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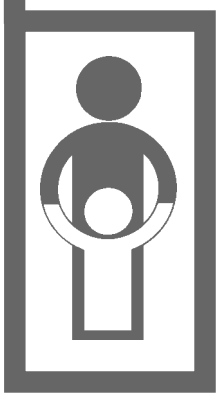
Report of the second meeting of the Steering Committee on Immunization Safety

Geneva, 26 -27 October 2000



Immunization Safety Priority Project

DEPARTMENT OF VACCINES AND BIOLOGICALS

World Health Organization
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International Federation of Red Cross and Red Crescent Societies (IFRC)
International Federation of Pharmaceutical Manufacturers' Associations (IFPMA)
International Council of Nurses (ICN)
Program for Appropriate Technologies for Health (PATH)
Safe Injection Global Network (SIGN)
United Nations Population Fund (UNFPA)
World Bank
World Medical Association (WMA)
and, most importantly, the national immunization programmes.

The Immunization Safety Priority Project would appreciate being informed of activities related to its mission and to learn of individual or institutional interest in collaborating with the Project.

Visit our web page: http://www.who.int/vaccines-diseases/safety/

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Abbreviations

AD	auto-disable (syringe)
AEFI	adverse events following immunization
BASICS	Basic Support for Institutionalizing Child Survival
DTP	diphtheria–tetanus–pertussis (vaccine)
BCT	Blood Safety and Clinical Technology
EPI	Expanded Programme on Immunization
GAVI	Global Alliance for Vaccines and Immunization
GFCV	Global Fund for Children's Vaccines
GTN	Global Training Network
HTP	Health Technology and Pharmaceuticals
HIV	human immunodeficiency virus
ICC	immunization coordination committee
ICN	International Council of Nurses
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
IFRC	International Federation of Red Cross and Red Crescent Societies
ISPP	Immunization Safety Priority Project
MSF	Médecins sans Frontières
OSD	organization of health service delivery
NRA	national regulatory authority
PATH	Program for Appropriate Technology in Health
R&D	research and development
SAGE	Strategic Advisory Group of Experts
SIGN	Safe Injection Global Network
SCIS	Steering Committee on Immunization Safety
TECHNET	Technical Network for Logistics in Health
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
V&B	Department of Vaccines and Biologicals
VVM	vaccine vial monitor
WMA	World Medical Association

Preface

Safety presents a paradox in the context of immunization programmes. Every year up to three million children's lives are saved by immunization and almost three million more could be saved from diseases that are preventable with existing vaccines. Yet in 1998 a third of vaccination-related injections were estimated to have been given in ways that did not guarantee sterility. Furthermore, vaccine safety issues and related rumours are poorly understood and handled by persons in charge of immunization programmes.

During its second meeting on 26-27 October 2000 the Steering Committee on Immunization Safety (SCIS) examined this paradox and proposed to advocate the full *and safe* immunization of children. While immunization programmes have received increased attention and support with the launch of the Global Alliance for Vaccines and Immunization (GAVI) in January 2000, immunization safety needs to be high on the agenda of decision-makers and the health community. For that reason the meeting focused on advocacy and the building of partnerships. Professional associations were invited to the meeting and demonstrated an enthusiasm for reinforcing partnerships and developing joint strategies with the Immunization Safety Priority Project (ISPP).

SCIS was formed to give advice on the strategic activities, constraints and requirements associated with accomplishing the ISPP goals. The recommendations at the end of the present report relate to these matters.

Part I summarizes the opening session and gives special attention to a subgroup meeting on indicators. Part II is a review of progress since the last meeting. Part III summarizes the presentations and discussion on advocacy and the building of partnerships. The conclusions and recommendations appear in Part IV.

Part I:
Opening session

I.1 Opening remarks

Dr Yasuhiro Suzuki, Executive Director of WHO's Health Technology and Pharmaceuticals (HTP) cluster, welcomed the SCIS members and associate members and all other participants. He drew attention to the importance of immunization safety, referring to ISPP, the Safe Injection Global Network (SIGN), and the Blood Safety and Clinical Technology (BCT) programme. He pointed out that other WHO clusters and departments were also collaborating with ISPP. For instance, the Protection of the Human Environment department was looking at the issue of waste disposal.

Dr Suzuki said that WHO's role was mainly as a catalyst for the establishment of a comprehensive system to ensure the safety of immunization at country level. ISPP involved partnership and extended collaboration. Nurses' and physicians' organizations had a major role to play. It was necessary to expand collaboration with them in particular.

GAVI had been officially launched in January 2000, and immunization safety had become very prominent on its agenda. The Global Fund for Children's Vaccines (GFCV) provided a major opportunity to assist countries in improving immunization safety.

WHO's Department of Vaccines and Biologicals (V&B) had been actively working towards the implementation of the very important recommendations made at the first SCIS meeting. SCIS had emphasized the need for increased advocacy, a crucial aspect of ISPP. The February 2000 issue of the *Bulletin of the World Health Organization* had featured immunization safety and had thus made a substantial contribution towards disseminating information on this subject.

Unfortunately, in 2000 there had been many new or resurfacing allegations on vaccine safety, relating to vaccines containing thiomersal (mercury), oral polio vaccine causing intussusception, simian virus and polio vaccine, and the issue of bovine spongiform encephalitis and polio vaccine.

A collaborative effort had been made with SIGN to develop an assessment tool for injection safety. This tool had been reviewed by a subgroup of SCIS in May 2000 and was subsequently field-tested in Burkina Faso, Ethiopia, and Niger.

Major progress was made in the use of auto-disable (AD) syringes following a joint statement issued by UNFPA, UNICEF and WHO and endorsed by IFRC. Some 300 million AD syringes were estimated to have been used during 2000, nearly twice as many as in 1999.

Other efforts had been made in the area of training, strengthening national regulatory authorities (NRAs), and fostering collaboration between NRAs and immunization programmes. All partners had been very active in their respective areas and were contributing greatly towards the achievement of common objectives.

I.2 Review of first SCIS meeting

Main outcomes

The SCIS Chairperson, Dr Carolyn Hardegree, recalled the main outcomes of the first meeting, during which the following terms of reference were specified.

- To review ISPP priorities and targets and propose modifications as appropriate.
- To review and criticize strategies that would best achieve the targets and strengthen the capacities of countries and WHO regional offices in all areas related to immunization safety.
- To assess progress in relation to the immunization safety work plan, milestones and indicators.
- To advise on the relative balance of focus, resources and activities for the achievement of the various products.
- To provide guidance in specific technical areas as necessary.
- To identify opportunities for enhancing the global visibility of and commitment to immunization safety in various areas, including that of resource mobilization.
- To explore ways of maximizing synergies with other partners involved in immunization safety.
- To advise on the possible contribution of ISPP to work in other parts of WHO.

During its first meeting, SCIS identified four particularly important areas: delivery of safe vaccines of high quality, with special attention to prevention and safety assurance; prompt monitoring and management of adverse events following immunization (AEFIs); strengthening NRAs; and developing collaboration between NRAs and the national managers of the immunization system. It was intended to measure progress with reference to these areas.

The first SCIS meeting approved ISPP as outlined in the V&B Strategic Plan for 2000-2003.

Recommendations of first SCIS meeting

Dr Hardegree reviewed the recommendations of the first SCIS meeting. Specific recommendations had been made in relation to vaccine safety, research and development on safer and simpler vaccine delivery systems, and the identification and management of risks related to immunization. Some general recommendations had been made on advocacy, general policies, training and monitoring.

I.3 Review of subgroup meeting on indicators

The first SCIS meeting recommended that a subgroup be formed to analyse and agree on indicators for measuring efforts to improve immunization safety. These indicators would assess safety in general terms and the impact of ISPP. A small number of SCIS members therefore met on 29 May 2000, together with specialists, to discuss outcome and progress measures related to immunization safety programmes.

Among the matters needing special attention were: the quality and safety of vaccines in the context of NRAs; the safety of immunization-related injections; the monitoring of AEFIs; and the management of injection waste. There were requirements to develop assessment tools for both routine activities and supplementary events such as mass campaigns.

It was necessary for the tools to be standardized and replicable, yet flexible enough to incorporate results from evaluations as they became available, i.e. they should be seen as undergoing development.

National Regulatory Authorities

Major progress had been made on strengthening NRA functions. The six NRA functions and performance indicators had been defined on the basis of input from 38 countries. During 2000, 25 assessments had been made and used to create a plan for the strengthening of NRAs.

The Global Training Network (GTN) was vital for the strengthening of NRAs. It consisted of 14 institutions that provided training in priority areas for vaccine production and control, using an approved syllabus and standardized documentation materials.

Injection Safety

A standard assessment tool for injection safety had been developed in collaboration with SIGN and Basic Support for Institutionalizing Child Survival (BASICS). This tool had been pilot-tested and in 2001 several injection safety assessments would be carried out in all regions. This new tool filled a gap in national injection safety policies. Recommendations had to be policy-oriented and had to give practical steps for reinforcing injection safety. Assessments would have to be repeated in order to monitor progress. Significant advances had been made in the assessment of injection safety.

Monitoring adverse events following immunization

ISPP had defined specific criteria for monitoring AEFIs: the availability of written programme guidelines; a list of adverse events to monitor, including serious unexpected ones; provision for communicating AEFI information for regulatory action; and provision for including AEFI monitoring as part of a vaccine licence. SCIS had noted that some countries had not reported any AEFIs for several years despite meeting these criteria. The absence of such reports was likely to indicate that a system was not functioning. Although it was impossible to suggest a significant expected rate of reporting of AEFIs which would fit all countries, it seemed that the existence of reports should be taken as an additional criterion.

Impact of ISPP

The subgroup was unable to come to detailed conclusions on how to evaluate the impact of ISPP on the overall global goal of improved immunization safety. The question was all the more complex because ISPP operated at the global, regional and country levels. However, it was desirable that further attention should eventually be given to this matter.

Recommendations

The subgroup made a number of specific recommendations on available assessment tools and mechanisms. Among these tools, the joint WHO/UNICEF reporting form for vaccine-preventable diseases was acknowledged as extremely useful. However, the inclusion was recommended of important immunization safety elements such as the number of AEFIs reported, the existence of a safety monitoring programme, the use of AD syringes, and the existence of mechanisms for the disposal of medical waste.

The subgroup recommended further development of mechanisms for:

- elaborating and monitoring concrete indicators for advocacy;
- developing indicators for preclinical and clinical studies;
- developing tools for evaluating the impact of training, notably GTN;
- building evaluation components into NRA development, specifically as it related to safety.

Part II: Progress since first SCIS meeting

II.1 Secretariat's progress report

Dr Philippe Duclos explained that ISPP encompassed four areas of work: research and development relating to safer and simpler delivery technologies; access to safe vaccine delivery systems and disposal; vaccine safety to the point of use; and risk identification and management. He recalled the strategies and targets and noted that ISPP played an important role in advocacy and information exchange.

Coordination and management

The V&B Strategic Plan was finalized in the first quarter of 2000 and provided ISPP with indicators and milestones for the close monitoring of activities. ISPP reported to the meetings of the Strategic Advisory Group of Experts (SAGE) held in November 1999 and June 2000.

Throughout the year, emphasis had been put on the development of assessment tools, on defining proper indicators and on safety during mass vaccination campaigns. Of vital importance had been the further support and attention needed for regional efforts.

Advocacy and information exchange

Progress had been made in the area of advocacy. A web page on immunization safety had been developed, covering "hot topics", a parents' forum, media and other matters, but the advances made were still too limited. The February 2000 issue of the *Bulletin of the World Health Organization* had successfully promoted immunization safety, and many conferences on immunization were now placing safety on their agendas. A CD-ROM dealing with immunization safety was under development and would offer an efficient means of disseminating information. The publication of a newsletter in the first months of 2001 would be a large step towards reaching immunization system managers and health care workers with safety messages. Other activities, such as a Cabinet paper leading to a possible World Health Assembly resolution on immunization safety, would contribute to ISPP's advocacy objective. A plan of communication would help to prioritize advocacy activities for the coming years.

ISPP had developed the following key messages on immunization safety.

To ensure vaccine safety:

- use only vaccines of demonstrated quality, safety and efficacy;
- optimize immunization safety by ensuring collaboration among all key players in the health community, particularly physicians and nurses;
- ensure commitment to child safety in the financing of immunization services;
- emphasize immunization safety as a priority in health system reform.

To secure injection safety:

- switch to AD syringes by 2003;
- rigorously adhere to sterilization procedures;
- do not recap syringes to prevent needle-stick.

To control safety of disposal:

- include immunization safety and waste disposal management in national immunization policies;
- raise awareness on medical waste disposal;
- implement these policies and procedures at all levels;
- ensure accountability for safe waste disposal.

SCIS endorsed the messages but requested that "strengthen NRAs" be added to the list of measures for ensuring vaccine safety.

It was worth noting the importance of GAVI and GFCV in providing a remarkable opportunity to improve safety. With the emergence of GAVI it became all the more important to assist Member States to deal with safety issues, particularly in the context of increased immunization activities. GAVI was also accelerating the development of safer novel delivery technologies.

Risk identification and management

WHO was participating in the Brighton collaboration, aiming to develop standard case definitions for AEFI monitoring. It was decided to merge GTN's training on AEFI monitoring with the building of media partnerships. Resource materials for these training activities had been published and were being translated into various languages. The Global Advisory Committee on Vaccine Safety was operational and had been utilized on several occasions. One of the largest challenges was that of post-marketing surveillance, because the rapid testing of false hypotheses could be very onerous and a large capacity was needed to validate data. International collaboration was crucial in this connection.. Such collaboration had proved particularly useful in relation to recurrent and new AEFIs that had occurred during the year. Among the important issues dealt with were concerns about measles-mumps-rubella vaccine in the United Kingdom, bovine spongiform encephalopathy and oral polio vaccine, the use of thiomersal in vaccines, rotavirus, and intussusception.

Safe vaccine administration and disposal

Surveys conducted in six countries during March 2000 showed that safe injection policies were not being implemented. The assessment tool for injection safety had proved extremely useful and would be further pilot-tested. In consultation with the regions, 60 countries would be identified and targeted for assessments. The proportion of targeted countries implementing a safe injection policy would become a key indicator.

Much progress had been made on the use of AD syringes: it was estimated that 300 million would have been used by the end of 2000, twice as many as in 1999. UNFPA, UNICEF and WHO had jointly made a firm commitment to increase the use of these syringes.

Significant progress had been made on safe disposal during 2000. A memorandum had been issued on waste disposal and the practical aspects of waste systems in relation to immunization activities. A database on local solutions for waste disposal would be available from WHO for people looking for practical low-cost solutions.

Vaccine quality

It was intended that 24 country assessments of the six functions of NRAs would be completed by the end of 2000. Training had been carried out through GTN, which was developed in 1996 as a means of strengthening vaccine regulators and producers so that all vaccines used in national immunization programmes would be of assured quality. GTN had become an important mechanism for ensuring standardized training and network-building for NRAs, qualified manufacturers and immunization and procurement staff.

Way forward in countries

Several activities were mentioned as requiring increased support in the coming years. It was considered that ISPP should give special attention to benchmarking ideal systems and indicators, that safety assessments should be pursued and that NRA functions should be further reinforced. There was a crucial need to develop plans of action in conjunction with the immunization coordination committees (ICCs) covering injection safety, immunization safety, and monitoring. It was also necessary to strengthen the link with NRAs, other health services, professional organizations and the media and to monitor the impact of interventions.

Progress

Major milestones had been achieved in 1999 and 2000, especially with respect to document preparation, and platforms had been established in specific technical areas, such as the Global Advisory Committee on Vaccine Safety, the Task Force on Cell Substrate, and SCIS. The priority project may lag behind in the areas of training and promotion of safe injection practices (as defined by the WHO standardized surveys).

II.2 Role of WHO in immunization safety: headquarters initiatives

Strategic Advisory Group of Experts

A brief presentation was given on SAGE and its interaction with ISPP. The meeting format of SAGE had been restructured such that on the first day there would be three parallel sessions reflecting the three objectives of V&B, with a special focus on accelerated vaccine introduction, immunization safety and polio eradication. On the second day there would be a plenary session.

SCIS was invited to participate in the session dealing with immunization safety. Some members of SCIS were already participating in SAGE. In general there was a need to reinforce synergies between SCIS and SAGE. For practical reasons it was proposed that the next meeting of SCIS be arranged in the same period and venue as SAGE meeting.

Global Alliance for Vaccines and Immunization

Michel Zaffran reported on GAVI, a partnership dedicated to ensuring that all children, however poor, had equal access to immunization. WHO is a member of the GAVI Board and is leading the task forces on country coordination and research and development.

GAVI has five strategic objectives: improvement of access to sustainable immunization services; expansion of the use of all existing cost-effective vaccines; accelerated introduction of new vaccines; acceleration of vaccine R&D for developing countries with respect to HIV, malaria and tuberculosis; and making immunization coverage a centrepiece in the design and assessment of international development efforts.

GFCV is GAVI's principal tool. The basic conditions for access to the fund are a population below 150 million, a GNP per capita below US$ 1000, a functional ICC or equivalent, an immunization assessment conducted in the last three years, and a multiyear plan for immunization. Programme performance based on DTP3 coverage determines which GFCV subaccount can be applied to by countries, as follows:

- For DTP3 coverage below 50%: the subaccount for strengthening immunization services only.
- For DTP3 coverage from 50% to 80%: the subaccounts for immunization services and new and underused vaccines.
- For DTP3 coverage above 80%: the subaccount for new and underused vaccines only.

Within the GFCV eligibility criteria, 24 applications had been received and 13 countries had been approved subject to clarification on key issues.

AD syringes and safety boxes would be supplied with all new vaccines introduced. All applicant countries were requested to confirm their commitment to WHO/UNICEF/UNFPA policy on injection safety.[1]

[1] *Safety of injections: WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services.* Geneva, World Health Organization, 1999 (WHO/V&B/99.25).

Immunization safety and GAVI

The participation of two members of SCIS in the GAVI review team dealing with applications to GFCV helped to ensure that safety was included in the GAVI process. In the mid-term review of countries receiving GAVI support, quality indicators would include immunization safety indicators, i.e. the use of AD syringes, waste management and AEFI monitoring. The Task Force on Research and Development offered another avenue for dealing with immunization safety. Similarly, the subaccount for research and development could be used for improving immunization safety. The Task Force on Advocacy would be able to adopt the safety issue as one of its activities.

Critical issues

Technical assistance is a key issue in the GAVI process. Countries needed increased support for capacity-building. The Task force on Country Coordination, under the leadership of WHO, provides support to several countries. The bundling policy on AD syringes is another issue requiring consideration by ICCs. Increased efforts were needed in the areas of waste management and AEFI monitoring. There were few effective systems in place and countries needed policies and multiyear planning in order to tackle these matters.

Where GAVI focused primarily on vaccine procurement there is a need for technical support in capacity-building. Although GFCV is making a big difference, partners will continue to play an important complementary role.

Safe Injection Global Network

Dr Yvan Hutin reported on the annual meeting of SIGN held in Cairo on 21-25 October 2000. He explained that SIGN was a network of nongovernmental organizations, United Nations agencies, associations, industry and governments. Its associates had agreed to collaborate in the exchange of information, the coordination of communication strategies and the development of a common strategic network.

The following areas of work were defined during the meeting.

- Great value was attached to the bundling policy for AD syringes and GAVI's support for it, although a number of challenges arose in this connection: the supply of safety boxes had to be adequate; AD syringes were provided only for certain vaccines, and this created some confusion in the vaccination programme.
- The promotion of coverage as the primary indicator of programme effectiveness would detract from safety. It was desirable to use safety as a primary indicator.
- SIGN could assist GAVI and immunization services in finding strategies to resolve the challenges created by multiple sources of injection equipment and sharps boxes. GAVI should push for a comprehensive approach to safe injection (behavioural change, integrated approach to provision of supplies, sharps waste management). There was a potential use of the assessment tool for injection safety.

Immunization safety within the health system

Dr Jean-Marc Olivé reported on the establishment of "strengthening immunization services" as a new priority project. WHO had defined four major functions of a health system as stewardship, resource development, financing, and service delivery. The goals and objectives of health systems were good health (survival free of disability), responsiveness (respect for persons, client orientation) and fairness (of financial contributions).

The five components of immunization services were vaccine supply and quality, logistics, service delivery, surveillance, and advocacy and communication. ISPP was attempting to strengthen the impact of immunization services as a component of health delivery systems.

Each team and the other priority projects within V&B had to develop an inventory of the areas of activity in each immunization component and related to each health system function. Furthermore, the main end goals and outputs had to be defined. The key questions were: "What are we doing that fits into these outputs?"; "What are we not doing and what should we do?" (i.e. identify gaps); "If what we are doing has no links with the output, should we be doing it?" (i.e. create a strategic plan).

Once the main gaps had been identified and agreement had been reached on the main activities, the work plan could be developed, a timeline defined, and the cost established.

Concern was expressed over this framework if it was to be used as an assessment methodology at country level. Within it, differing degrees of health sector reform might be badly reflected. However, the framework was internal to WHO and as such would not affect structures at country level.

Dr Naeema Al-Gasseer reported on the organization of health service delivery (OSD) in the context of immunization safety. The aim was to help Member States to improve the performance of health system functions so that they responded better to people's needs by promoting equity, quality, efficiency and the active involvement of civil society. OSD involved three teams:

- Capacity Strengthening for Planning and Management;
- Health Facilities and Services Provision;
- Human Resources for Health.

The latter related to immunization safety. OSD dealt with human resources development, performance monitoring, preservice curriculum, and accreditation. It focused on safe injection practices among nurses and midwives. Preservice training and the strengthening of management were major aspects of human resources for health. There was growing concern about high staff turnover and shortages of nurses and midwifes. Developed countries were recruiting staff from developing countries, thus aggravating the problem.

Dr Al-Gasseer emphasized that even with a proper provision of AD syringes and safety boxes, quality might not reach the expected standards unless a systemic approach was adopted.

New vaccination approaches

Dr Teresa Aguado reported on the status of several projects under the Steering Committee of New Vaccination Approaches. WHO is working with PATH and other bodies to expand the benefits of safer and simpler vaccination to impoverished populations. Attention will be concentrated on selected vaccination related technologies in order to address the principal bottlenecks. New Vaccination Approaches has a comprehensive objective of improving logistics, safety and access to full vaccination coverage. There are two specific research areas: a) the improvement of immunogenicity, focused on investigation into the immunization of special groups (e.g. neonates, HIV seropositive people) and the development of new immunization strategies (e.g. prime boost, reduced doses regimens) and b) the development of simplified delivery systems, using, for example, slow-release systems, mucosal vaccination, transcutaneous vaccination and sugar-stabilized vaccines.

Mucosal vaccines: as an alternative to parenteral administration of vaccines, mucosal vaccination either by nasal/oral routes offers obvious advantages in terms of safety as it eliminates the risks of infection (person-to-person, person-to-health worker and environmental), are generally more readily accepted than injectable vaccines and offer large logistic advantages for immunization programmes as the polio eradication initiative is demonstrating.

The successful experience with the oral trivalent attenuated Sabin poliovirus vaccine, which is the major driver in the global polio eradication effort, triggered research to develop and license new oral vaccine formulations. There have been a few successes such as the Ty21 a live oral typhoid vaccine, CVD 103-HgR live oral cholera vaccine, combined B-subunit inactivated *Vibrio cholerae* 01 strain oral vaccine, and the trivalent cold-adapted live intranasal influenza vaccine. There has also been some drawbacks, most notably the case of the oral tetravalent human-rhesus reassortant rotavirus vaccine which following studies suggesting a link between the vaccine and intussusception, was no longer recommended for infant use by the US Advisory Committee on Immunization Practices (ACIP).

New delivery systems are now being developed for the administration of non-living living vaccine antigens (proteosomes, cytokines) to mucosal surfaces. The application of recombinant DNA technology has also allowed for the construction of recombinant strains which may prove useful as either vaccines or vectors by which to deliver vaccine antigens. Furthermore, DNA vaccine plasmids have been successfully delivered in animal models via mucosal surfaces with non-living delivery systems and live vectors. Finally, the potential impact of oral vaccines could be even greater if one consider the possibility of using transgenic plants, such as tomatoes or bananas, as vehicles where vaccine antigens could be expressed and which would then be administered as edible vaccines. Subunit vaccines produced in plants against viruses (Norwalk, hepatitis B) or bacteria (ETEC, cholera) have been shown to induce strong immune responses in animals and encouraging data was also shown in a phase I

"proof of principle" clinical trial, where 90% of individuals who were fed small amounts of transgenic potato expressing LT B subunit developed significant rises in serum IgG LT antitoxin.

Transcutaneous immunization: (TCI), the simple introduction of antigens to the host using a topical application to intact skin, may have profound implications for immunization programmes both for their safety and immunological merits. From a safety point of view, TCI is a simple, needle-free vaccine delivery system with the potential to eliminate risks associated with injection devices. The feasibility of TCI is based on skin's role as a potent immunologic site. Penetration of the skin through hydration is a key component to target Langerhans cells, potent antigen-presenting cells found in the superficial layers of skin. Langerhans cells are abundant in the skin (25% of surface area) and are highly phagocytic, eliciting costimulatory molecules and cytokines. Pre-clinical studies have shown that TCI is able to induce priming and secondary humoral immune responses, without signs of local or systemic toxicity. Phase I and II trials are in progress.

Sugar-dried stabilized vaccines: air-drying in the presence of certain sugars such as trehalose or its derivatives, produces a powder which is chemically inert, completely heat-stable, unaffected by ambient humidity and whose particle size and rate of dissolution in aqueous liquid can be controlled accurately. Sugar-based dry powders may also allow the vaccine to be presented in the same form and the same volume in which it is to be administered. Besides, refinement of novel biocompatible sugar glasses may not only serve to stabilize vaccine antigens but also to control their release rate according to the glass composition. Release is triggered by contact with water or body fluids. This induces surface erosion of the glass so that the active remains embedded in the glass's protective matrix and will only come into contact with body fluids at the moment of release. If the sugar glass controlled-release version proves to be effective, the outlook for this technology as a fundamental component for drug and vaccine development will be most appealing. Already, sugar-based dry powder vaccines are starting to be tested in animals – and occasionally in humans – and few companies are currently focusing on the development of injection devices to deliver them. The most advanced, PowderJect™, is designed to deliver powder and could inject particles of sugar-dried vaccine directly into the epidermis and has already been tested in human volunteers.

II.3 Role of WHO in immunization safety: regional perspectives

African Region

Ms Boi-Betty Betts reported on immunization safety in the African Region, where several countries were struggling to integrate injection safety policy into their overall health systems.

Injection safety practices

Injection safety studies involving the use of AD syringes, standard disposable syringes and sterilizable syringes had recently been conducted by WHO in Côte d'Ivoire, Ghana, and Uganda. The risks of contamination between patients, between patients and health workers, and between patients and communities were much lower with AD syringes than with the other syringes. In many countries, disposable syringes were used more than once and not disposed of adequately. Health workers were

either not well trained or not properly applying the training they had received. Overall cost to the health service was nearly 10 times less costly with AD syringes than with the other syringes.

Logistics management

Some failings in injection safety were attributable to poor logistics management of both injection material and sharps disposal material and equipment. The causes were either inadequate materials or insufficient quantities of them in relation to the number of doses of various antigens given. There was a need to reinforce the bundling policy.

Limiting factors for injection safety

Most countries had either no national plan or did not implement their immunization safety plans. Assuring safe injections did not appear to be a priority in national programmes, despite the availability of adequate technology and resources for this purpose.

Most countries were still grappling with the idea of self-financing all their immunization needs, i.e. procurement of vaccines and acquisition of cold chain equipment, injection materials and other items, entirely from government budgets. Some countries were finding it difficult to meet the high cost of vaccines and other immunization materials. Very few were in a financial position to fulfil the objectives of the WHO/UNICEF safe injection policy.

The way forward

The five-year Strategic Plan proposed:

(a) to support all countries:

- in developing policies for the use of AD syringes in national programmes with appropriate funding plans by 2000;
- in establishing national policies for the safe disposal of injection materials with appropriate funding plans for implementation by 2002;
- in fully adopting and implementing WHO bundling policy for the use of AD syringes in the delivery of all immunization services by 2003;

(b) to support all countries using disposable syringes to switch to AD syringes by 2001;

(c) to support all countries using sterilizable syringes to switch to AD syringes by 2003;

(d) to provide support for at least two countries with immediate viable markets for AD syringes to produce them locally for national and subnational needs by 2004.

The plan for capacity-building in the area of immunization safety involved the training of health workers in all immunization delivery services. This would help health workers who were facing the challenges of new technologies. These activities would be conducted in collaboration with other partners involved in immunization safety practices (e.g. PATH, UNICEF). Training activities, and consequently immunization programmes, were adversely affected by high staff turnover. It was therefore necessary for such activities to be augmented.

Ms Betts pointed out that a more holistic approach to the safety of immunization injections was required, as safety in this field resulted from a combination of efforts. She also noted that there was a need to improve the law on environmental protection in some countries in order to cover safe disposal.

Region of the Americas

Dr Carlos Castillo considered the management of immunization safety concerns, the quality of vaccines, and the safety of injections in the Region of the Americas.

The monitoring of immunization safety and its integration into health systems represented a complex responsibility shared by national vaccination programmes, NRAs, quality control laboratories and health workers.

Managing immunization safety concerns

A guide had been prepared for health workers and professionals on effectively managing and responding to public concerns about the safety of vaccines. It was desirable that any adverse event perceived as being vaccine-related by the public, parents, recipients or health workers should be investigated immediately at the local level. The purpose of detecting, investigating and analysing such events was to take action on the basis of the conclusions derived.

Brazil and Cuba had prepared manuals for the education of health workers and had designed a system for monitoring the frequency of such events.

Other significant activities relating to immunization safety were as follows:

- The Bahamas, Brazil, Chile, and Guyana, and other countries of the English-speaking Caribbean, had established systems for monitoring adverse events attributed to vaccination campaigns.
- Brazil, Colombia, Guatemala, and Panama had provided a rapid response, analysing and investigating events attributed to the vaccines administered during systematic vaccination efforts.
- Cuba was conducting a causality study in respect of OPV vaccine and intussusception.

No evidence had been found linking cases investigated during the preceding year to vaccine quality. In some instances there were connections with operational aspects of programmes, and the appropriate corrective measures had immediately been implemented.

Press reporting of events had often led to public confusion. This underscored the need to work with the media in order to promote better understanding and communication with the community.

With a view to improving immunization safety at different levels, action had been taken to:

- notify, investigate and analyse events attributed to vaccines;
- ensure efficient and effective communication with populations, health workers and the media;
- reinforce training activities at all levels on the risks of negative reporting and on working with the media;
- raise awareness among health workers of the events caused by programme errors and of the types and frequencies of events attributed to specific vaccines;
- establish an alliance with the media;
- identify centres and laboratories capable of collaborating in the determination of causal relationships.

Vaccines of high quality

Ms Betts remarked that it was essential to use vaccines of proven quality in immunization systems. NRAs and immunization systems had to verify and insist that the objective of high quality was fulfilled.

The Pan American Health Organization had sought to strengthen the vaccine quality control system by organizing a network of certified national control laboratories responsible for testing the quality of vaccine and by harmonizing the regulatory procedures of NRAs of all countries.

Injection safety

The regional effort had focused on the recommended utilization of AD syringes. Any country using or introducing single-use disposable syringes had to provide the funds for the procurement of an adequate number of syringes and safety boxes, for the supervision of safe disposal of syringes, and for the collection and/or burning of used equipment. The Regional Office had provided support for development studies on needle injection devices.

Perspectives

It was foreseen that countries would continue to integrate immunization safety into health system reform in three major areas: 1) organizing the provision of services, 2) financing, and 3) executing a steering or regulatory role. In particular, countries were expected to reinforce their actions in:

- advocacy on safe immunization;
- proper costing of vaccination, including safe delivery systems and waste disposal;
- monitoring concerns about vaccination and injection safety;
- strengthening the functions of NRAs.

Eastern Mediterranean Region

Dr Taky Gaafar concentrated on mass campaigns, especially the measles elimination campaign, during which safety had been of particular significance.

The safety of injections had been included as a main component of the plan for immunization systems. The safety of immunization and the use of AD syringes were regularly on the agenda of the annual intercountry meeting. Two countries were already using AD syringes for routine activities. Waste disposal was the major problem in the Eastern Mediterranean Region, even where AD syringes were used for routine activities. Progress was being made in using safety boxes in routine activities. It was desirable to use safety boxes in all campaigns. The Region had tested and proposed to TECHNET a hot-air oven for the destruction of used syringes by creating a non-dangerous melted plastic cake. The cost of this oven was far less than that of the usual type of incinerator.

Dr Gaafar remarked that numerous training activities were available for health workers in various countries. A toolbox had been developed for the training of health workers. The training of trainers had started in a number of countries so that the regional toolbox could be used. Trainers in each country would train other health workers of Member States.

It was decided that plans for mass campaigns should be based on an assessment of the current safety situation in the country concerned, as revealed by a WHO standard assessment of injection safety. Such assessments were expected to start soon in Egypt and Morocco, and the results would be used in other Member States. The question of injection safety had to be considered in detail during the evaluation of any mass immunization campaign.

Every Member State would revise its national plan of action and provide a five-year plan that would include all aspects of safety for routine and supplementary immunizations. The assessment tool of injection safety would be used to prepare the plan of action for the future of the immunization system. The objective was that all Member States should have safe injection practices by 2005. The fact that AD syringes were going to be produced in Egypt would undoubtedly contribute to the attainment of this objective.

European Region

Dr Alenka Kraigher commented on issues related to immunization safety in the European Region.

Since the previous SCIS meeting there had been more proposals than action, and safety issues had not received special attention. AEFIs had been discussed at the last meeting of immunization programme managers in 1998.

The situation varied greatly between countries. Increased efforts were needed in countries in transition, where domestic vaccine production was limited because vaccines had previously been received from Russia. There was a need to focus on obtaining technical support that would lead to self-sufficiency in these countries. Support was needed in some countries for dealing with AEFIs. Training would be received in some countries through a GTN workshop organized in Armenia.

A project coordinated by Dr Patrick Olin for improving the monitoring of adverse events (EUVACSAFE) in the European Union had been submitted to the European Commission with a request for funding. The newly appointed regional adviser on immunization systems would soon develop a comprehensive regional plan of action on immunization safety.

South-East Asia Region

Ms Vidhya Genesh described the situation of immunization safety in the South-East Asia Region.

Injection safety assessments

Assessments had been made in Indonesia, Myanmar, and Nepal. Further surveys were planned for Bangladesh, Bhutan, and Nepal. NRAs had been assessed in India, Indonesia, Sri Lanka, and Thailand. The Region was participating in and giving support to GTN.

Regional issues

The bundling policy and GAVI policy were of particular concern for some Member States. The problem of AEFIs and the regulation of vaccine quality was also a matter of special concern: vaccine-related deaths occurred in India and Sri Lanka after the use of vaccines that had been produced in the absence of quality control. These instances highlighted the crucial role of NRAs in post-marketing surveillance and regulation.

Regional initiatives

The Regional Office for South-East Asia had created a Task Force on Regional Vaccine Security, whose next meeting was scheduled for January 2001. A Regional Working Group on Immunization had been created in response to a request from GAVI. Injection safety had been put on the agendas of all these meetings. An intercountry workshop on all aspects of immunization safety would be held in Sri Lanka.

SCIS discussed the difficulties related to the identification of AEFIs. Concerns were expressed about the transmission of HIV/AIDS through unsafe injection practices, although projections were extremely difficult to make. Attention was drawn to the need to improve regulations for waste disposal.

Western Pacific Region

No report was presented on immunization safety in the Western Pacific Region because no representative was able to attend the meeting.

Part III: Breaking new ground

The first SCIS meeting recommended that strategies be developed to assure advocacy for vaccine safety and to target appropriate levels of government and the health care delivery system, and not only the managers of immunization systems. It also recommended that WHO should continue to expand collaboration, communication and coordination with key partners. Professional organizations were therefore invited to the second meeting.

ISPP has developed advocacy messages on vaccine quality, injection safety and the safe disposal of waste. These messages are essential for the development of a strategy on advocacy.

III.1 Advocacy

BBC World Service Trust

The BBC World Service Trust is a non-profit, charitable organization. It operates by developing partnerships between ministries of health and local media. The building of such partnerships ensures local ownership of campaigns and cultural sensibility, results in skills being transferred to local media, and makes projects sustainable and affordable.

In collaboration with WHO the BBC World Service Trust has launched a campaign to promote safe immunization injections in Tanzania. Similar campaigns have shown that behaviour can change markedly in a short time. Partnership has always been a key factor in the success of campaigns, as, for instance, was found in India and Nepal.

A campaign always starts with a preliminary survey. In Tanzania the initial survey showed that 47% of observed injections were unsafe, that there was a crucial lack of disposal procedures in 84% of facilities, and that there was a general lack of awareness of the risks of unsafe practices. On this basis a magazine for health workers was created which contained safety messages in a photo story, cartoons, articles, and interviews, 15 000 copies were printed. A leaflet on safe disposal was produced for all preventive and curative staff. Posters dealing with the same subject were targeted at health workers and the communities around health centres. In the second phase of the campaign it is intended that radio and television will be used to promote and increase routine immunization coverage.

SCIS emphasized the need to work positively with the media. The safety of injections was a moral responsibility of all involved. Every child had the right to safe injections. No compromise was acceptable in this regard.

The question as to whether ISPP needed a champion for the purpose of advocacy was discussed. It was felt that this was not required but it was agreed that an advocacy strategy should be further elaborated with reference to the main results that were desired. Health professionals were the primary target of the advocacy strategy and messages. The three key ISPP advocacy messages were re-emphasized: ensuring the safety of vaccines, securing the safety of injections, and controlling the safety of disposals.

SCIS stressed the importance of advocacy as a means of reaching people at a high political level and of convincing them to include immunization safety in their activities.

SCIS urged that there should be a link between coverage and safety. The strong pressure for coverage associated with the GAVI process was positive if combined with a drive for safety. WHO's role was to ensure that recipients continued to trust immunization programmes, and this was only attainable if safety issues were dealt with.

III.2 Added value of professional organizations

Role of professional organizations

Ms Beverly Malone, Deputy Assistant Secretary for Health, USA, discussed the role of professional organizations in the context of immunization safety. She remarked that safety was a component of quality, in other words quality could not be achieved without safety. Higher quality standards would translate into better safety. Increasing the quality of training for health care workers would undoubtedly foster safety. It was essential for safety to be a concern of everyone dealing with health. The training of health professionals had to be reinforced, and special attention had to be given to cultural diversity.

Ms Malone remarked that the quality of the health system should be raised in order to increase its safety. Some elements in the system could lead to errors, no matter how much training was provided. Health care workers had to be encouraged to report errors and adverse events.

Ms Malone made the following recommendations for improving immunization safety:

- quality and safety should be considered within a systemic approach;
- minimum standards should be established for health professionals through their organizations;
- further steps should be taken to improve the diversity and cultural competence of health care workers, and to provide training in the treatment of chronic diseases and disabilities;
- health care workers should be encouraged to identify and report errors and instances of improper or dangerous care.

Professional organizations were important advocacy groups. Messages advocating immunization safety could undoubtedly be disseminated by these organizations. The question arose as to how safety could become a central concern for them.

Ms Malone was convinced that, when the public became engaged in safety matters, the professional organizations would follow. They could be expected to question how nurses, doctors and pharmacists were affected, and to ask how the training of health care workers might be improved in order to provide care more safely.

In order to stimulate effective collaboration with professional organizations the initial step might be to present a convincing success story. Other possibilities would be to:

- target long-term relationships with, and commitments of partners;
- develop joint funding opportunities;
- arrange face-to-face meetings with professional organizations;
- use a prominent public figure;
- design media campaigns in cetain countries.

The main obstacles were shortcomings in vision, models, leadership and communication. It was necessary to issue the same message repeatedly in diverse ways and at different locations. A network of people was needed to provide a constant message. Professional organizations were essential in the task of disseminating messages on immunization safety.

International Council of Nurses

Dr Tesfamicael Ghebrehiwet indicated how the International Council of Nurses (ICN) might contribute to immunization safety. There were 122 national nurses' associations representing over 11 million nurses. The ICN network could be used to disseminate materials and messages on immunization among almost all nurses. The effect could be maximized by establishing a partnership with WHO and others at the regional or country level. The ICN worked in three main areas:

- developing professional curriculum and training activities;
- issuing regulations on quality and standards;
- coordinating negotiations on the working conditions of nurses.

The following activities of ICN were designed to promote immunization safety:

- mobilization of its network of nurses around safety messages;
- continuous education programmes on immunization at its congresses;
- partnership with SIGN and contribution to the review of the policy on best practice.

ICN could easily communicate with nurses on safety issues as it had a strong outreach capacity. This potential could be used, for instance, to develop safety guidelines and other training materials, to develop fact sheets on immunization safety, to build capacity, and to be involved in training activities with WHO. Messages on safety could be channelled through the various media used by ICN. In partnership with WHO, ICN wished to create a culture of immunization safety and to promote the concept of the fully and safely immunized child.

World Medical Association

Dr Delon Human explained that the World Medical Association (WMA) comprised seven million physicians, concerned mainly with medical ethics, human rights and professional standards. In total, close to a billion patients were seen annually by members of ICN and WMA, and this represented a significant opportunity for disseminating safety messages and changing practices. WMA strongly believed that it could be a partner in lobbying for immunization safety with a patient-oriented focus. Dr Human said that WMA was ready to be included in initiatives and to use its network in the interest of immunization safety, ensuring which was a moral duty.

Médecins sans Frontières

Dr Jean-Pierre Van Geertruyden indicated that Médecins sans Frontières (MSF), a nongovernmental organization, had several thousand volunteers working in 84 countries. MSF carried out health activities in humanitarian emergencies, assisting and protecting populations in danger. Its projects were often in areas out of the reach of governments or United Nations agencies. Consequently, it could serve as a bottom-up facilitator for the dissemination of immunization safety messages and practice. MSF had the advantage of a short management line between its headquarters and the field, and could therefore disseminate messages or information on new policies quite rapidly.

MSF had recently launched the Access to Essential Medicine campaign, which, among other things, dealt with the quality and availability of drugs, including vaccines. Through this campaign, MSF was campaigning for fair prices for drugs in order to guarantee their accessibility.

MSF was tackling the problem of waste management. Dr Van Geertruyden expressed concern that AD syringes would not be used for all injections and that this would create extra problems in health centres.

III.3 Partner-led discussions

Partners play a key role in developing new technologies and new vaccines. It is widely recognized that progress cannot be made in the absence of strong collaboration with partners. Although objectives may vary, a strong commitment from everyone to immunization safety is vital.

International Federation of Pharmaceutical Manufacturers' Associations

Dr Robert Sharrar explained that the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA) represented the research-based pharmaceutical industry and manufacturers of prescription medicines. IFPMA had a central role in the exchange of information within the international industry and in the development of policy statements. It was the main channel of communication between the industry and various international organizations concerned with issues related to health and trade, including WHO, the World Bank, the World Trade Organization and the World Intellectual Property Organization.

Dr Sharrar drew attention to the important role of NRAs in the management and control of vaccines. He strongly recommended that they be further strengthened.

He pointed out that a long time inevitably elapsed between the initial research phase and the production and distribution of a new vaccine.

Program for Appropriate Technology in Health

Mr Carib Nelson described three immunization safety tools whose development had been assisted by PATH.

Vaccine vial monitors

Mr Nelson explained that vaccines had to be stored and transported to the point of use in such a way as to avoid harmful heat exposure. In the past there had been no way to detect the cumulative heat exposure of individual vials, so national immunization programmes had adopted conservative guidelines for vaccine handling and the disposal of vaccines when heat exposure was suspected. The use of special, heat-sensitive labels on vials to indicate heat exposure, known as vaccine vial monitors (VVMs), improved quality control and coverage and reduced unnecessary vaccine wastage. Mr Nelson described VVMs as small, circular indicators printed directly on vial labels or attached to the tops of vials, ampoules or tubes. The short-term objective was to have a VVM on every vial. UNICEF had specified that VVMs should be on all vaccines it purchased in 2001. Training was needed at all levels in countries in order to ensure that the greatest possible benefit was obtained from VVMs.

Uniject prefilled injection device

Mr Nelson explained that the Uniject syringe was a prefilled single-dose injection device designed to prevent attempts at reuse. It combined medicament, syringe and needle packaged in a sealed foil pouch. The device had been licensed to Becton Dickinson and Company, which had been developing the injection system for various applications in the public sector. The technology simplified the act of giving an injection, made the unsafe reuse of the syringe impossible, and simplified logistical arrangements by making premeasured medicament, needle and syringe available in the same place and at the same time. Uniject was possibly suitable for use in the home or community by outreach workers who did not traditionally deliver injections.

At least 37 pharmaceutical companies were well into the process of developing Uniject. Seventeen companies had conducted pilot tests and the first commercial Uniject products, for the delivery of hepatitis B vaccine and tetanus toxoid, had been developed by Bio-Farma in Indonesia. Nine million tetanus toxoid Unijects would be used in UNICEF programmes for tetanus elimination over the next three years.

Training manual: "*Giving safe injections with auto-disable syringes*"

Mr Nelson said that this manual, produced by PATH with support from WHO, was a very important tool, complementing the introduction of both VVMs and AD syringes. It was designed to be presented by a trainer to health workers who injected vaccines. Its five modules dealt with the health impact of unsafe injections, the selection of safe and effective vaccines, the safe reconstitution of vaccines, the prevention of needle-stick injuries, and the use of AD syringes. The manual was available for adaptation and free use by any programme seeking to improve immunization safety.

Part IV: Conclusions and recommendations

IV.1 Conclusions

SCIS noted that remarkable progress in immunization safety had been made during the year. Several propositions outlined by the Secretariat were endorsed, and support for the plan of action was reiterated. It was decided that there was no need to have another mid-year meeting on any particular subject.

The involvement of some SCIS members in other bodies was considered of value in placing immunization safety on their agendas. Two members were on the GAVI review panel for country applications and others belonged to SAGE.

In 2001, SAGE's meeting format would be restructured so that on the first day there will be three parallel sessions reflecting the three objectives of V&B: innovation, immunization systems, and accelerated disease control. There will be a plenary session on the second day. SCIS will be invited to participate in the session on immunization safety. The overall aim was to align SCIS more closely with SAGE.

It was vitally important to link coverage and safety, as had been discussed at length in GAVI. SCIS urged that they should not be perceived as opposing one another but rather as interconnected objectives.

It was noted that most regions had made significant progress in the field of immunization safety and that there was a continuous need for WHO and UNICEF to support the efforts of regions and countries. Thus, for instance, the rapid testing of hypotheses was necessary in respect of AEFI monitoring but few countries had the capacity to achieve this. It was therefore crucial to have WHO involvement centrally and other forms of international collaboration.

IV.2 Recommendations

SCIS acknowledged that GAVI, launched early in 2000, gave a strong impulse to immunization systems, especially with regard to safe practice. However, concerns were raised that safety was not high enough on the agenda of the GAVI Board. SCIS therefore made the following recommendations with a direct bearing on GAVI.

Global Alliance for Vaccines and Immunization

SCIS recognized that there was a potential conflict in using high vaccine coverage as the primary criterion for assessing the allocation of financial support to countries. If disproportionate weight were given to high coverage as opposed to safe service delivery there could be lapses in immunization safety. SCIS offered to collaborate with GAVI in order to solve this dilemma. It was recommended that:

- safety be accorded the same importance as coverage in the overall GAVI objectives;
- coverage and safe service delivery be encouraged simultaneously;
- the primary criterion be changed to "safe immunization coverage".

Furthermore, with regard to the functioning and structure of GAVI, it was recommended that:

- the disbursement of GAVI funds be considered in the light of performance on immunization safety as well as on coverage;
- an assessment tool for injection safety, developed and pilot-tested in response to a request of the subcommittee on assessment criteria, be used as a safety indicator for GAVI assessments;
- immunization safety be a priority activity for all GAVI task forces, particularly the one dealing with advocacy;
- all GAVI partners endorse and adopt the WHO/UNICEF *Joint Statement on the use of auto-disable syringes in immunization programmes*;
- the development of safer injection and disposal technologies be a priority for GAVI partners.

Advocacy and partnership-building

Since the first meeting of SCIS, advocacy and partnership-building have been the chief factors responsible for increasing concern and awareness about safety issues. These items were therefore high on the agenda of the second meeting. SCIS formulated the following recommendations on these matters.

- ISPP should communicate with all stakeholders, from users of immunizations to major donors and lenders, by using the full range of media, including the Internet.
- "Strengthen the NRAs" should be a key ISPP advocacy message.
- ISPP should use the concept of a "healthy child and safe vaccination" as its key message.
- When donors supply vaccines they should be encouraged to provide sufficient funds for waste disposal.
- Whenever possible, partnerships with professional stakeholders should be developed.

A number of other recommendations had a specific technical or field focus. Whereas advocacy and partnership related to the global aspect of immunization safety, the following recommendations dealt with practical steps that should be taken at the regional, country or local level in order to reinforce immunization safety.

- The standardization and strengthening of the curriculum on immunization safety, including the monitoring of adverse events, should be a key component of both preservice and continuing education for health care workers.
- Efforts within and between regions should be undertaken to improve communication and knowledge about available resources for immunization staff and other key personnel (strengthening of health systems).
- System indicators should be developed to monitor progress in immunization safety at country and regional level.
- The capacity to monitor, analyse and manage adverse events should continue to be developed.
- A systematic process for the quality control of all available AD syringes and other delivery systems, with specifications and international standards, should be developed in conjunction with NRAs.

SCIS recommended that no further assessment tools be developed at present.

Annex 1: Programme

26 October 2000

Morning — Opening session

Opening remarks

Yasuhiro Suzuki, Executive Director, Health Technology and Pharmaceuticals

Introduction of new partners, adoption of agenda, election of Rapporteur, review of SCIS recommendations

Carolyn Hardegree, Chairperson of SCIS

Progress report from Secretariat

Philippe Duclos, Project Leader

Interaction with SAGE and ISPP

Jean-Marc Olivé, Project Leader, and Michel Zaffran, Programme Manager

Expected outcome

Comments on synergies between SCIS, SAGE subgroups and ISPP.

SCIS subgroup on indicators to measure progress

Short presentation of outcome of meeting, progress since May 2000 on implementation of recommendations, discussion on gap areas and how to assess impact of ISPP.

Carolyn Hardegree

Expected outcome

Plan to monitor progress in safe immunization globally, and impact of ISPP on progress; plan should specify agreed responsibilities and have a time line.

26 October 2000 (cont.)

Global Alliance for Vaccines and Immunization

Overview, discussion on gaps and synergies

Michel Zaffran

Expected outcome

Recommendations as appropriate on: (i) injection safety component of country applications to GFCV; (ii) how to increase the visibility of ISPP messages in GAVI task forces.

Immunization safety and the strengthening of health systems

Collaboration with Department of Organization of Health Services Delivery and ISPP

Jean-Marc Olivé, Project Leader

Expected outcome

Commitment, especially through WHO/UNICEF regional and country offices, to increased focus on training, especially in-country and preservice training.

Afternoon

Regional and country perspectives on integrating immunization safety into health systems development and health sector reform

Each Region to facilitate a discussion around an issue of importance to immunization safety and from the regional perspective (e.g. injection safety, sharps waste management, capacity-building at country level, etc.).

Expected outcome

How and by whom to tackle the specific concerns raised.

27 October 2000

Advocacy

Which advocacy messages? Which champions? Discussion on indicators that could be used for advocacy.

Expected outcome

Adoption of advocacy messages and strategy.

Breaking new ground: the added value of professional organizations

Keynote address, *Beverly Malone, Deputy Assistant Secretary for Health, USA*.

Discussion on how to make the most of networks of professional organizations, particularly with country-level operations. Participation of invited organizations.

Expected outcome

Recommendation on how to reach out to professional organizations and secure their contribution to the improvement of immunization safety.

Partner-led discussions – commitment to the drive for safety

New technologies; contribution and constraints of industry; how to accelerate action in areas making little progress (clinical evaluation of vaccines, research and development, etc.).

Expected outcome

For each theme, agreement on roles of partners and action to bridge gaps.

Any other business

Operations of SCIS: communications, next meeting(s), planned activities, forthcoming events, etc.

Summary of recommendations of the meeting

Discussion and adoption.
Greg Sam, Rapporteur

Closing remarks

Carolyn Hardegree

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