted and funded, implementation of the safety plan, and careful monitoring. Managers also need to introduce a simple and fast monitoring system (if not already in place) for adverse events, as a minimum for campaigns. Such a system, in addition to supporting the campaign, provides opportunities for the identification of key immunization and injection safety issues that should be addressed in routine immunization activities and included in a longer-term immunization safety plan. AEFI monitoring during mass campaigns represents an additional opportunity to launch AEFI monitoring for routine immunizations and to learn more about the safety of specific vaccines.

Important success factors for the implementation of AEFI monitoring and management during mass vaccination campaigns include:

- commitment and leadership from decision-makers
- nomination of a focal point
- allocation of necessary resources
- overcoming of barriers within the health system
- training and follow-up
- preparedness to respond rapidly and effectively.

WHO has developed a number of specific support documents such as a document on reporting and investigating AEFI during mass measles immunization campaigns, practical
guidelines for planners and managers on the management of wastes from immunization campaign activities, and an aide-mémoire to ensure the efficiency and safety of mass immunization campaigns with injectable vaccines. This aide-mémoire is structured as a checklist around four areas: campaign planning; safe and efficient vaccine administration; sharps waste management; and AEFI management and monitoring. It is intended to serve as a supervisory tool, for planning and for checking if the level of preparedness is sufficient to ensure a successful campaign from the efficiency and safety point of view. These documents are all available on the following web site: http://www.who.int/immunization_safety/en.

5.2 Experience of the Islamic Republic of Iran with ensuring immunization safety during the measles catch-up campaign

*Dr A.-R. Estighmati*

The measles catch-up campaign of the Islamic Republic of Iran aimed to vaccinate 33 million people aged over 5–25 years, in a duration period of 3 weeks. In the first week, 15.7 million were vaccinated (until leaving the country to attend this meeting). Only eight adverse events of anaphylactic shock were reported; these were properly treated. Forty universities shared in this campaign as action units with 23 000 fixed posts and 9000 mobile teams, each team including 3–5 personnel (physician, recorder and vaccinators) working under the supervision of 11 000 supervisors. AD syringes and safety boxes were adequately supplied. The vaccine was purchased from the Serum Institute of India, which was pre-qualified by WHO and rechecked by NRA Iran. One hundred and seventy-four incinerators above 800 ºC were operating in urban areas; locally made incinerators were used in rural areas. The training of vaccinators was completed before the campaign.

An AEFI-monitoring system was also implemented. Thirty-four physicians were trained and a committee was formed to investigate any serious AEFI. A telephone number was printed on the back of the vaccination card given to each and every recipient, for reporting AEFI. Emergency kits were distributed during the campaign to deal with AEFI. Eight cases of anaphylaxis were reported during the first week of the campaign, for approximately 15 million injections. During the first day of the campaign, 5000 minor AEFI cases (such as headache) were reported.

5.3 Surveillance of AEFI

*Dr F. Mahoney*

Vaccines can cause adverse events from the inherent properties of the vaccine (vaccine reaction) or error in the immunization process (programme error). In addition, the event may be unrelated to the immunization but have a temporal association with it (coincidental event). Anxiety-related reactions can arise from fear of, or pain from, the injection rather than the vaccine (injection reactions). Surveillance for AEFI should prioritize detection of events resulting from programme errors and those occurring in clusters. Clusters are defined as ≥ 2 persons experiencing the same AEFI, who are related in time, geography or vaccine administered. AEFI negatively affect community confidence in immunization services. The steps for investigating AEFI clusters include case finding, collection of immunization history, and assessing common exposures among affected individuals.
It is important for immunization programme managers to develop guidelines for AEFI surveillance that include:

1. Events to be reported.
2. Who is responsible for detection and reporting.
4. Timing of reporting.
5. Who is responsible for collection and analysis of surveillance data.

The objectives of AEFI surveillance should be: to detect programme errors so that they can be resolved quickly and prevented in the future; to maintain the confidence of the community in immunization services by responding rapidly to reports of AEFI; and to ensure that coincidental events are not falsely blamed on vaccinations. If the cause of the event is clear, corrective action should be instituted immediately. If further investigation is required, it should be conducted immediately. Once the investigation is concluded and the cause of the AEFI is ascertained, corrective measures (if applicable) should be taken in consultation with the EPI unit at the central level. In case of a programme error, efforts must be taken to avoid future reoccurrences. Patients affected by the AEFI should be provided prompt and appropriate treatment. The community should be provided with transparent and clear explanations as to the causes of the AEFI. It is important not to assign blame to anyone or any group of individuals. AEFI monitoring should be seen as a learning experience rather than a blaming exercise. In the event of media involvement, pre-designated individuals should be responsible to address the media. It is essential to ensure that all messages to the media and the public are accurate and consistent.

Events that should be monitored include:

- deaths, hospitalizations or other severe/unusual events
- toxic shock syndrome
- severe local reactions
- sepsis
- injection site abscess
- BCG lymphadenitis
- any AEFI causing concern to the public or suspicion of vaccine relatedness.

Serious AEFI include anaphylaxis, persistent inconsolable screaming, hypotonic hyporesponsive episodes, seizures, encephalopathy, acute flaccid paralysis, brachial neuritis, thrombocytopenia, disseminated BCG infection, osteitis/osteomyelitis.

5.4 Group work: case study on AEFI

The notes for participants and facilitators are presented in Annex 4.
6. ADVOCACY AND PARTNERSHIP: PROJECT FOCUS IN THE SYRIAN ARAB REPUBLIC

Dr S. Khamassi

Project Focus is a pilot project launched by WHO headquarters, WMC/Tunis, EMRO and the WHO Regional Office for Africa (AFRO) aimed at improving immunization safety in two selected countries: Burkina Faso and the Syrian Arab Republic.

Following an immunization safety assessment in the Syrian Arab Republic using WHO tool C, the main issues were identified and a plan of action was developed in detail to cover the following areas.

- Administrative mobilization/advocacy, leading to the expansion of a national policy on injection safety and endorsement by the Minister of Health;
- Development of a communication strategy targeting the community in order to raise awareness and to create consumer demand for safe injections, and targeting the health worker in order to improve health service delivery and to address behavioural issues (such as reuse of injection equipments without sterilization and needle recapping);
- Ensuring provision of supplies and equipments;
- Safe sharp waste management: a national committee on waste management was created including representatives from the Ministry of Health (EPI, Communicable Diseases Unit, Occupational Safety Department) and the Ministry of Environment. Autoclaving was chosen by the committee as the option for safe waste disposal. Implementation of the autoclaves at the governorate level will start in 2004;
- Implementation of an AEFI surveillance and management system: the AEFI surveillance guidelines were translated into Arabic and training of health workers on AEFI surveillance was initiated;
- Training of health workers on best injection practices and safe waste disposal was initiated (700 out of 1700 health workers were trained);
- Monitoring and supervision were planned and a supervision sheet was developed, which included the main indicators of the assessment of injection safety in order to monitor them regularly;
- Evaluation: a reassessment of the safety of injection using tool C was planned for the first quarter of 2004 in order to measure and document progress.

The following challenges were identified:

- AD syringes technology transfer
- implementation of the autoclaves
- dissemination of the IEC materials to all health facilities.
7. INJECTION SAFETY IN IMMUNIZATION SERVICES: REGIONAL STRATEGY AND PLAN OF ACTION, 2002–2005

Dr N. Teleb

The situation with injection safety in the Eastern Mediterranean Region is, generally, unsatisfactory. Therefore, the EPI Regional Technical Advisory Group recommended in June 2002 that a regional injection safety plan be established by the end of the year. Accordingly, *Regional Strategy and Plan of Action on Injection Safety in Immunization Services, 2002–2005*, was developed with the goal of ensuring safety of all immunization injections throughout the Region. The successful injection safety strategies and activities would then be extended to other parts of the health care services. The regional strategies and proposed activities include:

1. Generating reliable data on injection safety by performing a standardized assessment using WHO tool C.

2. Ensuring political commitment and developing national policy and standards by: constituting a regional task force on injection safety; discussing injection safety during all regional meetings and workshops; using data for advocacy and mobilization of resources; establishing national-level policies, guidelines and plans of action on safety of injections and sharps waste management; developing appropriate national legislation.

3. Ensuring adequate supply of injection equipment by: using only prequalified or NRA-approved injection materials; establishing regular and sufficient “bundled” supply of vaccines, corresponding diluents, AD syringes, reconstitution syringes and safety boxes; ensuring sufficient and sustained technical and financial resources by integrating injection safety strategies into all relevant health programmes; mobilizing local stakeholders in countries of the Region.

4. Strengthening the management capacity and developing human resources by: establishing injection safety committees, units and appropriate staff positions; assigning injection safety management duties to EPI managers/focal points at provincial and district level; human resource capacity-building, according to a stated policy; introducing injection safety issues into pre-service training curricula of medical and paramedical staff; further integrating injection safety into accelerated disease control initiatives such as that of measles and maternal and neonatal tetanus.

5. Ensuring safe sharps waste collection and management by: assessing the situation and developing national policy and guidelines on appropriate waste management; developing a national committee that involves all relevant sectors; identifying and implementing waste disposal methods that are suitable for local situation; initiating research in cost-effective and environmentally-friendly disposal of injection waste.

6. Ensuring supervision, regular reporting, monitoring and evaluation by: integrating safety issues in the routine EPI reporting system; monitoring progress in the implementation of the injection safety programme using appropriate indicators;
establishing a system for supervision; strengthening surveillance systems for the
detection of AEFI; periodic evaluation of programme performance on the basis of
selected indicators.

7. Sustaining public information and communication, and initiating behavioural change
by: developing appropriate behavioural change strategies and IEC materials;
coordination and cooperation with other health programmes (e.g. HIV/AIDS, family
planning) and the private sector in promoting injection safety.

8. Extending successful strategies and activities to other parts of the health care services
by: including all partners involved in injection issues in the regional task force on
injection safety; forming multidisciplinary national committees on injection safety
including the interagency coordination committee (ICC), EPI, HIV/AIDS, essential
drugs, clinical care and family planning programmes, medical associations, nursing
councils, other ministries, consumer associations, non-governmental organizations and
others involved in injection provision to make recommendations to the Ministry of
Health and assist in coordinating injection safety activities on national, provincial and
district level; stimulating the reduction of injection overuse, of unnecessary
prescriptions and of access to injectable medications by initiating a revision of national
drug policies.

The regional strategy will be reviewed, in view of the meeting discussions, and will be
submitted to the Regional Committee for endorsement.

Discussion

It was re-emphasized that it is up to the countries to start with injection safety in the
immunization services, or with injection safety in the health care services in general, within
the framework of infection control. The approach should be tailored to suit the individual
country situation.

The targets and the timeframe of the presented regional plan need revision, especially
the timeframe.

The participants highlighted their concern about injection safety within curative
services, especially sharps waste disposal, which is inseparable from disposal of sharps waste
from the preventive/immunization services. Therefore, collaboration with the curative
services and other sectors, such as the environmental sector, is essential.
8. FROM IMMUNIZATION SAFETY TO INFECTION CONTROL

8.1 Infection control in the health care setting
Dr M. Talaat

Brief review on epidemiology of nosocomial infections

Nosocomial infections are emerging as an important public health problem throughout the world. High rates of nosocomial infections lead to an increase in antimicrobial resistance, high costs in health care, and increased morbidity and mortality. They are considered a particular problem in countries with rapid development in health care services and the introduction of new technologies, and where infection control is not a well-recognized discipline.

Transmission of nosocomial infections occurs mainly from patient to patient, less frequently from patient to health care worker and rarely from health care worker to patient. Risk factors for the development of nosocomial infections are categorized into host factors, agent factors, environmental factors and technological factors. Patients with underlying disease and compromised immune system are at greater risk of infection, as are those exposed to invasive procedures such as catheterization, where intravenous lines add to the risk. Extremes of age (very young and very old) and poor nutritional status are also significant host risk factors. Agent factors include the virulence of the organisms, such as Staphylococcus aureus and Pseudomonas; antimicrobial resistance is highly influenced by usage patterns. Organisms that have the ability to survive in the environment and have resistance to disinfectants are risk factors. Environmental factors such as pollution of air, contamination of water and contamination of environmental surfaces are significant risk factors. Advanced technology adds new portals of entry, thus increasing the risk of development of nosocomial infections.

Surveillance for nosocomial infections

Surveillance for nosocomial infections is a complicated process that requires case definitions and case investigations, which are mostly complex and require advanced laboratory capacity. Data are reported from health care facilities and require a well-trained infection control practitioner. To be considered nosocomial, an infection must develop in patients exposed to hospital or to medical/surgical procedures that occurred in a health care environment, in patients hospitalized for 48–72 hours and where infection was not present on admission.

Evolution of infection control programme in Egypt

Blood-borne pathogens are considered major public health problems in Egypt. Hepatitis C infection prevalence varies from 10%–15%. Treatment of infected persons is considered an economic burden on the economy of the country. Hepatitis B virus infection is intermediate in level and three outbreaks of HIV/AIDS are reported due to poor infection control practices.
The Ministry of Health and Population in Egypt has declared prevention of blood-borne pathogens to be a leading public health priority for the country. The conceptual framework of the programme to promote infection control is applied through three main targets:

- promotion of safe injection practices in the community
- promotion of infection control practices in health care facilities
- promotion of safe blood transfusions.

The goals of the programme to promote infection control are to reduce hepatitis C transmission and hepatitis-related chronic liver disease, to reduce transmission of infectious diseases in the health care setting and to improve the quality of health care services through promotion of infection control. The specific objectives of the programme are promotion of safe injection practices through reduction of unnecessary injections and raising the awareness of the general public on safe injections.

Implementation of standard infection control practices in health care facilities is done through: the development of national guidelines for infection control; strengthening the capacity of the Ministry of Health and Population to implement and monitor the infection control programme; training of health care workers; and the promotion of occupational safety. The national programme for infection control is adopting a strategy with eight main components in order to standardize infection control practices:

- developing an organizational structure
- development of national guidelines for infection control
- training and capacity building
- surveillance of nosocomial infections
- ensuring procurement and distribution of supplies
- development of occupational health programme
- advocacy
- development and implementation of communication strategy to raise awareness of health care workers and the public on injection safety.

### 8.2 Infection control project in Egypt

*Dr. A. Kandil*

Unsafe injection and medical procedures have been associated with high percentage of hepatitis C infection in Egypt. Hepatitis C infection in Egypt has been estimated at 8%–10% of the population.

Assessment of infection control practices in health care facilities conducted in Egypt in 2001 revealed poor infection control practices, inappropriate sterilization procedures and lack of waste management systems. Based on these findings, the Ministry of Health and Population recognized the need to develop a national infection control plan to reduce the transmission of nosocomial infections. A unique infection control training programme was developed to introduce infection control in phases, targeting both doctors and nurses. The
training programme, hosted in large hospitals, included both technical and managerial components to allow participants to conduct practical exercises.

After two years of assessment, the following had been achieved:

- A ministerial degree was issued to initiate a national infection control at the Ministry of Health and Population
- A national organizational structure was developed and the infection control programme was initiated
- 80 master trainers from 25 general hospitals had completed their training by 2002
- 6000 health care workers were trained later by the master trainers
- Guidelines and educational materials, along with training materials, were included in the training programme.

9. GROUP WORK: DEVELOPING NATIONAL PLANS FOR IMPROVING IMMUNIZATION SAFETY

Participants of each country developed/updated the national plan for improving injection safety in immunization services. It was agreed that the draft plans would be finalized, endorsed and shared with EMRO before the programme managers’ meeting scheduled for June 2004.

10. RECOMMENDATIONS

To Member States

Policies, plans and standards

1. All countries should develop a national policy and plan of action for injection safety in EPI and other immunization services, including school-based programmes and immunization campaigns. This plan should be finalized and endorsed by national health authorities and shared with EMRO before the next intercountry meeting of EPI managers at the end of June 2004.

2. Countries should include injection safety as a core component of immunization services and allocate the required resources accordingly. EPIs are encouraged to coordinate with other sectors to promote safe injections in the wider context of health care services.

3. All countries should establish a national committee on immunization safety and identify a focal point responsible for ensuring safe injections and appropriate waste management in immunization services.

4. All countries should take the necessary steps for involving the private sector and other non-Ministry of Health health care providers, including issuing necessary legislation to
involve a representative of the private sector in the national committee for injection safety/infection control and in the relevant meetings and workshops.

Regular provision of injection equipment and supplies

5. All countries should use AD syringes for immunization services, unless absence of reuse has been documented through the WHO standard injection safety assessment.

6. EPI managers should ensure sustainable and bundled supply of critical materials for injection safety in immunization services, including appropriate syringes, reconstitution syringes, and safety boxes.

7. Countries should consider local production of safety boxes that meet WHO specifications.

Measures for the injection providers

8. EPI managers should ensure that all health care workers providing immunization are appropriately trained on injection safety.

9. All countries should develop policies to protect with hepatitis B vaccine health care workers who have occupational exposure to blood.

Proper waste management

10. EPI managers should coordinate with other sectors to ensure proper waste management. Necessary guidelines are to be developed.

11. Operational research to identify local solutions and best options for waste management is encouraged.

Reliable data on injection safety and regular monitoring and evaluation

12. Countries that have not conducted an injection safety assessment in health care settings that provide immunization services should do so by the end of 2004, using the WHO standardized tool C.

13. All countries should monitor AEFI in routine immunization services and in campaigns, using WHO surveillance guidelines.

14. Countries should include immunization safety as part of routine reporting and supervisory visits.

15. Countries should monitor regularly and report to EMRO on an annual basis the following indicators:
• Proportion of health facilities using AD syringes regularly
• Proportion of districts with waste management activities according to national plan (as proved by supervision)
• Proportion of immunization providers who received training on immunization safety regularly according to the national policy
• Proportion of facilities where injections are administered safely according to a supervisory checklist
• Proportion of districts with one member of health staff responsible for monitoring immunization safety
• Proportion of districts reporting supervision activities according to their national plan
• Proportion of districts reporting AEFI to the national level.

Behavioural change

16. All countries should develop strategies for implementation of behavioural change, to ensure safe injections and waste management, through public information and communication.

To WHO

17. EMRO should assist countries in conducting baseline assessment and monitoring of injection safety.

18. WHO and WMC should expand Project Focus on injection safety to other countries in the Region.

19. EMRO should include the following indicators for monitoring injection safety in the regional EPI management system:

• Proportion of countries with a national committee on immunization safety
• Proportion of countries with a national plan for immunization safety including safe injections, sharps disposal, waste management, and AEFI surveillance system
• Proportion of countries using AD syringes in all EPI immunization clinics
• Proportion of countries with >80% of districts with waste management activities according to their national policy
• Proportion of countries with >80% districts reporting AEFI.

20. EMRO should revise the regional plan of action in light of feedback from this meeting and the current situation and present it to the Regional Committee for endorsement in 2004.

21. EMRO should assist with strengthening technical capacity for immunization safety at the country level.
Annex 1

PROGRAMME

Sunday, 14 December 2003

08:30–09:00  Registration
09:00–09:30  Opening session
  – Message from Dr Hussein A. Gezairy, Regional Director
  – Objectives of the meeting
  – Introduction of participants
  – Election of officers
  – Adoption of the programme
09:30–10:45  Overview on immunization safety
  – Global overview, Dr P. Duclos
  – Regional situation, Dr S. Youssouf
10:45–11:45  Ensuring safety of injection
  – Injection equipment, Dr P. Duclos
  – Waste management, Dr P. Duclos
  – Behavioural change, Dr S. Khamassi
11:45–13:30  Assessment, monitoring, evaluation and supervision of immunization safety
  – Monitoring, evaluation and supervision, Dr E. Mohsni
  – Assessment of injection safety, Dr C. Mantel
13:30–16:00  Group work
  – Group 1: Sustained availability of injection equipments (cost, technology transfer)
  – Group 2: Waste disposal: best options and local approaches
  – Group 3: Monitoring and supervision of immunization safety, AEFI surveillance
  – Group 4: Advocacy, IEC and behavioural change
16:00–17:00  Presentation and discussion of the outcome of the group work

Monday, 15 December 2003

08:00–09:00  Ensuring safety outside EPI routine activities, Dr P. Duclos
  – Experience of the Islamic Republic of Iran with ensuring immunization safety during the measles catch-up campaign, Dr A.-R. Estighmati
09:00–11:15  Surveillance of AEFI, Dr F. Mahoney
  – Case study: AEFI
11:15–11:45  Advocacy and partnership
  – Project Focus in Syrian Arab Republic, Dr S. Khamassi
11:45–12:15  Injection safety in immunization services: regional strategy and plan of action 2002–2005, Dr N. Teleb
12:15–14:00  From immunization safety to infection control
– Infection control in the health care setting, Dr M. Talaat
– Infection control project: Egypt, Dr A. Kandil

14:00–17:00 Group work: developing national plans for improving immunization safety

**Tuesday, 16 December 2003**

09:00–11:00 Group work: developing national plans for improving immunization safety
11:00–13:00 Presentation of national plans
13:00–13:30 Conclusion and recommendations
13:30 Closing
Annex 2

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Annex 3

OUTCOME OF GROUP WORK

GROUP 1: SUSTAINED AVAILABILITY OF INJECTION EQUIPMENTS (COST, TECHNOLOGY TRANSFER)

Policy issues and commitment

- Need for country wide policy and for sustainable provision of all materials
- Policy to be decided by the country by raising awareness (sustainability for routine EPI)
- Wider context than just immunization (start with EPI then expand to other sectors)
- Policy must include waste disposal
- Majority of countries are using AD syringes or planning to except where there has been documented absence of reuse (still some committed to AD introduction)
- Need for financial assistance to poor countries
- Legislation.

Cost of AD syringes and safety boxes

- AD syringes slightly more expensive but the issue of political commitment is more important
- Cost should not be the overwhelming factor. Importance of sustainability of the same equipment
- Encouragement of local production specially of safety boxes
- Forecasting demand will increase production
- Possibility for countries to purchase through UNICEF to guarantee quality and help lower cost.

Importation versus local production and technology transfer

- Determine if local production is possible and viable
- Encourage local production of safety boxes (easier than for ADs)
- Explore potential for AD syringes in curative sector
- Envision interim importation before local production
- Countries to join forces to buy or produce AD syringes
- Importation should encourage local production.
Training: technical issues and cost

- Identify technical concerns of health workers and implement behavioural change strategy
- Cost of training should be taken into consideration
- Need for exchange of guidelines and training materials among countries
- Need for managerial training including monitoring and evaluation
- Question was raised of difficulty to train vaccinators versus other health personnel
- Training should be comprehensive (use of ADs as well as safety of injections.

Sustainability (mostly for GAVI-eligible countries)

- Consider issues of sustainability now (before external funding stops)
- Explore other sources (non-governmental organizations, beneficiaries)
- Cost sharing (e.g. government and GAVI).
GROUP 2: WASTE DISPOSAL

Waste disposal: situation analysis

Most of the countries do not have an institution or body responsible for health care waste management. There are almost no specific guidelines or policies on waste management.

The present methods for immunization waste disposal are:

- Open burning at local level in drums or pits
- Medium temperature incineration (some)
- High temperature incineration after transport (rarely)
- Collection by municipalities (final disposal unknown).

Waste disposal: assessment

- Only few countries have done a health care waste disposal assessment so far.
- Syria has developed a plan of action as a pilot within the Focus Project.

Waste disposal: preferred options

- Governorate and district level: high temperature incineration
- Local level: locally produced medium temperature incinerators
- Remote areas: safe burying (and open burning)
- In towns: collection and transport for incineration
- Recycling?

Waste disposal: responsibility

- Ministry of Health as lead agency
- Focal point in the Ministry of Health: Infection Control Unit
- Collaboration with EPI, family planning, environmental health, hygiene and sanitation etc.
- Intersectoral collaboration with
  - Ministry of Environment
  - Ministry of Municipalities.
GROUP 3: MONITORING IMMUNIZATION SAFETY

Regional level indicators

- Proportion of countries with a national committee on immunization safety
- Proportion of countries with a national programme for immunization safety including safe injections, AEFI surveillance, vaccine safety, waste management, sharps collection.
- Proportion of countries using AD syringes in >80% of districts
- Proportion of countries with >80% of districts with waste management activities according to their national policy
- Proportion of countries with >80% of districts reporting AEFI.

National level indicators

- Proportion of districts reporting AEFI
- Proportion of immunization providers who received training on immunization safety regularly according to their national policy
- Proportion of facilities where injections (immunizations?) are administered “safely” according to supervisory checklists
- Proportion of districts with a focal point for immunization safety
- Proportion of districts reporting supervision activities according to the national plan.

Supervisory activities

- Objectives
  - ensure “immunization” safety (EPI cannot be responsible for all injection safety).
- Level
  - national
  - provincial
  - district.
- Method
  - national guidelines for supervisory visits
  - managed at the provincial level through district supervisors
  - responsibility of district level EPI person.
- Tool
  - checklists
- Frequency
  - all facilities are inspected and determined to be “safe” on an annual basis
  - if they fail, more frequent supervision.
CASE STUDY: AEFI IN GORAN

The notes for facilitators are shown in italics

Background

The purpose of this case study is to familiarize participants with approaches to surveillance for AEFI. Although the country is fictitious, the scenario is a real and representative example of AEFI. In this case study we will focus on important aspects of surveillance and investigation of adverse events.

Learning objectives

At the end of this case study, participants should be able to:

1. Describe the steps of AEFI surveillance, reporting, investigation, response, and evaluation.
2. Identify the type of data that should be collected as part of an AEFI case investigation.
3. Discuss data analysis investigation and response of AEFI.

Part 1: Detection and reporting of AEFI (45 minutes)

Goran is a prosperous country in the Middle East that has a strong EPI. The country is in the midst of polio eradication initiative and is planning a national immunization day (NID) for the end of December 1999. On 1 December, the EPI manager at the national level receives a telephone call from a provincial health officer from Urgut who reports that during a planning session for the NID, one of the district health officers reported there has been a cluster of three unexplained deaths among children who attended the same immunization clinic in a rural area of Bulungur district. Residents in the community felt that the infant deaths were related to receipt of vaccine. The provincial health officer was concerned that public concern about vaccine safety will have a negative impact on the NID and is requesting assistance to investigate these events. Goran does not have a formal mechanism for reporting AEFI.

1. What additional information would you like to ask for from the EPI manager from Urgut?
   a. What are the clinical features?
   b. Are they consistent with known AEFI?
   c. What is the outcome of persons affected?
   d. Important epidemiologic information includes data on person, place and time (e.g. who is affected [age, gender, relations among cases] where they live, and when events occurred)
   e. Specifications of vaccine used in the clinic
f. Operational aspects of EPI in the district

g. Any history of programme error in this district/clinic?

h. Is this a single event? Are there additional cases in the community?

i. Are non-immunized persons experiencing the AEFI?

2. What type of events should be reported in an AEFI surveillance system?

a. Serious vaccine reactions such as BCG lymphadenitis, vaccine-associated polio, anaphylaxis, encephalopathy

b. All programme errors such as injection abscesses

c. All unexplained deaths that occur within one month of an immunization

d. All adverse events that require hospitalization

e. All medical events that are believed to have been caused by an immunization and about which people are concerned

f. Routine side effects that are common with most vaccines do not need to be reported.

3. Who should be involved in AEFI investigations? What are the advantages and disadvantages of local staff completing the investigation of AEFI?

   Mild adverse events can initially be investigated by the health worker who detected the case (e.g. health centre staff person) and reported to the Ministry of Health through completion of a case investigation form.

   Serious adverse events, particularly those involving an unexplained death, should be investigated by specially trained staff. The advantages of local staff in completing AEFI investigations include familiarity with local conditions, background rates of disease, and access to patients.

4. Adverse events are often classified according to the scheme outlined in Table 1. What type of adverse event do you think happened in Bulungur?

Table 1. Classification scheme of AEFI

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine reaction</td>
<td>Event caused or precipitated by the vaccine when given correctly; caused by the inherent problems in the vaccine</td>
</tr>
<tr>
<td>Programme error</td>
<td>Event caused by an error in vaccine preparation, handling or administration</td>
</tr>
<tr>
<td>Coincidental</td>
<td>Event that happens after immunization but not caused by the vaccine – an association due to chance</td>
</tr>
<tr>
<td>Injection reaction</td>
<td>Event from anxiety about or pain from the injection rather than the vaccine</td>
</tr>
<tr>
<td>Unknown</td>
<td>Cause of event cannot be determined</td>
</tr>
</tbody>
</table>
At this point in the investigation, we are not sure what happened but it seems most likely there is a programme error.

The provincial health officer reports the initial investigation was completed by the district health officer from Bulunger who discovered that all three deaths occurred in infants aged 2 months and who had received their first scheduled immunizations with diphtheria, pertussis and tetanus (DPT), oral poliovirus (OPV) and hepatitis B virus (HBV) vaccines in an agricultural village (village A). The immunizations had been administered in the same session on 29 November 1999, at the village health centre. Thirty children received immunizations at this session, and none of the other 27 children who attended this clinic were known to have presented to health care practitioners, nor were any other untoward events reported to local public health officials following immunization.

All three affected infants had been healthy prior to immunization and developed severe symptoms at approximately 12 hours post-immunization and died within 40 hours of immunization. The provincial health officer also interviewed local clinicians who reported all three infants had been managed in the intensive care unit of a nearby University Hospital where laboratory tests had demonstrated a severe metabolic acidosis, which proved unresponsive to conventional therapy. One infant had a spinal tap with clear cerebrospinal fluid (CSF). One infant had a low-grade fever. Temperature recordings were not available for the other infants. A local professor reported the infants had DTP encephalopathy related to a genetically predetermined immune response to vaccine components.

5. Based on what you know, do you consider these deaths to be AEFI?
   a. Yes, all unexplained deaths occurring within 1 month after receiving a vaccine are considered AEFI.

6. Is the clinical presentation consistent with known adverse reactions following immunization? Do you think these infants had DTP encephalopathy?
   a. No, the clinical presentation is not consistent with known side effects of vaccines that were administered to these infants. At this point in the investigation, we do not have enough clinical information to make a diagnosis of what is wrong. Beware of unexplained diagnosis for patients with unexplained disease.

7. What are the next steps in this investigation? Who should be on the investigative team?
   a. Organize a field investigation: organize an investigative team and conduct a field investigation.
      i. Include specially trained health care workers with experience in AEFI surveillance (a medical epidemiologist, clinician, person familiar with vaccines, laboratory)
   b. Interview cases: the first step in the investigation should be to interview patients or guardians to get a better understanding of the clinical syndrome. It is particularly important to let parents and the community know you are concerned about the health of their children and safety of vaccines.
   c. Case finding:
      i. Develop a case definition
      ii. Initiate case finding in neighbouring districts and other provinces?
   d. Medical care: It is important to ensure all affected clients are provided with optimal medical care. In this instance all the patients had died, but there may be additional patients in the community with less severe presentation who need care.
8. The provincial health officer asks your advice regarding whether or not to continue immunization services at village A?
   a. *At this point, it is not clear what is going on with the vaccination clinic in village A. Since these are serious adverse events, it is prudent to stop immunization services until you are certain about the safety of immunizations provided by the clinic in village A.*

9. What data should be collected at this point in the investigation?
   a. **Data on each patient:**
      i. Demographic
      ii. History of present illness: symptoms, when they appeared, duration, treatment, outcome, diagnosis
      iii. History of past illness: reactions to previous doses, drug allergies, pre-existing medical conditions
      iv. Other exposures in the community: sick family members, current medications
      v. Immunization history
      vi. Medical tests and laboratory results.
   
   b. **Data about the vaccine:**
      i. Lot number
      ii. Expiration date
      iii. Manufacturer
      iv. When and from where vaccine was sent
      v. Laboratory results about the vaccine.
   
   c. **Program-related data:**
      i. Practices followed by health care workers in
         - storing,
         - handling vaccine during sessions
         - jandling vaccines after sessions
         - open vial policies
      ii. Practices in vaccine reconstitution and giving immunizations
         - correct dilents?
         - sterile diluents?
         - correct doses?
         - injection route
      iii. Availability of needles and syringes
         - any reuse of vaccine syringes?
   
   d. **Data on other persons in the area:**
      i. Number of persons who received vaccine from the same session, lot or both
      ii. Number of non-immunized persons or persons immunized with different lots who fell ill with similar symptoms.
   
   e. **Name of health care worker who immunized affected infants:**

10. How would you go about finding additional cases?
    a. *There are a variety of methods for case finding depending on the AEFI. Let the participants express different methods for this situation.*
Part 2: AEFI investigation in Bulungur

The Ministry of Health organized a field investigative team including epidemiologists, clinicians and vaccine experts. Medical records at four nearby hospitals were reviewed for infants meeting the following case definition:

Any child 9 months of age or less hospitalized in 1999 with convulsions, alteration in level of consciousness or a diagnosis of encephalitis, encephalopathy, unexplained death, or death due to pneumonia. Children with only febrile convulsions and/or bacterial meningitis were excluded.

Investigators identified three other infants admitted within the past two months who died of unexplained causes in the district General Hospital from a neighbouring village (village B). These deaths were also suspected of being connected to immunization and all three infants received immunization services from the same clinic as children in village A.

Hospital records of the six fatal cases from villages B and A were reviewed, and the physicians who had cared for these children were interviewed by an expert committee (Table 2).

<table>
<thead>
<tr>
<th>Infant/village</th>
<th>Date of immunization (1999)</th>
<th>Age (years)</th>
<th>Time interval from immunization to onset of illness (hours)</th>
<th>Interval to death (hours)</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 B</td>
<td>20 Sept</td>
<td>3</td>
<td>48</td>
<td>48</td>
<td>Pneumonia</td>
</tr>
<tr>
<td>2 B</td>
<td>11 Oct</td>
<td>6</td>
<td>33</td>
<td>64</td>
<td>Encephalitis</td>
</tr>
<tr>
<td>3 B</td>
<td>11 Oct</td>
<td>4</td>
<td>57</td>
<td>&gt;61</td>
<td>Encephalitis</td>
</tr>
<tr>
<td>4 A</td>
<td>29 Nov</td>
<td>2</td>
<td>21</td>
<td>31</td>
<td>Post-DTP encephalitis</td>
</tr>
<tr>
<td>5 A</td>
<td>29 Nov</td>
<td>2</td>
<td>21</td>
<td>31</td>
<td>Post-DTP encephalitis</td>
</tr>
<tr>
<td>6 A</td>
<td>29 Nov</td>
<td>2</td>
<td>8</td>
<td>31</td>
<td>Post-DTP encephalitis</td>
</tr>
</tbody>
</table>

The available history of the clinical events both before and after admission to the district General Hospital was less detailed for patients from village B than for the cluster in village A. Two of the three children from village B were reported to have had a temperature of 38 °C on admission. For these three infants, the medical notes do not record any examination findings, imaging or laboratory studies to support the diagnosis applied. The cluster which
prompted the investigation, cases 4–6, were all managed in the intensive care unit of a nearby University Hospital, where they all exhibited a diminished level of consciousness. Laboratory tests revealed a severe metabolic acidosis (pH 7.2, 6.9, and 6.9, respectively on admission). Three of the children (cases 3, 4 and 6) were reported to have had convulsions. Respiratory depression and other severe respiratory abnormalities were recorded for cases 4–6. One infant (1) was believed to have pneumonia, and case 3 received therapy appropriate for respiratory depression. All six children lapsed into coma soon after admission and died, despite intensive supportive therapy. None of the children has a rash.

11. Based on the clinical information, what is your impression of the cause of these AEFI?

   a. During any epidemiological investigation it is useful to view findings as an interaction between the host, agent and environment.

\[
\begin{array}{c}
\text{Agent} \\
\downarrow \\
\text{Host} \\
\downarrow \\
\text{Environment}
\end{array}
\]

   Let participants discuss whether the clinical picture and epidemiological investigation is consistent with an infectious disease, problems specific to the host, or environmental exposures. There are numerous clues at this point in the investigation that should direct the fieldwork. See if the participants can elicit these:

   i. The only affected clients seem to be young children. Infants at 2 months of age are particularly vulnerable to a variety of infectious diseases and environmental threats

   ii. There is no clear evidence this is an infectious disease process

   iii. The severe metabolic acidosis is a particularly important clue, in particular the degree of acidosis and non-response to therapy such as toxic poisoning

   iv. All infants received services from the same clinic suggesting a common exposure

   v. The clinical picture is not consistent with an infectious cause.

   Overall, the clinical findings strongly suggest an environmental exposure (poisoning) related to receiving immunizations in Bulungur.

12. What type of questions and exposures would you like to explore when visiting the immunization clinic in village A?

   a. All procedures related to vaccine handling as outlined in question 9 (above)

   b. Other exposures the children may receive in the immunization clinic such as antipyretics, antibiotics, local medicines.

   The six children who died had been immunized at three different vaccination sessions: on 20 September 1999 in village B (one death), on 11 October 1999 in village B (two deaths)
and 29 November 1999 in village A (three deaths). Vaccines from three manufacturers were administered in the clinic and included DTP, HBV and OPV. No single lot of vaccine was used in all three sessions or on all children who died. All lots had been distributed to other clinics around Goran and no other similar incidents or adverse events have been reported in conjunction with their use. One lot of DTP utilized in the 11 October and 29 November clinic sessions has been tested for toxicity, but no abnormality was demonstrated. No other vaccine lot was used in more than one session. All lots of vaccines from the most recent session were also sent for safety testing which did not identify any problems. A stringent review of vaccine production protocols for the implicated batches concluded that they were acceptable, and found no indication of any practice that would have deleteriously affected vaccine quality. Vaccine storage, handling and administration practices were found to be good, and adhered closely to EPI guidelines. The refrigerators in which vaccines are stored did not contain any other products, so administration of an incorrect substance or medication was ruled out. The vaccines did not require reconstitution, so the possibility of contamination through an erroneous choice of diluent was also excluded. In all three clinic sessions, other children who remained well had been immunized with vaccines from the same vials used for children who later died. Post-immunization care advice offered to parents included the use of paracetamol to treat mild fever, and the instruction to bring the child back to the clinic in the event of any more serious illness, as advised by the national EPI guidelines. The nursing staff of the clinic also recommended prophylactic application of alcohol compresses at injection sites to minimize local reactions.

13. Based on the above findings, do you think the unexplained deaths are AEFI?
   a. Yes. The probability of children dying like this due to factors unrelated to immunization is very low. It very important for programme managers to understand that just because all vaccine handling procedures are correct and appear to be safe, it does not mean these are not AEFI. In fact, the EPI had investigated the previous deaths in this village and concluded they were not related to EPI or programme error. However, the programme did not identify the cause of death and failed to identify an unusual example of programme error.

14. What do you think caused these infant deaths?
   a. The original investigators strongly suspected that infants were exposed to an antipyretic that was improperly mixed as a cause of this outbreak. There are well-documented outbreaks of infant deaths due to pharmacists substituting ethylene glycol for propylene glycol in the preparation of paracetamol liquid. Other potential common exposures include infant formula, antibiotics.

15. You have been asked to interview the parents of affected children in their homes. What information would you like to obtain?
   a. Information on other exposures
   b. Information on feeding
   c. Type of formula
   d. Other children sick
   e. Sample of any medications
   f. Let the participants brainstorm.
A survey was conducted among the parents of children attending the immunization clinic in November, collecting information about the child's health, and social events preceding and following the immunization. Questions were asked about feeds, medicines and traditional remedies administered. These interviews documented previously unrecorded illness among vaccines following the 29 November clinic session. In addition to the three children who died, it was discovered that another four children were reported to have experienced drowsiness/unresponsiveness after immunization, and that they recovered without obvious sequelae. The early manifestation of illness among children who died included cessation of suckling in the first few hours post-immunization, followed by sleeping for several hours, before waking up grunting and with an altered, weak cry. Two of the deaths occurred in cousins living in the same household, but these had no close geographical relation to the other affected infant who died. None of the three earlier fatal cases from village B had any close geographical or social contact with each other’s households. There were no common oral medications administered to infants after vaccination. One child had received paracetamol, and this child remained well. No children received aspirin.

Despite careful exploration of other substances and/or medications which might have been concurrently administered to the children, no common factor could be detected for cases resulting in death with the exception of the application of "red alcohol"-impregnated compresses to both DPT and HBV injection sites; compresses were applied for long periods of time. All four children who became drowsy or unresponsive had also received red alcohol-impregnated compresses. The association between illness and exposure to red alcohol was statistically significant. Moreover, there was a dose response relationship between time of exposure to red alcohol and likelihood of illness. All six infants who died experienced prolonged exposure to red alcohol compresses.

In addition to children who received red alcohol-impregnated compresses, a number of other children received compresses soaked with water or with medicinal (clear) alcohol. None of these children became sick. The use of compresses at an injection site as an anti-inflammatory measure appeared to be prevalent in this community and was recommended by staff from the local immunization clinic. This advice was not derived from accepted guidelines and appears to have resulted from a well-intentioned attempt to incorporate local practices in order to reduce the risk of AEFI. Further investigation revealed red alcohol is methanol and is a by-product of the sugar cane industry. It is supplied in bulk to a number of companies for bottling and distribution. Red dye is added to distinguish the toxic methanol from medicinal alcohol, but the toxic potential of methanol is not indicated on the label, and many people are unaware of this danger.

16. What do you think was the cause of death for these infants?

17. How would you classify these AEFI?

Refer to Table 1 and let the participants discuss whether this was a programme error.
Part 3: Taking corrective action

The Ministry of Health in Goran concluded that methanol exposure was the cause of the unexplained deaths in Bulungur. Methanol exposure explains some of the unusual findings that were noted early in the investigation.

a. Pure methanol has an anomalously high diffusion rate through the epidermis, compared to ethanol and isopropanol, because of the more severe damage it causes to the skin.

b. Young infants are particularly at risk of rapid accumulation of a toxic dose because of their high surface area to volume ratio and increased absorptive capacity.

c. Methanol is metabolized by alcohol dehydrogenase to formic acid, which accounts for the severe metabolic acidosis.

d. The practice of recommending use of an alcohol compress in Bulungur clinic accounts for the clustering patients in village A and B.

18. Based on the results of the investigation, what actions should be taken at in Urgut and Bulungur?

19. What actions should be taken by EPI in Goran?