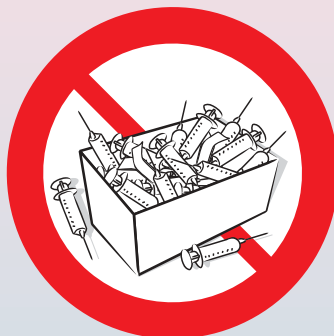


WORLD HEALTH ORGANIZATION PROGRESS REPORT TO DONORS AND PARTNERS

PROGRESS

TOWARDS THE SAFE AND APPROPRIATE
USE OF INJECTIONS WORLDWIDE

2000–2001



WHO/BCT/02.05.English

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*WHO's Department of Blood
Safety and Clinical Technology
thanks its donors and partners
for a productive collaboration
during 2000-2001. Thanks to
your support and commitment,
the global agenda of safe and
appropriate use of injections has
progressed considerably.*

Executive summary

BACKGROUND

In many developing and transitional countries, injection over-use and unsafe injection practices combine to transmit blood-borne pathogens on a large scale. In response, in 1999, WHO scaled up its injection safety activities and decided to host the secretariat of the Safe Injection Global Network (SIGN).

2000-2003 STRATEGY

The strategy for the safe and appropriate use of injections worldwide has four objectives:

1. Formulate national policies and plans for the safe and appropriate use of injections;
2. Ensure quality and safety of injection equipment;
3. Facilitate equitable access to injection equipment; and
4. Achieve appropriate, rational and cost-effective use of injections.

ACHIEVEMENTS IN 2000-2001

The SIGN alliance now provides a mechanism for information sharing between all partners through a weekly electronic newsletter, an Internet site and an annual coordination meeting. Progress towards the four objectives in 2000-2001 includes:

1. Policy. Countries assess their injection practices using the newly developed WHO standardized tools. Donor and partners use Global Burden of Disease estimates to support national plans based upon “Aide Mémoire” policy guides.

2. Quality and safety. First elements developed towards a comprehensive system to ensure the quality and safety of syringes and needles include ISO standards for auto-disable (AD) syringes, tools to evaluate injection equipment in the field, and guidance for National Regulatory Authorities.

3. Access. The concept of “bundling” is being extended to ensure that all supplies of injectable drugs are delivered with matching quantities of safe injection equipment and sharps collection boxes.

4. Use. Best practices for injections provide a reference for what a safe injection should be and a toolbox for communication gives countries a starting point to develop communication plans for the safe and appropriate use of injections.

FUTURE PERSPECTIVES FOR 2002-2003

Scaling up work at the regional and country level will ensure that safe and appropriate use of injections will save precious health care resources and prevent infections with bloodborne pathogens through a cross-cutting systems approach that integrates existing initiatives.

First do no harm: The need to use injections safely and appropriately

INJECTIONS ARE OVERUSED WORLDWIDE

Injections are probably the most common of all medical procedures. About 16 000 million injections are administered each year in developing and transitional countries. Most of these are unnecessary therapeutic injections. In many countries, patients and health care workers prefer medicines to be administered by injection. Overall, unnecessary injections lead to high out-of-pocket health care expenses for patients and their families.

UNSAFE INJECTIONS ARE COMMON

Many injections administered in the world are unsafe. Of particular concern is the reuse of injection equipment in the absence of sterilization – a frequent practice in developing countries and those in transition where syringes and needles are simply rinsed in containers of tepid water between injections. In these countries, injections account for a high proportion of new infections with hepatitis B and hepatitis C viruses and may transmit HIV.

Injections are probably the most common of all medical procedures.



The myth of powerful injections



Unsafe injection practices in Africa, 2000

Unsafe injections are common: Syringes and needles are simply rinsed in containers of tepid water between injections.

TOWARDS SAFE AND APPROPRIATE USE OF INJECTIONS WORLDWIDE

Three-element strategies can reduce overuse of injections and ensure safe practices. First, patients and health care workers must adopt safe practices and avoid unnecessary injections. Second, sufficient quantities of clean injection equipment and infection control supplies must be available in each health care facility. Third, sharps (i.e. needles and syringes) must be disposed of to ensure that dirty injection equipment is not reused and to prevent needle stick injuries.

Establishment of **safe and appropriate** use of injection activities at WHO

WORK BEFORE 1999

Before 1999, WHO conducted many activities for the safe and appropriate use of injections. First, the Drug Action Programme worked to reduce injection overuse. Second, the Expanded Programme on Immunization made efforts to achieve safe immunization injections. However, in 1999 it was felt that a new coordinating mechanism could add value.

THE SAFE INJECTION GLOBAL NETWORK (SIGN)

The Safe Injection Global Network (SIGN) was constituted as an international alliance of stakeholders who want to achieve safe and appropriate use of injections worldwide. SIGN is coordinated by a secretariat at WHO's Department of Blood Safety and Clinical Technology.



WHO strategy for the safe and appropriate use of injections



The WHO strategy for the safe and appropriate use of injections is integrated in the 2000–2003 strategy of the Department of Blood Safety and Clinical Technology (BCT). It has four objectives:

1. POLICY

Building capacity in countries to formulate, implement, evaluate and update national policies and plans.

2. QUALITY AND SAFETY

Ensuring the quality and safety of injection equipment.

3. ACCESS

Facilitating equitable access to injection equipment.

4. APPROPRIATE USE

Achieving appropriate, rational and cost-effective use of injections.

The “First do no harm” principle is at the foundation of preventive and curative health care.

“SIGNpost” currently has more than 800 subscribers in the six WHO regions, facilitating informal discussions and experience sharing.



Participants at the annual SIGN meeting, New Delhi, India (29-31 August 2001)

is a graphic reminder that injection safety is an issue of concern to all of us since we all are users of health care services. It also provides a reminder that the “First do no harm” principle is at the basis of preventive and curative health care.

ADDING VALUE TO THE WORK OF THE SIGN ALLIANCE

Annual meetings, a weekly moderated electronic mail newsletter and an Internet site facilitate the work of the SIGN alliance.

ANNUAL MEETINGS TO DEFINE ACTION POINTS

The annual SIGN meetings provide opportunities to review common progress and to decide on action points for the members of the SIGN alliance. The Internet is used to disseminate presentations to those who cannot attend and user-friendly reports summarize key issues in a format that is quick and easy to read.

SIGNPOST: A WEEKLY ELECTRONIC NEWSLETTER TO RAPIDLY DISSEMINATE INFORMATION

Each Wednesday, SIGN participants worldwide receive an electronic newsletter sent in text e-mail format. *SIGNpost* currently has more than 800 subscribers in the six WHO regions, facilitating informal discussions and experience sharing. *SIGNPost* is a powerful way to disseminate documents and to submit drafts to public comments. *SIGNpost* is highly appreciated by national public health managers. *SIGNpost* archives are also available on the Internet at <ftp://acithn.uq.edu.au/signfiles/SIGNpostArchives/>.

AN INTERNET SITE AT THE HEART OF THE NETWORK

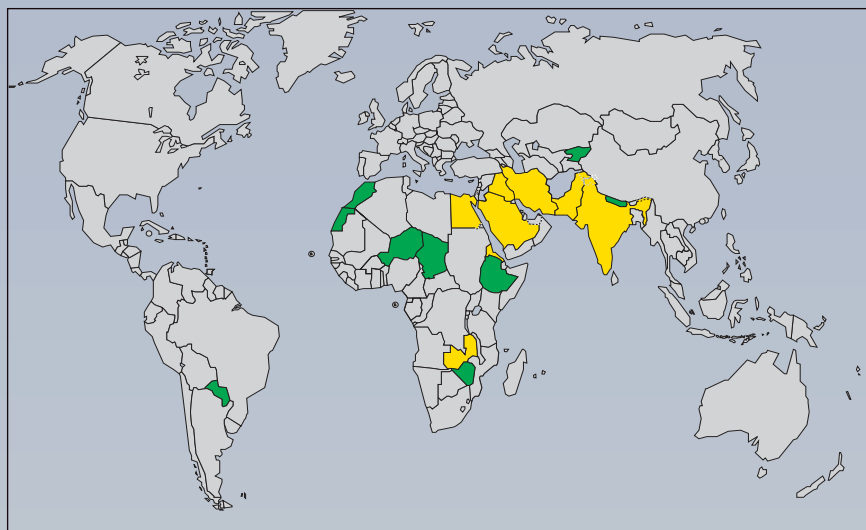
Operated in parallel with the Internet site of the SIGN secretariat at www.who.int/bct, the SIGN alliance Internet site at www.injectionsafety.org reaches out to alliance partners and ensures easy access through a user-oriented domain name. Regular updates, a ‘toolbox’ (resource centre) and a ‘headlines’ section make the site the place to go for the latest news about safe and appropriate use of injections.

MEASURING THE BURDEN OF DISEASE PREVENTED IN COUNTRIES

NEW TOOLS FOR ASSESSMENT AND EVALUATION

New tools prepared to assess and evaluate injection practices now allow people to document the situation in the field so that evidence can drive prevention efforts. Following a meeting of experts and pilot field testing, two tools are now being used. First, the “Tool to assess injection safety” was designed to estimate the proportion of health care facilities that engage in safe injection practices. In August 2001, seven countries had already conducted their assessment and an additional seven had firm plans to use it. Second, the “Rapid assessment and response guide” proposes to conduct a rapid assessment of injection overuse and injection safety, with the objective of initiating a national plan of action. This draft guide can be downloaded from the SIGN Internet site at www.injectionsafety.org.

Injection Safety Assessments June 2000 – August 2001



■ Assessments planned (14 countries)

■ Assessments done (14 countries)

New tools prepared to assess and evaluate injection practices now allow people to document the situation in the field so that evidence can drive prevention efforts.

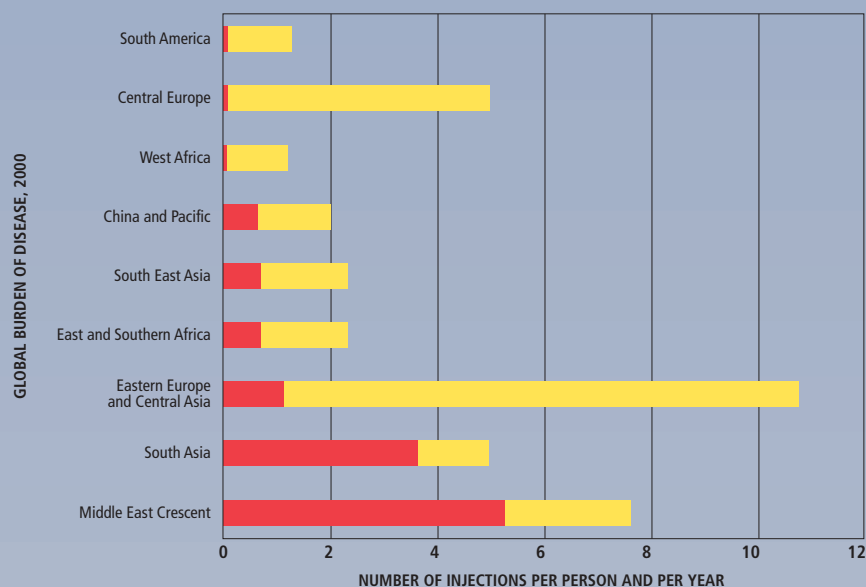
What a bank of information I am having now!

(All received from SIGNpost).

— Dr Patrick Ingoma,
EPI Uganda

Burden of disease estimates help generate donor and partner support for in-country prevention work.

Injections given with sterile and unsafe equipment worldwide



- Injections given with equipment reused in the absence of sterilization
- Total number of injections given

ESTIMATING THE GLOBAL BURDEN OF DISEASE ASSOCIATED WITH POOR INJECTION PRACTICES

As part of the 2000 update of the Global Burden of Disease study, a Comparative Risk Assessment was conducted in collaboration with WHO's Evidence and Information for Policy cluster. The objective was to estimate the annual toll of poor injection practices in terms of infections with bloodborne pathogens and Disability-Adjusted Life Years (DALYs). This work has been sent for peer review. Preliminary analysis suggests that annually, worldwide, contaminated injections may account for 33% of new hepatitis B virus infections (a total of 21.6 million infections), 42% of new hepatitis C virus infections (2 million infections) and 2% of new HIV infections (98 000 infections). An abstract summarizing the findings was presented to an international scientific meeting on infectious diseases (the Infectious Disease Society of America, IDSA). These burden of disease estimates help generate donor and partner support for in-country prevention work.

QUALITY AND SAFETY OF INJECTION EQUIPMENT

In a number of countries, injection equipment of poor or uncertain quality may expose injection recipients to adverse effects and is of concern to National Regulatory Authorities.

TOWARDS INTERNATIONAL STANDARDS FOR AUTO-DISABLE (AD) SYRINGES

Auto-disable (AD) syringes are syringes that have been modified to inactivate themselves after one use through plunger breaking or plunger blocking. AD syringes provide an opportunity to prevent reuse of injection equipment in the absence of sterilization. WHO, in collaboration with selected partners from SIGN, formulated a “New Work Item Proposal” for AD syringes to the International Standards Organization (ISO). Availability of ISO standards will provide the capacity to countries to formulate national regulations that demand compliance with the newly defined international standard and contribute to safer injection practices.

EVALUATING INJECTION EQUIPMENT

While various designs of syringes and needles are available, little information is available to determine how each design performs in the field when it reaches the hand of the end-user. The current development and pilot testing of a tool to evaluate injection equipment in the field will allow the identification of injection equipment that offers the highest level of safety and user preference.

ENSURING THE QUALITY AND SAFETY OF SYRINGES AND NEEDLES

Tools have been made available in recent years to assist National Regulatory Authorities to ensure the quality and safety of vaccines and essential drugs. However, ensuring the quality and safety of medical devices has usually not benefited from the same development. Initial work is now under way to prepare a comprehensive system that will ensure the quality and safety of injection equipment through the strengthening of National Regulatory Authorities.

Auto-disable (AD) syringes are syringes that have been modified to inactivate themselves after one use through plunger breaking or plunger blocking.

AD syringe designed to inactivate itself automatically after an injection





ACCESS TO INJECTION EQUIPMENT UNDERSTANDING SUCCESS STORIES: THE BURKINA FASO EXPERIENCE

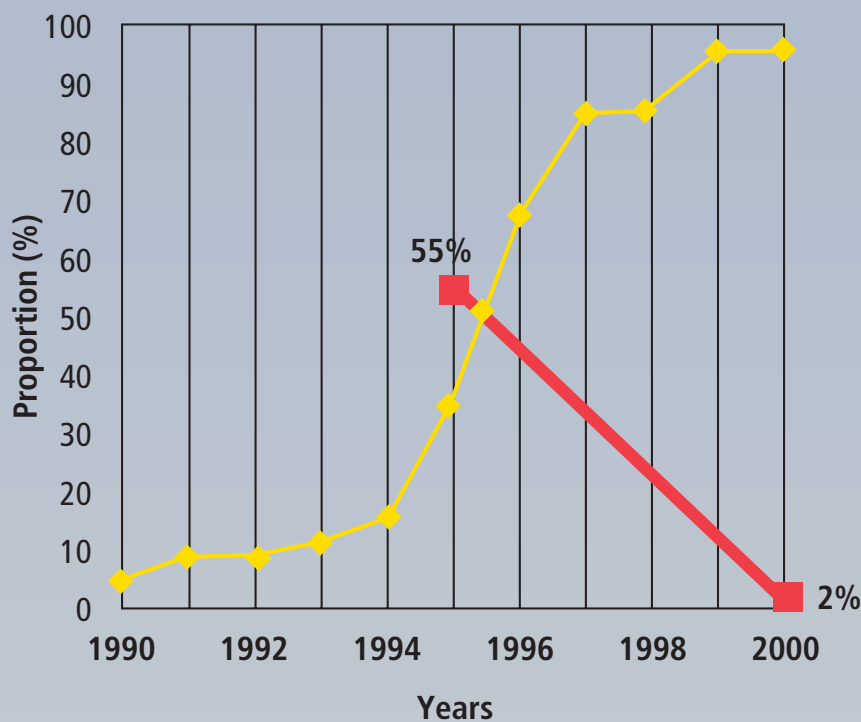
A system analysis conducted by the logistics project of WHO's Regional Office for Africa (AFRO) reported that in immunization services of sub-Saharan African countries, funds made available to purchase vaccines rarely covered injection equipment. This failure to systematically fund sufficient supplies of injection equipment as part of immunization services was identified as a key determinant of widespread reuse of syringes and needles in the absence of sterilization.

Burkina Faso managed to increase access to injection equipment and improve injection safety between 1995 and 2000. To

Injectables should always be delivered with injection equipment and safety boxes

Failure to systematically fund sufficient supplies of injection equipment as part of immunization services was identified as a key determinant of widespread reuse of syringes and needles.

Improvement of access to injection equipment parallels improvement of injection safety in Burkina Faso in the 1990s



■ Proportion of health care facilities equipped with a community pharmacy
 ■ Proportion of reuse of injection equipment without sterilization

find out more, WHO commissioned *Pharmaciens Sans Frontières*, a non-governmental organization and SIGN alliance partner, to conduct a field study. Results of this study indicate that between 1995 and 2000, increasing availability of disposable injection equipment through community pharmacies almost eliminated reuse of injection equipment in the absence of sterilization. Reuse of non-sterile injection equipment dropped from 50% in 1995 to 4% in 2000 in the country. Simultaneously, the proportion of health care facilities equipped with a community pharmacy increased from 5% to 95%. This new network of community pharmacies improved access to safe disposable injection equipment. The sale of 5ml syringe and needle sets, the most used size of syringes in Burkina Faso, has more than doubled in four years from 1996 to 2000. Of interest, no data suggested that improved access to injection equipment increased irrational use of injections. The indicator measuring the proportion of prescriptions including at least one injection remained stable during this period (26.5% in 1995 versus 23.8% 2000).

GENERALIZING THE USE OF THE "BUNDLING" CONCEPT

Building on the experience acquired on access to injection equipment in Burkina Faso, work is under way to expand the concept of "bundling" to the WHO model essential drug list and the inter-agency guidelines for drug donations. Currently, these do not address the need to "bundle" orders and deliveries of injectable medications with matching quantities of injection equipment and safety boxes. Policy changes will ensure that lack of supplies is not the limiting factor causing unsafe injection practices in developing and transitional countries.

APPROPRIATE, RATIONAL AND COST-EFFECTIVE USE OF INJECTIONS DEFINING INJECTION SAFETY STANDARDS

No universally accepted evidence-based standards were available in the area of injection safety. Now, WHO best practices for skin-piercing, intradermal, subcutaneous and intramuscular

Policy changes will ensure that lack of supplies is not the limiting factor causing unsafe injection practices in developing and transitional countries.

WHO best practices for injections provide a reference for efforts to change unsafe behaviours.



To achieve safe and appropriate use of injections worldwide, the communication toolbox proposes to engage patients and health care workers in six key behaviours.

injections provide a reference for efforts to change unsafe behaviours. To facilitate understanding of the two-page guidelines, the best practices document was illustrated using easy-to-read pictogrammes. In addition to the WHO and SIGN alliance dissemination channels, the International Council of Nurses (ICN), a SIGN partner that collaborated actively in the formulation of the best practices, will assist in mobilizing nurses around the world to promote them.



Using a new syringe, discarding used equipment in a box and managing sharps waste: The critical steps of a safe injection according to best practices

DEVELOPING COMMUNICATION TOOLS FOR BEHAVIOUR CHANGE

To achieve safe and appropriate use of injections worldwide, the communication toolbox proposes to reach three key groups (injection prescribers, injection providers and injection recipients) to engage them in six key behaviours:

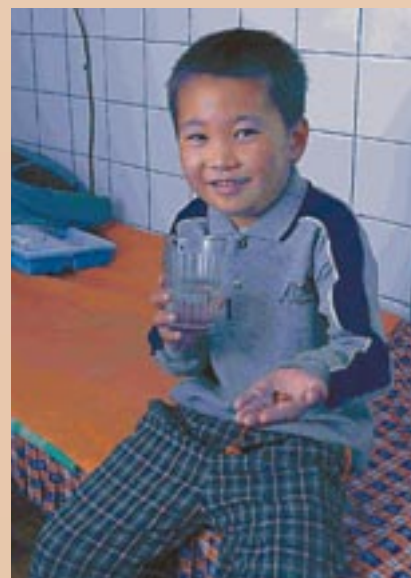
1. Prescribe oral medication wherever possible (prescribers);
2. If prescribed an injection, ask if medication can be given orally instead (recipients);
3. Demand that a syringe and needle be taken from a new, sealed and undamaged package (recipients);
4. Use a sterile needle and syringe for every injection (providers);
5. Place syringes and needles in a safety box immediately after use without recapping (providers);
6. Manage injection waste safely and appropriately (providers).

For each of these six key behaviours, the strategy outlines a proposed behaviour, the current behaviour, the reasons that explain the current behaviour, the barriers to change (referred to as 'locks'), the strategy for change (referred to as 'keys'), a reference to a specific tool and indicators.

Following the formulation of an overall strategy which was peer-reviewed and submitted to public comments, work is now under way to produce template material for Information, Education and Communication (IEC). These templates are made available as they are produced on the SIGN Internet site at www.injectionsafety.org/toolbox.

SHARPS WASTE MANAGEMENT

Safe sharps waste management is one of the three arms of the proposed strategy for the safe and appropriate use of injections. WHO activities in this field are conducted by the Department of Protection of the Human Environment (PHE) in collaboration with the SIGN alliance and the SIGN secretariat.



Promoting oral medications

Future perspectives

Future work during the 2002-2003 biennium will build upon recent achievements along the “policy”, “quality and safety”, “access” and “appropriate use” objectives. Two sets of activities need to be differentiated. First, the BCT department will continue to facilitate the work of the SIGN alliance and to coordinate the global safe and appropriate use of injections agenda. Second, prevention work must be scaled up in countries through the WHO regional offices.

2002-2003 PERSPECTIVES FOR BCT

Specific priorities for each objective will include:

1. POLICY

Assist countries with an injection safety planner and an interactive model to estimate the cost-effectiveness of safe and appropriate use of injections policies.

2. QUALITY AND SAFETY

Organize a comprehensive system to ensure the quality and safety of injection equipment through the strengthening of National Regulatory Authorities.

3. ACCESS

Expand the bundling principle to the whole curative sector, including the private sector.

4. APPROPRIATE USE

Develop a full set of communication tools for behavioural impact in the field of safe and appropriate use of injections.

2002-2003 PERSPECTIVES FOR WHO

As discussed at the meeting of the cabinet of the Director-General in May 2001, WHO will implement a three-point global collaborative strategy at the regional, country and headquarter levels.

1. IDENTIFY FOCAL POINTS IN ALL REGIONAL OFFICES FOR RATIONAL USE OF MEDICATIONS, INCLUDING SAFE AND APPROPRIATE USE OF INJECTIONS.

WHO will identify focal points in each regional office. These officers will act as regional counterparts for the WHO SIGN secretariat.

2. PLAN AND IMPLEMENT COUNTRY-SPECIFIC BURDEN-BASED PLANS FOR THE SAFE AND APPROPRIATE USE OF INJECTIONS.

WHO will assist countries in implementing a sector-wide approach to the safe and appropriate use of injections within national drug, immunization, and blood transfusion policies. Safe and appropriate use of injection policies implemented as a careful coordination of existing initiatives rather than as the creation of a new programme will strengthen health systems. Injection practice indicators will also be used as a critical quality assessment indicator for health systems, particularly in countries that are reforming such systems. On a practical note, this should start with a limited number of countries, where feasible, and gradually aim to cover all countries.

3. ESTABLISH A CROSS-THEMATIC WORK PLAN AT WHO HEADQUARTERS FOR THE SAFE AND APPROPRIATE USE OF INJECTIONS.

WHO should lead global safe and appropriate use of injections efforts through building upon existing initiatives to create a cross-thematic work plan. Key groups will include Essential Drugs and Medicines Policy (Building safe and appropriate use of injections within National Drug Policies), HIV prevention and care (Risk communication) and Protection of the Human Environment (Sharps waste management).

Implementation analysis

(Updated: 30 November 2001)

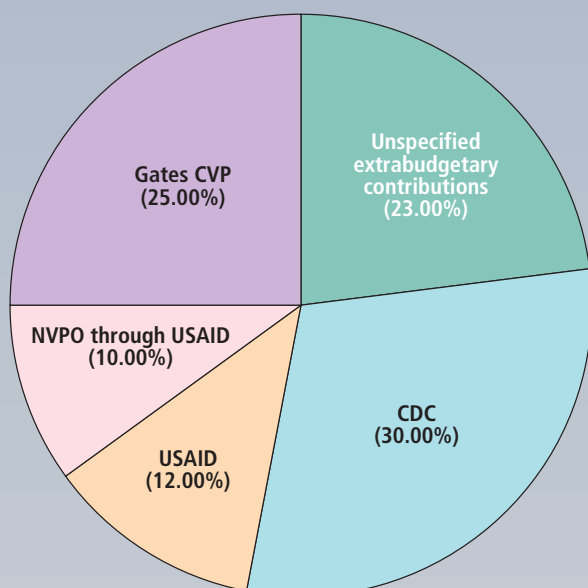
BUDGET

At the Meeting of Interested Parties (MIP) in April 2000, the operating budget for the safe and appropriate use of injections in the BCT department was US\$ 500 000, with US\$ 1 500 000 of unmet needs. Resource mobilization during the biennium filled part of these unmet needs to deliver a set of key products for the first two years of the project.

INCOME

Income for the 2000-2001 biennium consisted of specified and unspecified extrabudgetary funds for a total of US\$ 1 101 075.

Income 2000-2001



SPECIFIED EXTRABUDGETARY FUNDS

Funds were made available from the United States Centers for Disease Control and Prevention to prevent viral hepatitis through the development of safe and appropriate use of injection policies (US\$ 325 239), from the United States Agency for International Development (USAID) to support the SIGN secretariat and best injection safety practices (US\$ 135 600), from the United States National Vaccine Program Office through USAID to support the development of assessment tools (US\$ 113 000), and from the Bill and Melinda Gates Children's Vaccine Program to support the development of a toolbox for communication (US\$ 278 000).

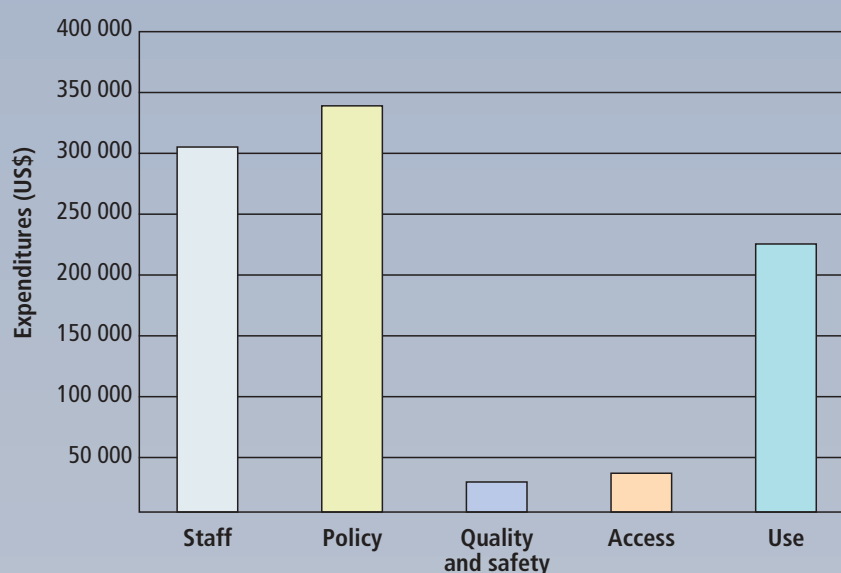
UNSPECIFIED FUNDS

A total of US\$ 249 236 of unspecified extrabudgetary funds were made available by WHO to support various objectives of the work plan. Donors and partners contributing to the unspecified extrabudgetary funds of the Department of Blood Safety and Clinical Technology include the governments of the Netherlands, United Kingdom and Norway.

EXPENDITURES

Resources available in 2000-2001 were allocated to critical products to provide an evidence base to the project and key communication tools for implementation. Initial priorities identified included the 'policy' objective (Global burden of disease and assessment tools) and the 'use' objective (Toolbox for communication). Total funds obligated amounted to US\$ 924 152. In the next biennium, more resources will be allocated to activities to ensure quality and safety of injection equipment and access to injection equipment in health care facilities.

Expenditures by objective 2000-2001



Executive summary

In many countries, injections transmit bloodborne pathogens on a large scale. In response, WHO scaled up its injection safety activities and decided to host the secretariat of the Safe Injection Global Network (SIGN).

The WHO strategy for the safe and appropriate use of injections worldwide has four objectives: (1) formulate national policies and plans for the safe and appropriate use of injections, (2) ensure quality and safety of injection equipment, (3) facilitate equitable access to injection equipment and (4) achieve appropriate, rational and cost-effective use of injections.

The SIGN alliance now provides a mechanism for information sharing between all partners through a weekly electronic newsletter, an Internet site and an annual coordination meeting. Progress along the four objectives in 2000-2001 include:

- The establishment of an evidence base (including assessment tools);
- The first elements of a comprehensive system to ensure the quality and safety of syringes and needles;
- Progress to extend the concept of “bundling” to ensure that all supplies of injectable drugs are delivered with matching quantities of safe injection equipment and sharps collection boxes
- Best practices standards for injections and communication tools.

In 2002-2003, scaling up work at the regional and country level will ensure that safe and appropriate use of injections will save precious health care resources and prevent infections with bloodborne pathogens through a cross-cutting systems approach that integrates existing initiatives.