



Safe Injection Global Network (SIGN)

Initial Meeting Report



Disposable syringes and needles waiting to be re-used without sterilization in a pot of tepid water, Asia, February 2000.



Secretariat of the Safe Injection Global Network (SIGN)
World Health Organisation, Health Technology and Pharmaceuticals, Blood Safety and Clinical Technology
20 Avenue Appia, CH -1211 Geneva 27, Switzerland
Tel: +41 22 791 3680 – Fax: +41 22 791 4836 – E-mail: sign@who.int

Executive Summary

As a response to an increasing burden of evidence suggesting that injection overuse and unsafe practices combine to transmit bloodborne pathogens on a large scale worldwide, stakeholders sharing a common interest in safe and appropriate use of injections met on October 4th and 5th, 1999 to join forces as a Safe Injection Global Network (SIGN).

Throughout the world, injections are overused to administer medications and unsafe injection practices, particularly re-use of syringes and needles without sterilization, are common. As a result, in many developing and transitional countries where hepatitis B virus and hepatitis C virus infections are highly endemic and where studies have been conducted, unsafe injection practices account for a large proportion of new infections. In addition, a mathematical model suggests that each year, world-wide, unsafe injections may cause 8-16 million cases of hepatitis B virus infection, 2.3-4.5 million cases of hepatitis C virus infection, and 80,000-160,000 cases of HIV infection.

The SIGN associates wish to constitute a free association facilitated by a secretariat based at the World Health Organization headquarters. SIGN associates agree to exchange information, to coordinate their advocacy strategies, and to define a common strategic framework.

The SIGN strategic framework has two broad objectives. Under the first one, "Innovation in approaches", the SIGN associates want to conduct pilot interventions to test the feasibility of approaches to safe and appropriate use of injections and to achieve large-scale introductions of newer technologies supporting safer use of injections. Under the second one, "Achieving safe and appropriate use of injections", SIGN wants to obtain the implementation of national policies and plans for safe and appropriate use of injections in all countries world-wide and to promote injection safety in donor or lender-funded services making use of injections.

Safe Injection Global Network (SIGN)

Initial Meeting Report

October 4-5, 1999

WHO headquarters, Geneva, Switzerland

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Chairperson

Harold Margolis,
Hepatitis Branch
Centers for Disease Control and Prevention
Atlanta, GA 30333
USA

Rapporteur

Steve Luby
Assistant Visiting Professor
Aga Khan University
Karachi
Pakistan

Summary

An increasing body of evidence suggests that unsafe injection practices and overuse of therapeutic injections combine to account for large-scale bloodborne pathogen transmission worldwide. As a response to this emerging concern, stakeholders sharing a common interest in safe and appropriate use of injections worldwide joined their forces in a Safe Injection Global Network (SIGN).

The SIGN associates met for the first time on October 4th and 5th, 1999. The objectives of this meeting were to review the available evidence in term of injections and their adverse effects, to define terms of association for SIGN, and to obtain consensus on a common strategic framework.

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The SIGN associates wish to constitute a free association of stakeholders sharing a common interest for safe and appropriate use of injections. A secretariat, based at the World Health Organization headquarters should facilitate the activities of the network. SIGN associates agree to exchange information, coordinate their communication and advocacy strategies, and to define a common strategic framework.

The SIGN strategic framework has two broad objectives. Under the first one, "Innovation in approaches", the SIGN associates want to conduct pilot interventions to test the feasibility of approaches to safe and appropriate use of injections and to achieve large-scale introductions of newer technologies supporting safer use of injections. Under the second one, "Achieving safe and appropriate use of injections", SIGN wants to obtain the implementation of national policies and plans for safe and appropriate use of injections in all countries world-wide and to promote injection safety in donor or lender-funded services making use of injections.

SIGN provides a multidisciplinary response to a complex and important public health problem. SIGN associates need to define how their organizations will contribute to the strategic framework and need to think broadly in planing strategies and interventions.

Table of content

SAFE INJECTION GLOBAL NETWORK (SIGN) INITIAL MEETING REPORT OCTOBER 4-5, 1999 WHO HEADQUARTERS, GENEVA, SWITZERLAND.....	3
CHAIRPERSON	3
RAPPORTEUR.....	3
EXECUTIVE SUMMARY	5
TABLE OF CONTENT	7
OPENING SPEECH.....	9
UNSAFE INJECTIONS, THEIR CONSEQUENCES, AND POTENTIAL SOLUTIONS.....	11
THE SIGN TERMS OF ASSOCIATION.....	20
THE SIGN STRATEGIC FRAMEWORK.....	22
CROSS CUTTING ISSUES WITHIN SIGN STRATEGIC OBJECTIVES.....	26
CONCLUSION OF THE MEETING.....	31
APPENDICES	32
REFERENCES.....	63

Opening speech

Michael Scholtz
Executive Director
Health Technology and Pharmaceutical Cluster
World Health Organization

Ladies and Gentlemen, dear Colleagues,

On behalf of the Director General, it is a pleasure for me to welcome you to WHO headquarters and to this initial meeting of the Safe Injection Global Network. Many of you have traveled a long way to be here today and I would like to thank them for joining us.

As we review the successes and failures in global health at the end of the twentieth century, a pattern emerges suggesting that the “first do no harm” principle may be being challenged due to inappropriate and unsafe injection practices. An increasing body of evidence now suggests that in many developing countries, injection overuse and unsafe practices combine to account for a substantial proportion of the new infections with hepatitis B virus, hepatitis C virus, and HIV/AIDS. In an article to be published this month in the Bulletin of the World Health Organisation, researchers have modeled the likely consequent global impact of such practices, estimating that 8-16 million hepatitis B infections, 2-4.5 million hepatitis C infections, and 80,000-160,000 HIV/AIDS cases may be caused by re-use of syringes and needles without sterilisation annually world-wide. Because the initial phase of these infections is usually asymptomatic, the adverse effects of unsafe injections have been under-appreciated. However, the burden of diseases and death associated with unsafe injections as well as their cost to society can no longer be ignored. Research conducted suggest that the toll may reach 1.3 million deaths annually in the future, for a total of 26 million of years of life lost, accounting for and an annual direct medical cost of 535 million US dollars.

Injections given in formal and informal health care settings are probably the most common percutaneous procedure worldwide. WHO estimates that currently over 12 thousand million injections are administered annually. For each vaccination injection, nine therapeutic injections are given. Since many medications used in primary health care can now be administered orally, these estimates along with a number of population-based injection frequency surveys indicate overuse of therapeutic injections.

In the industrialised world, recognition of the risks associated with unsafe injections led to improvements in infection control practices, with disposable injection equipment becoming the standard in the 1970s. Today, against a background of high awareness, sufficient supplies, and appropriate waste disposal, in developed countries injection-associated bloodborne pathogen infections occur almost exclusively among health care workers through needlestick injuries and among injecting drug users through syringes and needle sharing.

In contrast, in developing countries, the introduction of disposable injection equipment without adequate training, supplies, or waste disposal has led to the large-scale reuse of such equipment without sterilization and to improperly disposed sharps as an environmental hazard. Use of sterilizable syringes and needles is cost-effective and produces smaller quantities of waste. However, the training, supervision, adequate supplies, and maintenance that this option require may not be sustainable in all countries. New “auto-disable” (AD) syringes (previously called “auto-destruct”) should limit re-use since they automatically inactivate themselves by locking the plunger after use. The cost of a syringe should not be an incentive for re-use: the price of AD syringes has decreased and should decrease more to result in an improved availability for use in immunization and family planning efforts. Large-scale field testing of this technology in primary health care will determine whether other new prevention opportunities exist and whether the additional burden of sharps waste can be successfully handled.

In immunization activities, where safe injections are particularly important, many initiatives have been launched to improve injection safety. Through the efforts of the Expanded Programme on Immunization (EPI), equipment developed and supplied to the field has included steam sterilizers, AD syringes, combination vaccines, and puncture-proof safety boxes for disposal of sharps. Training has been conducted at all levels on the appropriate use of this equipment. The WHO/UNICEF “bundling strategy” now recommends the inclusion of the costs of injection safety in estimates for the expense of routine and emergency vaccination programmes, before donors are solicited for funding. Finally, a new generation of safer needle-free “jet” injectors is being developed.

Although EPI has made efforts to improve injection safety, fewer initiatives have been taken to prevent the transmission of bloodborne pathogens through therapeutic injections. Because injections are overused to administer medications, injection safety programmes should also aim at reducing the number of therapeutic injections. Such programmes may be better conducted if initial assessments are made to estimate the frequency of injections and to identify the determinants of injection overuse among patients and health care workers.

Regardless of the choice of injection technology, only a broad, multidisciplinary approach addressing technologies, policies, standards, systems, and behaviour can ensure injection safety. Partners from within WHO and outside of WHO are now here today to join our forces in the Safe Injection Global Network. SIGN will aim to co-ordinate activities, advocate for changes in policy, define standards for safe injections, develop new behaviours, take advantage of health care reform, increase the availability of safer injection technologies, promote appropriate waste disposal, and define adapted information, education, and communication strategies. In these two days of meeting, we will first review together what we know today in term of injections and their adverse effects. Then, we will work together on the draft terms of reference for SIGN and the strategic plan, so that together, we can obtain a consensus to the strategic plan for the next three years and agree to a plan of work, identify areas of responsibilities and assist in the identification of funding. I wish you two very fruitful days of work.

Unsafe injections, their consequences, and potential solutions

Safe Injection Global Network: Historical Perspective

Michel Zaffran
World Health Organization

Injection safety: a long time concern of immunization programs

Because injection safety is essential to immunization programmes, efforts towards a safe use of injections initially focused to the field of immunization. Equipment developed for introduction in the field included plastic sterilisable syringes (1982), steam sterilisers (1984), auto-disable syringes (1985), and Time Steam Temperature (TST) indicators (1991). In addition, training material and injection survey materials were developed.

Limitation of injection safety approaches restricted to immunizations

At the end of the 1990's, public health professionals involved in immunization injection safety recognized that the safety of immunization injections could not be addressed alone. Efforts towards an injection safety initiative had to reach outside of the field of immunization to address therapeutic injections that represent the majority of the injections administered worldwide.

Unsafe injections recognized as a major source of infection with bloodborne pathogens

While the international immunization community recognized the need for a broad strategy to make injections safe, evidence became available suggesting that in a number of countries where hepatitis B virus or hepatitis C virus infections were highly endemic, including Egypt,¹ Pakistan,² and Moldova,³ overuse of therapeutic injections combine with unsafe injection practices to account for a large proportion of the new cases of infection.

Origins of the Safe Injection Global Network

In 1999, public health professionals from various different backgrounds sharing a common interest in a safe and appropriate use of injections joined forces as a Safe Injection Global Network (SIGN). SIGN is coordinated by a secretariat based in the Blood Safety and Clinical Technology department of the World Health Organization Headquarters, in Geneva, Switzerland.

A Comprehensive Approach to Blood Safety

Jean Emmanuel
World Health Organization

HBV, HCV, and HIV account for the largest burden of bloodborne infections

Among bloodborne pathogens, HBV, HCV, and HIV account for the largest burden of diseases worldwide, with an estimated 370, 180, and 30 million cases of chronic infections respectively worldwide in 1998. Modes of transmission of these bloodborne pathogens include transfusion of contaminated blood or blood products, unsafe injection practices, and other percutaneous or permucosal procedures conducted in medically related or traditional settings.

Prevention strategies for infections with bloodborne pathogens

Prevention strategies differ to address the three modes of bloodborne pathogen transmission. Prevention of bloodborne pathogen transmission through transfusion of blood and blood products requires national blood transfusion service policies, recruitment of voluntary safe blood donors, universal serological testing of blood, appropriate viral inactivation procedures, and appropriate clinical use of blood and blood products in clinical medicine. The prevention of bloodborne pathogen transmission through injections requires

awareness regarding the risks associated with unsafe injection practices, availability of sufficient and adequate supplies of injection equipment and infection control supplies, setup of an appropriate waste management system, and reduction of injection overuse. The prevention of bloodborne pathogen transmission through other percutaneous or permucosal procedures in medically related or traditional setting requires the implementation of universal precautions in all settings where these procedures occur.

Need for an comprehensive approach to prevention infections with bloodborne pathogens

While prevention strategies differ, unsafe blood, unsafe injections, and other unsafe percutaneous or permucosal procedures lead to identical disease outcomes. Thus these prevention strategies should be coordinated and evaluated using public health surveillance for HIV, HBV, and HCV infection as outcome indicators of prevention effectiveness.

Unsafe Injections and the Transmission of Bloodborne Pathogens

Lone Simonsen
World Health Organization

Injections are overused to administer medications

There is anecdotal evidence that physicians, nurses, and lay healthcare workers have used injections widely to administer medications in many countries since the 1970's. The proportion of outpatients who receive an injection for a healthcare visit was developed as an indicator for injection use in healthcare setting by the Drug Action Programme (DAP, now parts of Essential Drugs and Medicines policy, EDM). Review of information collected using this indicator suggests that in many countries, between 25% and 96% of persons presenting to a health care provider receive an injection.⁴ Additional studies indicate that the proportion of immunization injections among injections received by the population ranges between 2% and 15% in many developing and transitional countries with a median of 5%.^{4,5,6} Among injections administered for therapeutic purposes, between 70% and 99% were found to be unnecessary according to external review criteria.⁴ Furthermore, in addition to injections administered in the formal healthcare setting, unqualified persons administer many injections.⁷ In Uganda, deterioration of the formal healthcare system led to an increase in the proportion of injections administered by lay healthcare workers.⁸

Many injections are unsafe

A safe injection is one that does not harm the recipient, does not expose the healthcare worker to any avoidable risk, and does not result in any waste that is dangerous for other people. However, most observational studies of injection safety have focused on estimating the proportion of injections administered with a re-used syringe and or needle. One method used in the field consists of an observation of injections to determine the proportion of injections administered with a syringe and or needle re-used without sterilization.⁴ A second method consists of an observation of the number of consecutive injections administered without sterilization with the same syringe and needle. Studies conducted using this method suggest that syringes are often re-used two or three times without sterilization⁴. The data generated directly or indirectly through these two methods in published or unpublished studies suggests that the proportion of re-use of syringes and needles without sterilisation in many developing countries ranges from 31% to 95%, with few countries actually demonstrating absence of re-use. Overall, in 19 countries studied, a median of 50% of injections involved equipment reused without sterilization. Limited information is available to determine whether injection safety is generally improving or deteriorating world-wide. Experience in some countries suggests that changes may occur rapidly (e.g., injection practices improved considerably in Romania between 1991⁹ and 1998¹⁰ because of the awareness that followed the episode of HIV transmission in orphanages).

In selected countries where information is available, injections are associated with large scale bloodborne pathogen transmission

The association between infection with bloodborne pathogens and receiving injections has been reported in a number of published studies conducted within populations or during an outbreak. Methodological approaches used in these studies include cohort studies,¹¹ case-control studies,^{3,12} cross sectional studies,² and use of public health surveillance data.¹³ Bloodborne pathogens most often associated with injections are

HBV, HCV, and HIV. In five population-based studies for which a population attributable risk could be calculated, at least 20% of new cases of HBV infection were attributed to unsafe injection practices in Moldova, Romania, India, and the Taiwan province of China.⁴ In addition, cross sectional studies have indicated an association between HCV infection and receiving injections.² Finally, two nosocomial outbreaks of HIV infection associated with injections have been reported among children in Eastern Europe.^{4,9} Infections with other bloodborne pathogens, including viral hemorrhagic fever viruses, occur less commonly, usually during time-limited outbreaks.

Mathematical models suggest that unsafe injections might lead to millions of cases of hepatitis B and C virus infection annually worldwide

In the absence of epidemiological data in many countries, a region-based simple mass action mathematical model was developed to estimate the annual incidence of injection-associated infections with HBV, HCV, and HIV. The parameters of the model included injection frequency, frequency of syringe and/or needle re-use without sterilization, and the prevalence of infection with bloodborne pathogen.¹⁴ Values for the parameters of the model (Figure 1) were determined on the basis of a review of published and unpublished studies. Results of the analysis suggests that unsafe injection practices might cause 8-16 million cases of HBV infection, 2.3-4.7 million cases of HCV infection, and 80 – 160,000 cases of HIV infection annually worldwide. These estimates only reflect the consequences of clinical use of injections, exclude recreational use of injections, exclude the Americas because of an absence of information, and are limited by the caveats of the model.¹⁴

Figure 1: Equation of the Adam Kane model.

$$P(\text{inf}) = 1 - \{1 - P(\text{sus}) \times P(\text{ex}) \times P(\text{trans})\}^n$$

P (inf) is the annual probability of infection with a given bloodborne pathogen, P (sus) is the prevalence of susceptibility to the bloodborne pathogen in the population, P (ex) is the probability of exposure (prevalence of active infection in the population multiplied by the proportion of injections administered with a syringe and or needle re-used without sterilization), P (trans) is the probability of transmission of a bloodborne pathogen following a percutaneous exposure according to needlestick studies among healthcare workers, and n is the annual number of injections received by an individual.*

Assessing Injection Use and Safety

Steve Luby
Centers for Disease Control and Prevention

Injection practices should be assessed to identify local issues, provide a sound basis for evaluation and help connecting with local target groups

First, assessing injection practices identifies relevant local issues so that focused interventions can be conducted with greater effectiveness and at lower costs. Second, assessing injection practices provides a sound basis for evaluation by providing baseline indicators regarding processes (e.g., injection frequency, proportion of unsafe injections) and outcomes (the incidence of injection-associated infections with bloodborne pathogens). Third, the collection and feedback of information by the investigators who assess injection practices initiates communication between public health professionals and the various groups that a future behavior change strategy will likely want to target for subsequent interventions.

Injection practice assessments should address injection use, injection safety, and the association between injections and infections with bloodborne pathogens

Injection use may be characterized in terms of frequency (through population-based surveys, healthcare facility based surveillance, or analysis of market data) and qualitative determinants for use of injections (including medical indications, knowledge of risks, personal/social meaning, psychological needs, and

* HBV: 30%, HCV: 3%, and HIV: 3%

economic incentives). To assess injection safety, all steps of injection administration should be characterized, including the use of a sterile syringe and/or needle, the sterility of the vial used to draw medications, the sterility of the procedure, and the mode of disposal of the sharp equipment. Triangulation may be a useful approach to compare (a) reported infection control practices with (b) available equipment and (c) observed practices. Finally, to measure the strength of the association between infection with bloodborne pathogen and injections, analytical epidemiological studies may be conducted using the case-control approach,³ the cross sectional approach,² or the cohort approach.¹¹ In addition, surveillance data may provide a useful base for nested case-control studies.¹³ To obtain unbiased analysis results, cases of infection with bloodborne pathogens identified for these studies should ideally be recent (i.e., incident rather than prevalent) and laboratory confirmed. Thus, because of the absence of a serological marker of acute infection, the association between acute HCV infection and injections is more difficult to measure than the association between acute HBV infection and injections.

Injection practice assessments should be focused, action-oriented, and standardized.

Although in-depth studies conducted in the past have been useful to understand the causes of injection overuse and unsafe injections, assessment of injection use and injection safety should be focused, action oriented, and aim primarily at directing prevention programs. Standardization of methods used would be useful to compare various countries or settings using identical indicators collected with comparable methodologies.

Reducing Injection Use: Approaches and Evaluation

Sri Suryawati
Gadjah Mada University

Injections were overused in healthcare setting in Indonesia

Of persons attending outpatient clinics in Indonesia in 1987, 44% of under five and 74% of five years of age and older received at least one injection. Of all these injections administered, 10% were determined to be necessary. Factors that influenced drug use included knowledge deficiency and knowledge habits from the provider; cultural beliefs and patients' demands in the area of provider-patient interactions; peer norms, relation, authority, and power in the social structure of providers; excessive workload and lack of drug availability in the working environment; and finally, influence of industry marketing. In addition, in the specific case of the private sector, there was a financial incentive for providers to prescribe injections.

An approach combining formative studies, intervention studies, and follow-up

The general approach of the International Network for the Rational Use of Drugs (INRUD) in Indonesia starts from formative studies to define the problem and identify motivating factors. Then, a controlled intervention study is chosen from among a list of all possible options. After completion of the study, cost effective interventions are implemented on a large scale, partially effective or costly interventions are revised and re-studied, and ineffective interventions are abandoned.

Addressing cognitive dissonance between patients and providers through Interactional Group Discussions (IGD)

In Indonesia, formative studies indicated that patients attribute injection overuse to the will of prescribers while prescribers attribute it to patients' demand. This discrepancy was named "cognitive dissonance". A controlled intervention study based upon Interactional Group Discussions (IGD) of six prescribers and six patients facilitated by a behavioural scientist and a pharmacologist during 90 to 120 minutes focused on the discrepancy between the patient and prescriber perspectives. The risks of bloodborne pathogen transmission through injection was also addressed during these discussions. Results of the analysis suggested that the IGD-based intervention was successful in obtaining a reduction in injection use in healthcare settings that was sustained for at least two years (Figure 2).¹⁵ Reduction of injection overuse was observed in both the intervention and the control groups, as a probable result of contamination of the intervention. Hypothesised mechanisms for behaviour change include the reality testing of prescribers' assumptions about patients' beliefs, the provision of scientific information about injection efficacy, and the establishment of peer norms

about correct behaviour. The economic crisis in Indonesia is an unlikely explanation for the observed impact since the reduction of injection use was observed before the crisis.

Communicating research results to broaden the scope of the intervention

Communication of the results of this intervention study to health officials, healthcare workers, and the general public lead to larger scale implementation of this approach with substantial impact on injection use in Indonesia. Persisting constraints, including requests for injections from a small proportion of patients, providers' concerns that patients are not satisfied if they do not receive an injection, and fears of losing patients if an injection is not prescribed are being addressed through newer strategies, including small group discussions involving patients and prescriber facilitated by health center physicians, and other information, education, and communication activities. Because this work focused on the public sector, conclusions cannot be generalized to the private sector where injection practices may have differed. Providers working in both the public and private sector may even have behaved differently according to their type of practice.

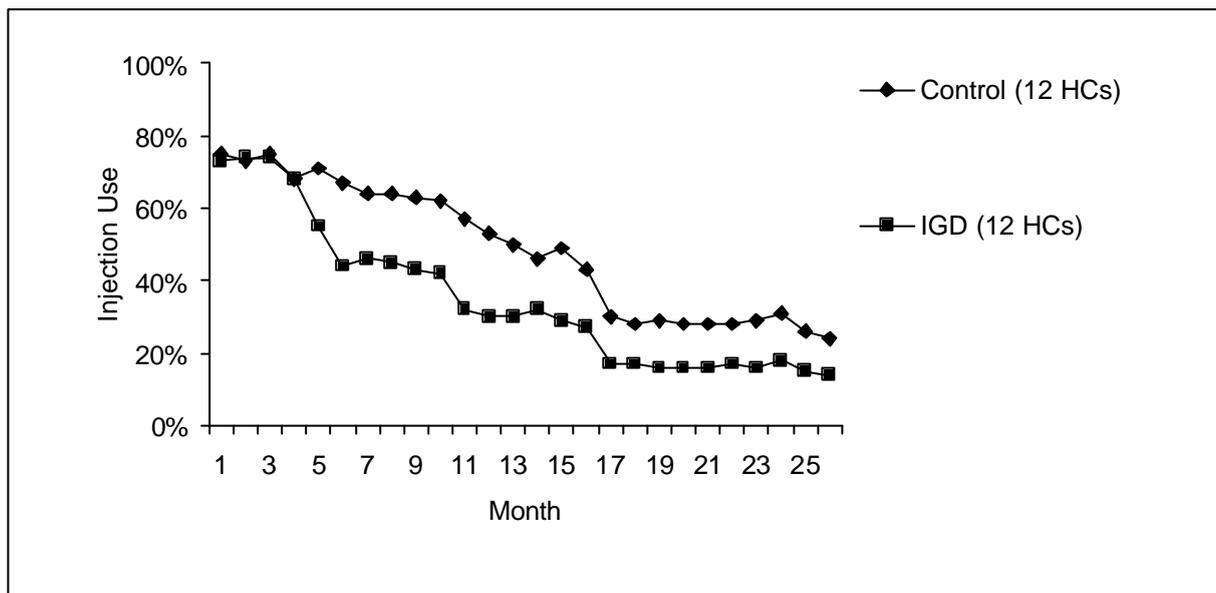


Figure 2: Proportion of outpatients receiving an injection in 12 health centres where Interactive Group Discussion (IGD) were conducted and in 12 controls, Indonesia, 1996.

Interventions to achieve injection safety should address the high transmission potential of hepatitis B virus

Needlestick studies conducted among healthcare workers provide information about the transmission potential of bloodborne pathogens through percutaneous exposures.^{16,17,18} Among 100 susceptible healthcare workers stuck with a needle used on an infected source patient, the proportion who will acquire infection in the absence of prophylaxis ranges from 30% for HBV, to 3% for HCV, and 0.3% for HIV. Reasons for the high transmissibility of HBV through percutaneous exposures include the high concentration of viruses in the blood of infected patients and the resistance of HBV in the environment (HBV persists as an infective virus at least a week in the environment).¹⁹ Factors that might facilitate HBV transmission from patient to patient in healthcare settings include a high prevalence of chronic HBV infection among patients, a high frequency of procedures that lead to environmental contamination with blood, a high frequency of percutaneous procedures, and the presence of patients with high levels of viremia. In the specific setting of hemodialysis that cumulate all these factors and where HBV transmission has frequently been described, nosocomial transmission of HBV has been reported in the absence of reuse of disposable equipment.²⁰ Likewise, in countries like Romania where HBV is highly endemic, injections are overused, exposure to blood is common, and where many children are actively replicating the virus, HBV may be transmitted through injections in the absence of re-use of syringes and needles though preparation of injections in contaminated environment and inappropriate use of multi-dose vials (Figure 3).¹⁰

Figure 3. Injection preparation table in a Romanian hospital, 1998. Breaks in injection safety that may account for HBV transmission through injections in the absence of re-use of syringes and needles include preparation of injections (1) on a table where open blood samples are handled (2), bloody needles (3) and used syringes (4) are abandoned, and needles are left in multi-dose vials (5). (Photo: Catherine Dentinger)



More community-based experience is needed on success stories to achieve injection safety

Although there is anecdotal evidence of improvements of injection safety in selected settings (e.g., injection practices in Romania between 1990 and 1997 as a result of many years of ground softening,^{9,10} infection control practices in dental offices and other healthcare setting in the United States since the early 1980's) or in specific programs (e.g., the Expanded Programme on Immunization [EPI]), few community-wide interventions have been conducted to achieve injection safety. In Mwanza, Tanzania, between 1991 and 1993, a baseline assessment was conducted that showed unsafe injection practices and injection overuse.²¹ An intervention was initiated through education and provision of treatment and sterilisation guidelines. Results of the evaluation indicated that the proportion of outpatient visits associated with an injection

decreased from 23% to 10% and that the proportion of injections considered safe according to the criteria used by the authors increased from 35 to 67%.²²

Approaches to injection safety should combine behavior change, provision of supplies, and set-up of a waste management system.

Causes of unsafe injection practices include a lack of awareness regarding risk, a lack of injection equipment and infection control supplies (including water), and a lack of appropriate disposal for sharps. Thus, to achieve injection safety, approaches should combine behavior change strategies, provision of supplies, and setup of a waste management system. While newer technologies that decrease the probability of equipment re-use (e.g., auto-disable ["AD"] syringes) are promising, the choice of an injection technology should be tailored to the needs in the specific settings according to the results of an initial assessment. In addition, effectiveness of AD syringes in preventing bloodborne pathogen transmission through injections may be enhanced if this technology is introduced in the context of a broader behavior change strategy. Finally, setting up of a waste management system is essential to prevent accidental needlestick injuries and scavenging of used syringes and needles for re-sale.

Evaluation of injection safety programs should be based on process and outcome indicators

Under the principle of "what gets measured gets done", process indicators of injection safety are important to monitor the effectiveness of the programme. However, to quantify the impact of a prevention initiative and evaluate overall cost-effectiveness, outcome indicators reflecting the incidence injection-associated infections are needed. Viral hepatitis B and C that represent the highest burden of disease associated with injections are good indicators of injection safety as their incidence is high in many countries, acute phases of infection are often symptomatic, standardized case definitions are available, and viral hepatitis is a reportable disease in many countries. Monitoring of injection abscesses may also be useful to evaluate impact in areas where they are common.²³

A Benchmark Survey of Decision Makers Regarding Injection Safety in Africa, Asia, East Europe, and Latin America

Mary McIntosh
Princeton Survey and Associates

Princeton Survey and Associates conducted a survey of decision makers regarding injection safety in Africa, Asia, Eastern Europe, and Latin America. Key informants in 33 countries were probed regarding how decision makers think about injection safety. The survey addressed four areas:

1. the perception of unsafe injection practices as a public health problem;
2. identified causes of unsafe injection practices;
3. proposed solutions to the problem;
4. information sources valued by stakeholders.

Perception of unsafe injection practices as a public health problem

Stakeholders were rarely able to quantify the burden of disease and death associated with unsafe injection practices and few listed unsafe injection practices among their top five public health priorities. There was a tendency for respondents in Africa and in Asia to include unsafe injection practices in the top five list more often. Inappropriate sharps disposal was commonly identified as a major problem.

Identified causes of unsafe injection practices

Respondents perceived causes of unsafe injection practices as multi-factorial. Identified causes included the absence of awareness among patients and healthcare workers, injection overuse, lack of sufficient injection equipment and sterilization supplies, and absence of guidelines.

Proposed solutions to the problem

Stakeholders mentioned a need for training and national guidelines but lacked a system and behavioral approach to unsafe injection practices and did not perceive a need for much more additional financial resources. With respect to financial resources required, they reported that funding sources should originate from donors as well as from the ministry of health budgets. A majority expressed a preference for the disposable injection technology.

Valued information sources

Information sources valued by the respondents included studies published in the international literature and discussions with peers.

Communication Strategy for the initial Meeting of the Safe Injection Global Network

Danièle Letoré
Genevensis

During the autumn of 1998, the San Francisco Chronicle published an alarming article regarding unsafe injections. As a response, WHO prepared a position paper and some questions and answers. During the summer 1999, although the article in the San Francisco Chronicle was not picked up by other reporters, there was a need to prepare for events, including the SIGN initial meeting and the publication of a special issue of the Bulletin of the World Health Organization. To prepare for a potential crisis, a decision was made to prepare a communication kit that included a backgrounder, a glossary of terms, facts and figures, and some questions and answers (Provided in appendix 5, page 52, and available on the WHO internet site). The WHO Bulletin special issue, some photographs, and a pamphlet describing SIGN will be added to this communication kit and it will be shared with the press. In the longer term, a broader communication strategy will be prepared as one of the products of the network to ensure a large commitment to a safe and appropriate use of injections world-wide.

The Immunization Safety Priority Project

Philippe Duclos
World Health Organization

Immunization safety as a need for immunization programs

Today, immunization programs are facing important challenges with respect to safety. Examples of these challenges are the fact that up to one-third of immunization injections are not carried out in a way that guarantees sterility, and that adverse events following immunization and related rumors are poorly understood and handled by those in charge of the immunization programs.

Immunization safety as a priority project for the department of Vaccines and Biologicals (V&B)

Immunization Safety has been chosen as a Priority Project by the WHO Department of Vaccines and Biologicals (V&B) to establish a comprehensive system to ensure the safety of all immunizations given in national immunization programs by the year 2003. The strategy aims at bringing an overall culture of safety to allow for the prevention, early detection, and quick response to adverse events related to immunization programs to lessen their negative impact on health and on the programs. Countries are the primary focus and therefore key players. Beyond national authorities and relevant WHO programs, the partner coalition also includes UNICEF, the World Bank, PATH, the Bill and Melinda Gates Children Vaccine Program, the industry (vaccine and device manufacturers), as well as national and international professional organizations. Several development and/or technical agencies such as CIDA, JICA, USAID, and CDC are also participating in the project. Several of the activities such as injection safety and media training are far reaching and involve interdepartmental and cross cluster collaboration within WHO.

Main activities of the immunization safety priority project

To coordinate the activities towards improving immunization safety, human and financial resources have been earmarked at WHO/HQ, and strong collaboration established with the WHO Regional Offices. In addition, an internal cross-cluster coordination group meets regularly to share information and monitor progress, and a Steering Committee on Immunization Safety has been created to provide technical and scientific advice on the strategies, activities, constraints, and requirements to accomplish the mission of the project. The project has four major product areas that include vaccine safety, research and development of safer/simpler vaccine delivery systems, expanded access to safe and effective delivery technologies and their disposal, and identification and management of immunization related risks.

Main phases of the immunization safety priority project

1. Establish the necessary experts and partners to form the project platform;
2. Carry out studies and surveillance activities to improve safety (e.g., cost-benefit analysis and investigation of risk factors);
3. Develop comprehensive information, training materials, and guidelines;
4. Obtain consensus and political will to implement good practices in immunization programs;
5. Provide technical expertise to support countries in implementing planned activities;
6. Develop new technologies to minimize risks or potential risks of adverse events.

Indicators for the immunization safety priority project

Indicators for the immunization safety priority project include the proportion/number of countries reporting a safe injections component of the national work plan (including procurement of syringes, needles, safety boxes, and sterilizers) and the proportion/number of countries reporting any functioning surveillance for adverse events following immunization.

The SIGN Terms of Association

Steve Landry
United States Agency for International Development

Michael Free
Program for Appropriate Technology in Health

Bob Chen
Centers for Disease Control and Prevention

John Lloyd
World Health Organization

After a review of the proposed draft terms of reference of SIGN, the associates proposed amendments to take into account expressed concerns regarding the SIGN mission statement, the SIGN structure and function; the communication exchange within SIGN, and the SIGN reports. Proposed changes to the SIGN terms of reference were facilitated by a panel of rapporteurs. The SIGN associates proposed to replace the terms of reference for SIGN by 1) terms of association for the network and 2) terms of reference for its secretariat. While a summary of the discussions can be found below, the final SIGN terms of association are attached in appendix 3, page 45.

The SIGN Mission Statement

SIGN wants to achieve prevention of bloodborne pathogen transmission and other adverse effects of poor injection practices through the achievement of injection safety and a reduction of injection overuse. Thus, within SIGN, care should be taken to always refer to “safe and appropriate injections” rather than simply to “safe injections”. This goal should be reached using a multidisciplinary approach, through concerted actions, and under a common strategic framework.

Because failure of persons to understand and act upon germ theory contributes to unsafe injection practices, the activities of the SIGN associates should aim at helping target audiences to conceptualize the risk of bloodborne pathogen transmission through injections and other percutaneous or permucosal procedures. Thus, injection safety should be achieved through all aspects, including waste management systems, which has been neglected in the past.

SIGN will need to give definition to “injections” and to what “safe and appropriate use of injections” is. SIGN wants to promote the idea that governments, health workers and their employers, and individual patients are all responsible for safe and appropriate use of injections. While unsafe injection practices are of particular concern to SIGN associates because they account for a large proportion of bloodborne pathogen transmission worldwide, SIGN wants to also address other percutaneous procedures that are conducted in formal and informal healthcare setting.

The SIGN Structure and Function

SIGN is a voluntary association of stakeholders sharing a common interest in safe and appropriate use of injections. The purpose of SIGN is to bring added value through co-ordination of the action of the SIGN associates. Thus, participation in the network as an associate should not impose restrictions on the activities conducted by the associates.

The associates who join forces to form SIGN should be clearly differentiated from the SIGN secretariat at WHO. In addition, the role of WHO as secretariat of SIGN and the role of WHO as one of the SIGN associates implementing activities should also be differentiated since the Blood Safety and Clinical Technology department at WHO acts as both secretariat for SIGN and one of the SIGN associates. In the eventuality that the SIGN terms of association are not acceptable to WHO, the secretariat may be placed in another organization.

The SIGN terms of association should reflect that SIGN is a network for action. Recognizing the large amount of work to be done to achieve a safe and appropriate use of injections world-wide, SIGN should

welcome rather than exclude potential new associates. Countries, the industry, and others who want to contribute constructively to the prevention of bloodborne pathogens and other adverse effects of poor injection practices should be allowed to take part in SIGN activities without restrictions. Associations of medical and nursing students should also be invited to join SIGN as they represent the next generation of healthcare workers.

Representation from developing countries should be encouraged for the future of SIGN activities. In contrast to other networks, (e.g., The International Network for Rational Use of Drugs [INRUD]), SIGN was initially organized with a top-to-bottom approach. After initial structural issues are addressed, SIGN should aim at branching out.

Communication exchange within SIGN

SIGN should produce a newsletter and inform associates of activities completed, ongoing, or planned. SIGN meetings should be organized at least annually. Additional working group meetings may also be organized as needed. Finally, SIGN will setup an electronic mail list server to stimulate informal debates regarding safe and appropriate use of injections.

The SIGN reports

Because SIGN associates cannot speak with full authority on policy commitment of their own organizations, reports and recommendations formulated during SIGN meetings should not be binding on the organizations from which SIGN associates come.

Care should be taken in SIGN activities to develop standards using a participatory approach. Global standards are useless if they are imposed from the outside and if local health officials have not measured the extent and the causes of the problems that they are facing.

The SIGN Strategic Framework

The purpose of the SIGN strategic framework is to keep track of activities conducted by the associates and to co-ordinate activities aiming at achieving safe and appropriate use of injections.

Two broad objectives: “Innovation in approaches” and “Achieving safe and appropriate use of injections”

The SIGN strategic framework has two broad objectives: **“Innovation in approaches”** and **“Achieving safe and appropriate use of injections”**. SIGN associates do not consider that more research is needed before country plans are implemented. However, SIGN associates recognize the need for innovation in their approaches to achieving safe and appropriate use of injections while they implement prevention programmes.

Under the first objective, “Innovation in approaches”, the SIGN associates wish to implement pilot interventions aiming at safe and appropriate use of injections (Target A) and to achieve large-scale introductions of newer technologies supporting safer use of injections (Target B). Under the second objective, “Achieving safe and appropriate use of injections”, SIGN seeks to obtain the implementation of national policies and plans for safe and appropriate use of injections in all countries world-wide (Target C) and to promote injection safety in donor or lender-funded services making use of injections (Target D). The full SIGN strategic framework is detailed in appendix 4, page 48 .

Target A: Pilot interventions

Harold Margolis
Centers for Disease Control and Prevention

Objectives of pilot interventions

The objective of pilot interventions would be to develop, test, and evaluate approaches in interventions for a safe and appropriate use of injections.

Population

Pilot interventions should be conducted in a small number of districts and / or small countries in various regions of the world where there is evidence of unsafe practices or where bloodborne pathogen transmission through injection has been documented.

Intervention design

There may be a need for some true pilot studies to test out methods in different settings. A number of design options are available for pilot interventions (by decreasing order of scientific quality):

1. Randomized community trial;
2. Before / after evaluation with control area (s);
3. Before / after evaluation, without control areas;
4. Post hoc evaluation after an already conducted intervention.

A choice among these options should be made according to:

- Local infrastructure;
- Partnership and expertise that can be mobilized;
- Resources available.

Whilst randomized community trials are ideal, they require a large sample size, have potential ethical problems, and are unlikely to be conducted in more than one place. Efforts should be made to reach at least the level of a before / after evaluation with a control area (option 2) since controlled evaluation would generate the strong evidence of effectiveness that is needed for global advocacy.

Components of pilot interventions

Pilot interventions should be preceded by an initial broad based, all-cause assessment. The intervention component itself should be tailored according to the results of that assessment. It should involve multiple sectors and include behavior change, along with provision of injection supplies and setting up a waste management system. Within the behavior change strategy, the impact of policies and structures that affect safety (e.g., remuneration) should be addressed. Costs should be documented, and the sustainability of interventions needs to be considered.

Evaluation of pilot interventions

In addition to process and outcome indicators that could be measured in an inexpensive and easy fashion, pilot interventions should evaluate the impact of setting up of waste management system.

Target B: Access to newer technologies

Michael Free
Program for Appropriate Technology in Health

Overarching Priorities

- Prevention of re-use of dirty syringes and needles is the highest priority since re-use poses the greatest risk of transmission of bloodborne pathogens.
- Wide scale adoption of currently available auto-disable syringes and pre-filled pouch and needle technologies would greatly improve injection safety in immunization and family planning programs. It would also greatly improve the delivery of antibiotics and other intra-muscular fixed dose injectable medications. Only 7% of immunizations use auto-disable technology. One of the challenges is to create a large enough demand that prices come down.
- Financing and distribution impediments need to be dealt with to enable wide scale adoption of the available safe injection technologies.
- Newer, safer injection technologies are urgently needed for intravenous and other curative skin piercing procedures.
- Improved management systems for safe injection are fundamental to the success and sustainability of any safe injection intervention.

Products within the access to newer technologies target

Training and promotion material regarding injection technologies

Priority materials include training modules for health service providers. A prototype training module conveying the fundamentals of an integrated safe injection program should be developed. This 'boiler plate' could be adapted by AD syringe suppliers or others and applied to specific AD technologies. By this means, all training materials would convey the same SIGN-recommended principles of basic practices.

Decision-making guide regarding injection technologies for health service programs.

These tools should include pros and cons of each available technology, their best-suited applications, price ranges, and sources. A rapid assessment tool should also be developed to facilitate analysis by local managers of clinic or program safe injection practices.

Cost reduction of AD syringes.

Although new designs and improved manufacturing efficiencies will help to reduce cost, the biggest impact is likely to result from a large increase in the market. Creative financing schemes, ‘bundling’ and vigorous generic promotion strategies will help to achieve this higher scale of use.

Availability of a jet injector that can be used for mass vaccination campaigns.

SIGN can facilitate this development by clearly defining standards for upstream contamination and helping to define the market for this technology. Cost sharing for regulatory clearance and field validation may also be required. Two technologies appear promising at this time.

Evaluation of new administration devices through post-market surveillance

Studies should include cost-effectiveness, ‘whole system’ analysis including the operational impact on the health centers, and enabling budget mechanisms. A standard protocol should be developed. Sites for study of AD syringes impact should be identified based upon UNICEF distribution data.

List of options in waste disposal or which development should be promoted

Newer waste disposal options are needed because there are problems with collection, disposal, and emission of toxic air pollutants secondary to incineration with the use of auto-disable syringes. Criteria for promotion of development of waste disposal options include low environmental impact, affordability, and low cost of upkeep. Candidate solutions should address the needs of peripheral and higher level health centers in rural and urban settings.

Evaluation of new waste disposal techniques through field demonstration projects

Evaluations are currently planned or underway, including, among others, point-of-use needle destroyers, a plasma glass melter system, and several incinerator technologies. Model collection and central destruction systems should be developed for application in countries where suitable levels of infrastructure exist. Best current practice manuals should be developed to help managers cope with waste disposal under current typical conditions in peripheral health centers.

Target C: Country policies and plans for safe and appropriate use of injections

Rachel Feilden
Feilden, Battersby Health Analysts

Approach to implementation of country policies and plans for safe and appropriate use of injections

Compared to other networks, the SIGN initiative originated from international organizations and donors. To achieve safe and appropriate use of injections world-wide, SIGN will need to acquire experience and commitments in the field, particularly in developing countries. Work at country level should be multidisciplinary. Strong advocacy, as used in the polio eradication program, will be essential.

Toolboxes for the development of policies and plans for safe and appropriate use of injections

While reference documents would be useful to assist countries in the formulation, implementation, evaluation, and update of national policies and plans for safe and appropriate use of injections, the format of flexible “toolboxes” should be preferred to the format of rigid guidelines.

Obtaining commitment from each of the organizations and institutions from which the SIGN associates come

SIGN associates should advocate within their organizations and institutions to develop internal working groups and collaborations for safe and appropriate use of injections. In the specific case of WHO, a cabinet paper would be useful to achieve this goal.

Setting standards in a participatory fashion

SIGN should use participatory methods to develop standards in injection safety.

Target D: Bundling for all donor and lender funded programs

Bradley Hersh
International Federation of the Red Cross and Red Crescent Societies

Bundling should be concrete and well-defined

Bundling should be concrete and well defined. It should include tangible costs (e.g., for the Expanded Programme on Immunization [EPI], good quality vaccine, auto-disable syringes, and safety boxes) but also intangible costs (e.g., training and costs of disposal). These intangible costs of training and disposal must be considered as part of the bundle and should be budgeted. Creative funding mechanisms for these costs should be explored (e.g., Green or environment fees). Full bundle cost should be included in program budget. Donor support should be sought in this approach. In some countries undergoing healthcare reform, there may be opportunities to incorporate injection safety in the budgeting process.

Use of EPI bundling as a model for other programs

Bundling as it has been proposed for the EPI should be used as a model for other public health services making use of injections (e.g., injected contraceptives). These services need to develop their own injection safety bundles. While the overall target should be injection safety within all healthcare services, donor or lender funded programs should aim at reaching higher sub targets and should be role models. Dialogue with the industry should be increased to develop procurement and ensure safe injection (e.g., bundling at source).

Responsibilities of donors and lenders

Donors and lender agencies should also be responsible for requiring that loan funded public health programs routinely document injection safety.

Cross Cutting Issues within SIGN Strategic Objectives

Assessment and Evaluation

Andy Hall
London School of Hygiene and Tropical Medicine

Developing practical definitions

To assess and evaluate injection practices, some of the words and concepts used by SIGN should be defined.

Injections

There is a need to define what the network considers an appropriate working definition of an injection. Although SIGN will initially focus on injections because they contribute most to the transmission of blood borne pathogens, there is a need to promote prevention of bloodborne pathogen transmission through conceptualization of the germ theory.

Safe injection

SIGN defines a safe injection as one that does not harm the recipient, does not expose the healthcare worker to any avoidable risk, and does not result in any waste that is dangerous to other people. Although this definition is useful as a reference definition, an operational definition of a safe injection should be developed to define what criteria should be used to determine whether an injection is safe during an observational assessment or evaluation.

Necessary injections

If the frequency of injection were reduced, the task of making the remainder safe would be more manageable. In addition, injections carried out safely, can lead to adverse events in case of overuse (e.g., injection-induced polio provocation paralysis²⁴). Methods that could be used to develop a definition of what a necessary injection is include a *delphi* approach through a group of experts and team work based upon observation of current practices.

Initial assessment of current state of injection practices

Assessment of current state of injection practices should be broad. This assessment should address and involve healthcare workers, ministries of health and welfare, pharmacists, public health managers, population, traditional healers, incinerator operators, and hospital administrators (especially for disposal). Methods that should be used for assessment include survey of practices, focus groups, key informants discussions, observational methods, Knowledge Attitude, and Practices (KAP) surveys, surveillance for specific viral hepatitis, and resource inventory linking supplies to injections given.

Indicators of safe and appropriate use of injections

Indicators that may be used to assess and evaluate safe and appropriate use of injections include injection rates, proportion of injections that are necessary, proportion of injections administered under safe circumstances, stock records, and surveillance for viral hepatitis B and C (depending on which is most appropriate). Acute hepatitis due to HBV had been used as a useful indicator of injection-associated infections with bloodborne pathogens even in populations with relatively high levels of vaccine coverage. Studies should be conducted to determine the usefulness of injection site abscesses as an outcome indicator of injection safety.

Defining Policies regarding appropriate sharps waste management

There is currently a discrepancy between the WHO recommendations on waste disposal and the implementation of these measures. An absence of appeal and understanding of waste disposal issues for decision-makers may explain this discrepancy. Advocacy needs to be conducted through SIGN to promote sharps waste management policies that:

- Recognize waste management as integral part of strategies to achieve injection safety;
- Require health systems and manufacturers to budget for waste management since supply, use, and disposal are integral parts of the syringe and needle lifecycle (e.g., supply of kerosene to support pit or drum burning of used syringes during mass campaigns in the WHO AFRO region, cost- and risk-sharing, manufacturer's responsibilities, and green tax concept [PATH]);
- Recommend including waste treatment and disposal criteria when making a choice of injection technology;
- Encourage and provide assistance in the development of appropriate national policies for the management of sharps;
- Evaluate and develop the capacity to monitor and enforce the regulations (i.e., laboratories, equipment, and inspector);
- Enforce essential policy aspects through regulations.

Foster development of safe, low-cost, waste management systems

Environmental reservations have been expressed to the use of incineration for the destruction of sharps waste. In some cases, the absence of quantified data regarding the adverse effects of inappropriate waste disposal has limited the use of a "comparative risk" approach that would show that the inconvenience of incineration is outweighed by the benefit gained through the destruction of sharps waste. Research and development should be conducted to foster development and field evaluation of environment-friendly, affordable solutions in sharps waste disposal. Consideration should be given to the design and construction of reliable equipment for the treatment and disposal of sharps at the local and regional level.

Waste disposal solution presently or recently pilot tested include, among others:

- Auto-combustion incinerators in several countries (WHO/WPRO);
- Separation of needles from syringes before separate disposal (MSF /France);
- Melting and encapsulation of syringes and needles into blocks to be used for landfill, road building, etc (WHO HQ, Vaccines and Biologicals);
- Use of concrete-lined medical waste pits and/or pit latrines (WHO/AFRO)
- Small volume/low cost incinerators (including types produced in South Africa)
- Point-of-use needle destroyers - ("de-fanging") (PATH)
- Guidelines for health workers on incineration options and concept of "incineration chain" (PAHO)

In addition, research and development should be conducted using proper methodologies aiming at obtaining reliable data to foster development and field evaluation of injection devices that minimize the quantity of waste and the risks associated with them, including:

Devices presently or recently studied/ evaluated include:

- Pouch & needle system (CDC);
- Soluble syringes & needles (WHO HQ, Vaccines and Biologicals).

Access to waste treatment and disposal

Information should be made widely available regarding waste treatment and disposal solutions available and contacts necessary for implementation. Donors and lenders should be guided in rational procurement of waste treatment and disposal solutions. Finally, assistance should be provided to countries for them to set up a waste management infrastructure (storage, collection etc.).

Promoting appropriate use of waste management systems

Awareness must be raised on the hazards related to inadequate management of healthcare waste. Implementation requires guidance and training at various levels. The “Teacher's guide on management of wastes from health care activities” assists training at the level of policy makers and managers of healthcare facilities. Other aspects of waste management are laid out in the existing guidelines, “Safe management of wastes from health care activities”. In addition, guides should be designed to assist primary care facilities and hospitals to make rational decision in waste disposal. Thorough training programme should be provided to all members of healthcare facilities (administration, physicians, nurses, and others) on the importance and approaches to managing healthcare waste. Training programme should be specifically developed for the various categories of healthcare workers.

Behavior Change and Advocacy

Dana Faulkner
The Change Project

Scott Wittet
Bill and Melinda Gates Children Vaccine Program

Behavior change within the strategic framework of SIGN

Behavior change issues and the behavioral dimension of safe and appropriate use of injections were incorporated into the SIGN strategic framework as an integral part of the objectives. This integration, rather than an isolation of behavioral issues in a separate category, is important and productive. However, it will be necessary to carefully review the strategic framework as it is developed to ensure that the behavioral dimension of each objective is fully reflected. For example, within the Target B that proposes to increase the availability of newer technologies, the following additional behavioral issues should be considered:

- The behavioral effects of changing storage and procurement through the introduction of newer technologies that support safer use of injections ;
- The need to foster dialog among those affected by the newer, safer technologies (e.g., decision-makers and health workers; health workers and patients);
- The need to target training and promotion broadly to include the informal sector;
- The importance of demand driven strategies to success in introducing newer, safer technologies.

To ensure full consideration of these behavioral issues, behavioral specialists should be included in the working groups that will develop each objective. In addition, the expression “Information, Education, and Communication (IEC)” should be replaced by “Behavior change” in the strategic framework document.

Sustained behavior change requires more than transfer of information

Sustained behavior change requires more than impacting knowledge through the transfer of information. Many other elements need to be also addressed, including attitudes, emotions, power relationships, belief systems, norms, systems, and incentives. Thus, information-based messaging cannot be the only method used to address the behavioral dimensions of safe injections.

Defining the audiences for interventions to achieve safe and appropriate use of injections

For behavior change activities to be effective in achieving safe and appropriate use of injections, audiences for interventions need to be fully defined. These audiences include but are not limited to:

- Donor/lending agency leadership;
- Donor/lending agency staff;
- Programme managers;
- Country directors;
- Organizational supporters (UNICEF National Committees);
- Developed country political leaders;
- Decision-makers;
- Opinion leaders;
- Developing country political leaders;
- Developing country regulators;
- Bureaucratic leadership;
- Division heads and programme directors;
- Developing country healthcare workers in the public, private, formal, and informal sector, curative, and preventive sector;
- Academics;
- Researchers;
- Professional associations;
- Philanthropic organizations (e.g. Rotary International);
- Commercial concerns (vaccine manufacturers, device manufacturers, other);
- Consumers.

Communicating and disseminating the lessons learned through SIGN

The experiences of SIGN associates in their attempt to achieve safe and appropriate use of injections should be communicated and disseminated effectively so that the lessons learned by SIGN can be shared broadly. This activity should be a core function of the SIGN secretariat.

Infection Control Practices

Mary Catlin
Program for Appropriate Technology in Health

Need of consensus on the level of standards

Areas of controversy regarding injection safety have been identified in existing guidelines.²⁵ SIGN will need to reach a consensus regarding the level of standards to use among minimal, recommended, or gold standards. Defining minimal standards for injection safety under which the risk of harming is greater than the potential benefit is subject to debate. However, clinicians and clinical services managers recognize that defining minimal standards is a common, useful concept used for quality assurance. Minimal standards give the health care worker a framework for deciding not to give unsafe injections and reinforces the importance of actually improving care. In the absence of minimal standards, healthcare workers will always be funded at a level of resources that can not safely immunize the population of patients and they will be expected to give injections even if unsafe. Surveys have documented the poor correlation between effective therapy and diagnosis. There are relatively few emergent conditions for which A) persons may die without immediate receipt of an injection, and B) peripheral health care workers can be expected to correctly diagnose and change the outcome. One could study the deaths potentially caused by these conditions as currently managed, and compare the toll to estimates of the number of persons potentially harmed by indiscriminate

use of contaminated needles. Alternatively, these life-threatening conditions or symptoms could be described and workers told that more harm than good would result from the failure to intervene.

*The process of planing, developing, and implementing standards*²⁶

Planning

Standards should cover those areas needed to provide a safe injection, even though different workers or levels may address them (e.g., standards for inventory management of injection equipment are as important as technique of injecting). The participants of the SIGN initial meeting lacked some of the relevant expertise that would be needed to develop standards of injection safety. To achieve such a task, more input from developing country supervisors who would ultimately implement the standards would be needed. A committee of stakeholders with relevant expertise, including WHO staff and other experts but also ad hoc expertise as needed, could be formed to create the working group that will develop the standard.

Developing

Input, processes, and outcome of injections should be identified through a flow chart, since the impact of recommendations, from procurement to waste management, needs to be reviewed with respect to their feasibility and impact on disease. Input should be sought in all areas impacted by the standards. Current practices and resources should be also described. A measurable, feasible, reliable, and valid standard should be developed as well as indicators. Consensus should be obtained before proceeding to field testing of the standard.

Implementing.

Piloting the standards regionally to monitor for unanticipated side effects would help assess their feasibility since regional differences in implementation and monitoring may generate hypotheses about effective implementation. Recommendations and final approval need to include plans for marketing, disseminating, and monitoring compliance since the creation of standards themselves is not expected to have an impact. Standards introduction, monitoring, and enforcement should be part of existing programs. For example, there are standard quality monitoring protocols for sexually transmitted diseases (STD). Elements about management of used equipment, minimization of injectable medication doses, etc could be added to existing programme monitoring. Adapted supplements could be given to improve quality within programs that are currently funded, including tuberculosis, leprosy control programs, malaria control programs, integrated management of childhood illnesses (ICMI), and reproductive health.

Conclusion of the meeting

Barbara Stilwell
World Health Organization

The “SIGN’R’Us” slogan can be proposed to summarize the meeting that was successful in creating a new forum to promote safe and appropriate use of injections. SIGN associates realize that their network provides a multidisciplinary response to a complex and important public health problem and subscribe to a common message. Work has already begun in many areas, but SIGN associates need to define how their organizations will contribute to the strategic framework and need to think broadly in planing strategies and interventions.

Appendices

Appendix 1: List of participants

Appendix 2: Programme of work

Appendix 3: SIGN terms of association

Appendix 4: SIGN strategic Framework

Appendix 5: SIGN communication kit

Appendix 1: List of participants

Temporary WHO advisers

AOUN El Saied Aly

Under Secretary of the Preventive Affairs, Ministry of Health and Population
3 Magles El Shaap Street
Cairo - EGYPT
Tel: 202-354 8227 - Fax: 202 - 356 0973

BATTERSBY Anthony

Feilden, Battersby, Health System Analysts (FBA)
Riverside Cottage
Tellisford, Bath BA3 6RL – UK
Tel: 44-1373 830322 - Fax: 44-1373 831038
e-mail: fa@compuserve.com

BUCKERIDGE Lesley G.

International Federation of Pharmaceutical Manufacturer Association (IFPMA)
Smithkline Beecham Biologicals
Rue de l'Institut, 89
1330 Rixensart, BELGIUM
Tel: 32 2 656 9684 – Fax: 32 2 656 8127
e-mail: lesley.buckeridge@sbbio.be

CATLIN Mary

Program Officer, Program for Appropriate Technology in Health (PATH)
4 Nickerson Street
Seattle, WA 98109-1699 – USA
Tel: 1-206 285 3500 - Fax: 1-206 285 6619/3500
e-mail: mcatlin@path.org

CHEN Robert

Chief, Vaccine Safety and Development Branch
Centers for Disease Control & Prevention (CDC)
MS E61, 1600 Clifton Road
Atlanta, GA 30333 – USA
Tel: 1-404 639 8256 - Fax: 1-404 639 8834
e-mail: rtc1@cdc.gov

DORLENCOURT Fabienne

Medical Epidemiologist, EPICENTRE
4, rue St Sabin
F-75011 Paris – FRANCE
Tel: 33-140 21 2848 - Fax: 33-140 21 2803
e-mail: epimail@epicentre.msg.org

FAULKNER Dana

Director, The Change Project
The Academy for Educational Development (AED)
1875 Connecticut Ave, NW, Suite 900
Washington, DC 20009 – USA
Tel: 1-202 884 8730 - Fax: 1-202 884 8454
e-mail: dfaulkne@aed.org

FEILDEN Rachel M
Feilden, Battersby, Health Systems Analysts (FBA)
Riverside Cottage
Tellisford, Bath BA3 6RL – UK
Tel: 44-1373 830322 - Fax: 44-1373 831038
e-mail: fa@compuserve.com

FIELDS Rebecca
Technical Officer, BASICS Project
1600 Wilson Blvd, Suite 300
Arlington, VA 22209 – USA
Tel: 1-703 312 6800 - Fax: 1-703 312 6900
e-mail: rfields@basics.org

FONT SIERRA Fidel
Senior Officer, Community Health, Community Health and Social Welfare Department
International Federation Red Cross & Red Crescent Societies (IFRCRCS)
Chemin Pre Colomb 34
1290 Versoix - SWITZERLAND
Tel: 41-22 755 4033 - Fax: 41-22 733 0395
e-mail: font@ifrc.org

FOX Elizabeth
Senior Adviser, Health Communications and Behaviour Change
Center for Population, Health and Nutrition
US Agency for International Development (USAID)
1300 Pennsylvania Avenue, N.W.
Washington, DC 20523-3600 – USA
Tel: 1-202 712 5777 - Fax: 1-202 216 3702
e-mail: efox@usaid.gov

FREE Michael
Vice President, Program for Appropriate Technology in Health (PATH)
4 Nickerson Street
Seattle, WA 98109-1699 – USA
Tel: 1-206 285 3500 - Fax: 1-206 285 6619
e-mail: mfree@path.org

GHEBREHIWET Tesfaael
Consultant, Nursing & Health Policy, International Council of Nurses (ICN)
3, place Jean-Marteau
1201 Geneva - SWITZERLAND
Tel: 41-22 908 0100 - Fax: 41-22 908 0101
e-mail: tesfamic@uniza.unige.ch

GISSELQUIST David
Consultant, World Bank
5th floor H bldg, ECSSD
World Bank
Washington, DC 20433 – USA
Tel: 1-202 473 3834 - Fax: 1-202 614 0698 or 614 0696
e-mail: dgisselquist@worldbank.org

HALL Andrew J.
Reader, London School of Hygiene & Tropical Medicine
Keppel Street
London, WC1E 7HT – UK
Tel: 44-171 927 2272 - Fax: 44-171 637 4314
e-mail: a.hall@lshtm.ac.uk

HARRINGTON Robert W.
Chairman, Association of Needle-free Injector Manufacturers (ANFIM)
880 Orchard Lane
Lansdale, PA 19446-4520 – USA
Tel: 1-215 362 4815 - Fax: 1-215 362 4819
e-mail: amojet@aol.com

HASAN Syed Imtiaz
Pathologist, Federal Government Services Hospital
643, Street-75, G-10/4
Islamabad – PAKISTAN
Tel: 92-51 291270
e-mail: imtiaz99@comsats.net.pk

HERSH Bradley
Senior Medical Epidemiologist, International Federation of Red Cross & Red Crescent Societies (IFRCRCs)
17, ch. Des Crêts - Petit Saconnex
CH-1211 Geneva 19 – SWITZERLAND
Tel: 41-22 730 4340 - Fax: 41-22 733 0395
e-mail: hersh@ifrc.org

KANE Mark
Director, Gates Children's Vaccine Program at PATH
4, Nickerson Street
Seattle, WA 98109 – USA
Tel: 1-206 285 3500 - Fax: 1-206 285 6619
e-mail: info@childrensvaccine.org

LANDRY Stephen
Children's Vaccine Program, USAID
Office of Health & Nutrition - Ronald Reagan Building
Washington, DC 20523 – USA
Tel: 1-202 712 4808 - Fax: 1-202 216 3702
e-mail: slandry@usaid.gov

LETORE Danièle
Managing Director, Genevensis
Hamo II
CH-1262 Eysins – SWITZERLAND
Tel: 41-22 362 30 22 - Fax: 41-22 362 3022
e-mail: daniele@span.ch

LUBY Stephen
Visiting Scientist, Foodborne & Diarrhoeal Diseases
Centers for Disease Control (CDC)
MS A-38
1600 Clifton Road
Atlanta, GA 30333 – USA
Tel: 1-404 639 4348 - Fax: 1-404 639 2205
e-mail: slx12@cdc.gov

LUCIANI Silvia
Communication Officer, United Nations Children Fund (UNICEF)
3, UN Plaza
New York, NY 10017 – USA
Tel: 1-212 824 6608 - Fax: 1-212 824 6484
e-mail: sluciani@unicef.org

MacAULAY Catherine
Senior QA Advisor, University Research Co
7200 Wisconsin Ave, Suite 600
Bethesda, MD 20814 – USA
Tel: 1-301 941 8414 - Fax: 1-301 941 8427
e-mail: cmacaulay@urc-chs.com

MARGOLIS Harold
Chief, Hepatitis Branch
Centers for Disease Control (CDC)
MS G37, 1600 Clifton Road
Atlanta, GA 30333 – USA
Tel: 1-404 639 2339 - Fax: 1-404 639 1563
e-mail: hsml@cdc.gov

McINTOSH Mary
Vice President, Princeton Survey Research Associates (PRSA)
1211 Connecticut Avenue, NW, Suite 305
Washington DC 20036 – USA
Tel: 1-202 293 4710 - Fax: 1-202 293 4757
e-mail mary.mcintosh@psra.com

PERRIENS Joseph
The Joint United Nations Program on HIV/AIDS (UNAIDS)
20, Ave Appia
1211 Geneva 27 - SWITZERLAND
Tel: 41-22 791 44 56 - Fax: 41-22 791 4741
e-mail: perriens@unaids.org

PRINGLE Angus
Technical Officer, United Nations Children Fund (UNICEF), Supply Division
UNICEF Plads, Freeport
DK-2100 Copenhagen 0 – DENMARK
Tel: 45-35 27 35 27 - Fax: 45-35 26 94 21
e-mail: aprangle@unicef.dk

REELER Anne
Managing Director, Health Access International (HAI)
130 High Street
Melbourn, Royston, Herts SG8 6AL – UK
Tel: 44-1 974 920 298 - Fax: 44-1 763 220 563
e-mail: avreeler@bluewin.ch

ROSENBERG Zeil
Health Industry Manufacturers Association (HIMA)
Becton Dickinson and Co.
1 Becton Drive, MC 204
Franklin Lakes, New Jersey 07417-1884 – USA
Tel: 1-201 847 4827 - Fax: 1-201 847 4845
e-mail: zeil_rosenberg@bd.com

SAKAI Suomi
Senior Health Advisor, Immunisation, United Nations Children Fund (UNICEF)
3 UN Plaza (TA24A-24)
New York, NY 1017 – USA
Tel: 1-212 824 6313 - Fax: 1-212 824 6460
e-mail: ssakai@unicef.org

STOECKEL Philippe J.

Director General, Association pour l'Aide à la Médecine Préventive (AMP)
5, bld. Montparnasse
F-75006 Paris – FRANCE
Tel: 33-147 95 80 30 - Fax: 33-147 95 80 35
e-mail: pstoekel@compuserve.com

SURYAWATI Sri

Country Coordinator, International Network for the Rational
Use of Drugs (INRUD)
Head, Department Clinical Pharmacology
Faculty of Medicine
Gadjah Mada University
PO Box 6215/YK85
Yogyakarta 55281 – Indonesia
Tel: 62-274 563 596 - Fax: 62-274 563 596
e-mail: suryawati@yogya.wasantara.net.id

VAN DAMME Pierre

Viral Hepatitis Prevention Board (VHPB)
Unit of Epidemiology and Community Medicine
University of Antwerp
Universiteitsplein, 1
2610 Wilryk, Antwerp – BELGIUM
Tel: 32-3 820 2538 - Fax: 32-3 820 2640
e-mail: pydamme@uia.ua.ac.be

VOIRET Isabelle

Infection Control Project Coordinator, Médecins Sans Frontière (MSF)
8, rue St Sabin
F-75011 Paris – FRANCE
Tel: 33-140 21 29 29 - Fax: 33-148 06 68 68
e-mail: ivoiret@paris.msf.org

WITTET Scott

Communications Director, Gates Children's Vaccine Program at PATH
4 Nickerson Street
Seattle, WA 98109-1699 – USA
Tel: 1-206 285 3500 - Fax: 1-206 285 6619
e-mail: swittet@path.org

YU Jingjin

Director, Division of Vaccine Preventable Diseases
Department of Disease Control and Prevention
Ministry of Health
No. 1 Xi Zhi Men Wai Nan Lu
Xi Cheng District, Beijing 100044 – CHINA
Tel: 86-10-68792358 – Fax: 86-10-68792514
e-mail: ddcyjj@public3.bta.net.cn

WHO regional offices

Regional office for Africa

DICKO Modibo
Technical Officer for Logistics and Cold Chain
c/o WHO/AFRO
P.O. Box BE 773
Harare – Zimbabwe
Tel: (1) 407 733 9154 – Fax: (1) 407 733 9000
e-mail: dickom@whoafr.org

TAPKO J.-B.
Blood Safety and Clinical Technology
Harare – Zimbabwe
e-mail: tapkoj@whoafr.org

Regional office for the Americas

CARRASCO P.
Communicable Disease Prevention and Control
Washington – USA
e-mail: carrascp@paho.org

Regional office for the Eastern Mediterranean

SADRIZADEH B.
Director, Communicable Disease Control
Alexandria – Egypt
e-mail: sadrizadehB@who.sci.eg

WHO headquarters secretariat

SCHOLTZ , Michael	Executive Director Health Technology and Pharmaceuticals Tel: 41-22 791 4798/4804 - e-mail: scholtzm@who.int
EMMANUEL , Jean	Director, Blood Safety and Clinical Technology Tel: 41-22 791 4387/4385 - e-mail: emmanuelj@who.int
HUTIN , Yvan	Project Leader, SIGN - Devices and Clinical Technology Blood Safety and Clinical Technology Tel: 41-22 791 3431/3680 - e-mail: hutiny@who.int
PADILLA , Ana	Quality Assurance and Safety: Blood Derivatives Blood Safety and Clinical Technology Tel: 41-22 791 3892- e-mail: padillaa@who.int
VEROLLET , Gérald	Devices and Clinical Technology Blood Safety and Clinical Technology Tel: 41-22 791 2160/3680 - e-mail: verolletg@who.int
COGHLAN , Renia	Blood Safety and Clinical Technology Tel: 41-22 791 3727 - e-mail: coghlanr@who.int
AL GASSEER , Naeema	Health Systems and Community Health Tel: 41-22 791 2325 - e-mail: algasseern@who.int
BALL , Andrew	Substance Abuse Tel: 41-22 791 4792 - e-mail: balla@who.int
BARTRAM , Jamie	Protection of the Human Environment Tel: 41-22 791 3537 - e-mail: bartramj@who.int
BOND , Kay	Vaccines and Biologicals Tel: 41-22 791 2262 - e-mail: bondk@who.int
DUCLOS , Philippe	Vaccines and Biologicals Tel: 41-22 791 4527 - e-mail: duclosp@who.int
FRESLE , Daphnee	Essential Drugs and Medicines policy Tel: 41-22 791 3513 - e-mail: fresled@who.int
GAVINIO , Pilar	Communicable Disease Surveillance and Response Tel: 41-22 791 2844 - e-mail: gaviniop@who.int
HOLLOWAY , Kathleen	Essential Drugs and Medicines policy Tel: 41-22 791 2336 - e-mail: hollowayk@who.int
ISLAM , Monirul	Reproductive Health and Research Tel: 41-22 791 4816 - e-mail: islamm@who.int
LLOYD , John	Access to Technologies - Vaccines and Biologicals Tel: 41-22 791 4375 - e-mail: lloydj@who.int
MELGAARD , Bjorn	Director, Vaccines and Biologicals Tel: 41-22 791 4408 - e-mail: melggardb@who.int

MILSTIEN, Julie	Access to Technologies - Vaccines and Biologicals Tel: 41-22 791 3564 - e-mail: milstienj@who.int
OLIVE, Jean Marc	Expanded Programme on Immunisation Tel: 41-22 791 4409 - e-mail: olivej@who.int
QUICK, Jonathan	Director, Essential Drugs and Medicines policy Tel: 41-22 791 4443 - e-mail: quickj@who.int
ROGLIC, Gojka	Diabetes Mellitus - Noncommunicable Disease Surveillance Tel: 41-22 791 4306 - e-mail: roglicg@who.int
SIMONSEN, Lone	Communicable Disease Surveillance and Response Tel: 41-22 791 2686 - e-mail: simonsenl@who.int
STILWELL, Barbara	Health Systems and Community Health Tel: 41-22 791 4701 - e-mail: stilwellb@who.int
TEKLE HAIMANOT, Awash	Communicable Disease Prevention and Control Tel: 41-22 791 3749 - e-mail: teklehaimahota@who.int
ZAFFRAN, Michel	Vaccines and Biologicals Tel: 41-22 791 4373 - e-mail: zaffranm@who.ch
ZHANG, Xiaorui	Traditional Medicine - Essential Drugs and Medicines policy Tel: 41-22 791 3639 - e-mail: zhangx@who.int

Appendix 2: Programme of work

Day 1, morning: Rationale for a new initiative for a safe and appropriate use of injections

	Topic	Speaker	Time
08:30 - 09:00	Registration		
09:00 - 09:15	Opening of the meeting – Welcome	Michael Scholtz	5'
	Election of Chairman and rapporteurs		10'
09:15 - 09:30	History of the injection safety initiative	Michel Zaffran	10'
	Questions		5'
09:30 – 9:45	Preventing bloodborne pathogen transmission	Jean Emmanuel	10'
	Questions		5'
09:45 - 10:15	Bloodborne pathogen transmission and other adverse events associated with injections	Lone Simonsen	20'
	Questions		10'
10:15 – 10:45	Assessment of injection practices	Steve Luby	20'
	Questions		10'
COFFEE BREAK			
11:15 – 11:45	Reducing injection overuse: Approaches and evaluation	Sri Suryawati	20'
	Questions		10'
11:45 – 12:15	Achieving injection safety: Approaches and evaluation	Yvan Hutin	20'
	Questions		10'
12:15 – 12:45	Perception of stakeholders regarding injection safety	Mary McIntosh	15'
	Questions and debate:		15'
	- Recommendations for the advocacy strategy		
	- Recommendations for the strategic approach		
12:45 – 13:00	Proposed communication strategy for SIGN	Danièle Letoré	5'
	Questions		10'

Day 1, afternoon: Terms of reference and proposed strategy for the Safe Injection Global Network

	Topic	Speaker	Time
14:00 – 14:20	The SIGN terms of reference: Mission statement	Steve Landry	5'
	Discussion		15'
14:20 – 14:45	The SIGN terms of reference: Structure and function	Bob Chen	5'
	Discussion		20'
14:45 – 15:10	The SIGN terms of reference: Information exchange	Michael Free	5'
	Discussion		20'
15:10 – 15:30	The SIGN terms of reference: Reports	John Lloyd	5'
	Discussion		15'
15:30 – 15:45	Identification of a group to edit the terms of reference (The group will present a revised version of the TORs for the next morning)		
15:45 – 16:00	The immunisation safety priority project	Philippe Duclos	10'
	Questions		5'
COFFEE BREAK			
16:30 – 17:30	Strategic plan for SIGN: Objectives and targets	Yvan Hutin	15'
	Questions and discussion		45'

Day 2, morning: Plan of work, areas of responsibilities, and identification of funding for the strategic plan

	Topic	Speaker	Time
09:00- 9:15	Presentation of the revised terms of reference	Working group	5'
	Questions		10'
09:15- 9:30	Presentation of the working plan for the day	Silvia Luciani	10'
	Questions		5'
09:30 –10:30	Breakout session (1): Plan of work, responsibilities, and funding (4 groups) Group 1: Demonstration projects (Moderator: Harold Margolis) Group 2: Access to new technologies (Moderator: Micheal Free) Group 3: Towards country plans and a WHA resolution (Moderator: Steve Landry) Group 4: Bundling for all donor funded programs (Moderator: Bob Chen)		60'
COFFEE BREAK			
11:00 –12:30	Breakout session (1, cont'.):		90'

Day 2, afternoon: Plan of work, areas of responsibilities and identification of funding for the strategic plan (Cont'd.)

Topic	Speaker	Time	
14:00- 15:00	Synthesis: Products and plans of responsibilities	Group rapporteurs	60'
15:00 –16:30	Breakout session (2): Addressing cross sectional issues (4 groups) Group A: Assessment and evaluation (Moderator: Andy Hall) Group B: Behaviour change and advocacy (Moderator: Elisabeth Fox and Scott Wittet) Group C: Waste management (Moderator: James Bartram) Group D: Infection control practices (Moderator: Mary Catlin and Linda Ciarello)		60'
COFFEE BREAK			
17:00-17:30	Synthesis- Cross sectional issues	Group rapporteurs	30'
17:30 –18:00	Synthesis of the meeting, final approval on the terms of reference	Barbara Stillwell	30'

Appendix 3: SIGN terms of association

The Safe Injection Global Network (SIGN)

A safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community.

Unsafe injection practices are increasingly recognised as a major source of infection with blood-borne pathogens. While it is the responsibility of all health care workers, their employers, the public, and national governments to ensure safe and appropriate use of injections, the prevention of blood-borne pathogen transmission and other adverse events associated with injections will require improved collaboration between organisations and individuals sharing a common interest in attaining this goal.

To achieve this collaboration, the “Safe Injection Global Network” (SIGN) has been established. SIGN is a voluntary association of stakeholders aiming to achieve safe and appropriate use of injections throughout the world. The network is supported by a permanent secretariat located within the Blood Safety and Clinical Technology (BCT) department of the World Health Organisation (WHO).

1. Terms of Association for the Safe Injection Global Network (SIGN)

1.1. Mission statement

The mission of SIGN is to achieve safe and appropriate use of injections world-wide by concerted action under a common strategic framework. SIGN will initially focus on those procedures that contribute most to the transmission of blood borne pathogens.

The SIGN associates agree to collaborate in the following areas:

1. Develop and maintain a strategic planning framework;
2. Plan, implement, and evaluate activities within the strategic framework;
3. Promote the development and implementation of standards;
4. Advocate;
5. Raise political commitment;
6. Mobilise resources;
7. Share information, ideas, and updates;
8. Encourage innovative, cost-effective solutions.

1.2. SIGN structure and function

SIGN is made up of individuals, representatives of public and private organisations, and national public health officials. These groups and individuals share a common interest, are active internationally, and have a recognised expertise in the field of preventing blood-borne pathogen transmission and other adverse events associated with poor injection practices.

1.2.1. New associates . Participation as an associate in SIGN is open to all individuals, representatives of public and private organisations, and to national public health officials that share a common interest, are active internationally, and have a recognised expertise in the field of preventing blood-borne pathogen transmission and other adverse events associated with poor injection practices.

1.2.2. Activities conducted by SIGN associates. SIGN associates are encouraged to conduct activities which are consistent with the strategic framework under their own responsibility and according to their respective policies and principles. Fund-raising efforts of SIGN associates for their own activities will be subject to their own respective policies and principles..

1.3. Information exchange

SIGN associates intend to discuss matters of relevance to SIGN and share information through annual meetings, e-mail list servers, web sites, newsletters and working groups.

1.3.1. Annual meetings. SIGN associates will meet at least annually. Meetings will focus on the development of consensus recommendations and adjustments to the overall strategic framework. Updates and information exchange preparatory to such meetings will be circulated.

1.3.2. E-mail list server and internet Site. A moderated E-mail list server and an internet site will facilitate informal discussion groups and the distribution of documents.

1.3.3. Newsletter. A newsletter will be published to disseminate information and reports regarding completed, planned, or ongoing activities of the SIGN associates.

1.3.4. Working groups. Within SIGN, working groups may be created to address specific issues as needed.

1.4. Reports

Reports should be generated for SIGN meetings or SIGN working groups meetings.

1.5. Consensus recommendations

Consensus recommendations contained in SIGN meeting or SIGN working group reports, or developed through other SIGN processes, will be made available to SIGN associates and all other interested parties. These recommendations will not be binding on any associate of SIGN or on the secretariat. However, they may be used as the basis for guidelines or official policy according to the mandate and internal rules of associate organisations.

2. Terms of reference for the SIGN Secretariat

2.1. Functions of the secretariat

The secretariat is located in WHO/BCT and will support SIGN by the following functions:

- Co-ordinate the organisation of SIGN meetings and ad hoc working groups;
- Organise a central repository of information and documents relevant to SIGN;
- Maintain a database of associates' activities completed, ongoing, or planned;
- Inform the network of activities, ongoing, or planned.
- Prepare and distribute draft meeting agendas, meeting reports, and progress reports for adoption by the network;
- Maintain the SIGN strategic framework;
- Co-ordinate the communication strategies;
- Create and manage an email list server and a SIGN internet site;

- Produce the SIGN newsletter;
- Arrange review of documents as requested by associates;
- Receive expressions of interest from prospective associates (sign@who.int).

2.2. Funds for the secretariat

Funds will need to be raised to support SIGN secretariat activities. Fundraising by WHO/BCT to support the work of SIGN will be undertaken in accordance with WHO's policies and principles. SIGN associates may be required to make financial contributions to support the meetings of SIGN and the work of WHO/BCT in providing secretariat for SIGN.

The WHO BCT will administer financial contributions intended to support the work of the SIGN secretariat through an allotment entitled Safe Injection Global Network. This allotment will be administered in accordance with WHO's financial regulations, rules, and practices and will be subject to WHO's normal programme support costs.

2.3. Accountability

Annual financial reports will be provided by WHO/BCT to the SIGN associates, justifying how funds designated to support the activities of the SIGN secretariat have been used.

Appendix 4: SIGN strategic Framework

The purpose of the SIGN strategic framework is to keep track of activities conducted by the associates and to co-ordinate activities aiming at achieving safe and appropriate use of injections.

Objective 1: Innovation in approaches

Target A

Pilot interventions aiming at safe and appropriate use of injections.

Indicators

1. Annual number of injections received per person in pilot intervention areas (as measured by population surveys or public health surveillance).
2. Proportion of injections identified to be safe in pilot intervention areas (as measured by a checklist evaluation of practices).
3. Incidence of injection-associated bloodborne pathogen infections in pilot intervention areas (as measured by public health surveillance).

Products

Compilation of lessons learned from successful and unsuccessful attempts to achieve injection safety.

Preliminary toolboxes for field testing in the pilot intervention site, including *

- Preliminary toolbox to assess and evaluate injection practices
- Preliminary toolbox to develop pilot interventions for safe and appropriate use of injections
- Preliminary toolbox to develop IEC/ behavior development strategy †
- Preliminary toolbox to manage healthcare waste at the primary care level (focusing on sharps waste)

Implementation of pilot interventions

Evaluation of pilot interventions using process and outcome indicators

* These toolboxes would then be edited according to feedback from the field and merged to develop the toolbox for the development of programs for safe and appropriate use of injections described page 50.

† Including the prevention of bloodborne pathogen transmission through other percutaneous and permucosal procedures.

Target B

Large-scale introductions of newer technologies supporting safer use of injections.

Indicator

1. New administration devices shown useful to support safer use of injections and made available for large-scale use (number, distribution).
2. New waste management systems shown effective and available for large-scale use (number, distribution).

Products

Training and promotion material regarding injection technologies

Decision making guide regarding injection technologies for health services programme managers

Cost reduction for auto-disable (AD) syringes

Availability of a jet injector that can be used for mass vaccination campaigns

Evaluation of new administration devices through pilot testing and post introduction (market) surveillance

List of options in waste management for which development should be promoted

Evaluation of new waste disposal techniques through pilot introduction projects

Objective 2: Achieving safe and appropriate use of injections

Target C

Implementation of national policies and plans for safe and appropriate use of injections.

Indicator:

Number of countries adopting national policies and plans for safe and appropriate use of injections.

Products

Establishment of the Safe Injection Global Network and inclusion of new participants

Establishment of plans of action for the organizations from which the SIGN associates come

Support and leadership for countries that want to set-up injection safety plans

Standard guidelines on safe injection practices

Advocacy and communication strategy to increase public, healthcare professionals, and donors' awareness to injection safety issues

Vote of a World Health Assembly Resolution on the right to a safe and appropriate use of injections

Accelerated introduction of safer administration technologies

Safe sharps waste management at all levels of healthcare

Toolbox for the development of programs for safe and appropriate use of injections*

Identification of funding mechanism for country plans

Launch of country plans for safe and appropriate use of injections

* This manual would be constituted from the merged preliminary toolboxes described in page 48 after editing according to feedback from the field.

Target D:

Injection safety in donor or lender-funded services making use of injections.

Indicator

Number of donor or lender funded services routinely documenting injection safety using a checklist evaluation of practices.

Products

Plans for inclusion of injection safety costs to programme costs in all donor or lender-funded services making use of injections (bundling).

Implementation of injection safety plans in donor or lender-funded services.

Implementation of routine evaluation of injection safety in donor or lender-funded services.

Appendix 5: Communication kit

Safety of injections: A brief background

Injections are a skin puncturing procedure performed with a syringe and needle to introduce a substance for prophylactic, curative, or recreational purposes. Injections can be given intravenously, intramuscularly, intradermally, or subcutaneously. Injections are among the most frequently used medical procedures, with an estimated 12 billion injections administered each year world-wide. A large majority (more than 90%) of these injections are administered for curative purposes (for every vaccination injection, 20 curative injections are administered).

Injections have been used effectively for many years in preventive and curative healthcare. In preventive healthcare, injections have been used to administer vaccinations that have had a major impact in reducing childhood mortality due to measles and other vaccine-preventable diseases. While injections are still necessary today to administer most vaccinations, the number of vaccination injections could be reduced through the use of combination vaccines.

In curative healthcare, injections have been used to administer such antibiotics as penicillin, streptomycin as well as many other life-saving medications. Today, safe and effective alternatives to injected medications are available and most medications used in primary care can be administered orally. Injections are predominantly needed for the treatment of severe diseases, mostly in hospital settings. Nevertheless, injections are overused to administer medications in many countries because of an ingrained preference for injections among healthcare workers and patients.

Unsafe injection practice causes cross-infection

A safe injection does no harm to the recipient, does not expose the healthcare worker to any risk, and does not result in waste that is dangerous for the community. To achieve this, an injection needs to be prepared with clean hands in a clean area, using medication drawn from a sterile vial. The injection must be administered using a sterile syringe and needle. After administration, sharp equipment such as needles needs to be discarded in a puncture-proof container for appropriate disposal. When these rules are not followed, injections are unsafe and may expose recipients, healthcare workers, or the community to infections. Among unsafe practices, syringe or needle re-use between patients without sterilisation is associated with a high risk of bloodborne pathogen transmission (see below). Unsafe injections occur in many parts of the world, and more particularly in developing countries where up to 50% of injections are administered with re-used syringes and needles.

The transmission of bloodborne pathogens through unsafe injections was documented as early as 1917, when an outbreak of malaria among British soldiers was linked to injection treatment for syphilis. Since then, unsafe injection practices have been linked to the transmission of many pathogens between patients (cross infection), including the hepatitis viruses, HIV (the virus that causes AIDS), Ebola virus, dengue fever virus, and the malaria parasite. In addition, unsafe injections may cause abscesses, septicaemia, or increase the risk of paralysis when patients are infected with the polio virus. Of all the adverse effects of unsafe injections, the hepatitis B and hepatitis C viruses, which are transmitted respectively a hundred times and ten times more effectively through unsafe injections than HIV/AIDS, cause the heaviest burden of disease.

Cross infection associated with injections – a complex problem

When breaks in safe injection practices occur, overuse of injections increases opportunities for bloodborne pathogen transmission. Reasons for popular demand for injections include beliefs that injections are stronger medications (Pakistan*), that injections work faster (Romania †), that the pain of the injection is a marker of efficacy (some African countries ‡), that a drug is

* Luby S. P. et al. *Epidemiol. Infect.* 1997; 119: 349-56.

† Population focus group results, CDC unpublished data 1998.

‡ Reeler AV. *Soc Sci Med* 1990; 31: 1119-25.

more efficient when entering the body directly (Colombia, Thailand ‡), and that injections represent a more advanced technology (many developing countries ‡). Among healthcare workers, motivations for overuse of injections include belief of a better efficacy of injected drugs (Romania *), ability to directly observe therapy, and thus compliance with treatment regimens, and, sometimes, financial incentives. In some healthcare systems (e.g., Pakistan *), healthcare providers can charge a higher fee if they administer an injection.

Reasons that explain unsafe injection practices include lack of awareness regarding the risks associated with unsafe injections, lack of injection supplies, and lack of disposal infrastructure for injection equipment. Injection technology has developed considerably since its beginnings in the eighteenth century, moving from glass syringes that require sterilization after each use to plastic disposable syringes designed to be discarded after one single use. More recently, auto-disableable disposable syringes modified to disable themselves automatically by the plunger blocking after one single use have been developed. Nevertheless, many countries cannot afford these more advanced technologies, which may cost twice as much as standard injection equipment. In some countries, such as India †, syringes are scavenged for resale. On other continents, such as Africa, syringes and needles are reused until they break, as culturally, waste is not acceptable. For health budgets with limited resources purchasing policies can only address the most immediate concerns and thus cannot ensure safe equipment and increased supplies.

A heavy burden of disease

In many countries where hepatitis B and hepatitis C are highly endemic, unsafe injection practices account for a large proportion of infections. The proportion of new cases of hepatitis B that are attributable to unsafe injections was 60% in Taiwan in 1977 ‡ and 52% in Moldova in 1994 §. In Egypt, the proportion of new cases of hepatitis C that are attributable to unsafe injections exceeded 40% in 1996 **. The burden of disease associated with hepatitis B virus (HBV) and hepatitis C virus (HCV) has been likened to a 'silent epidemic,' as these diseases typically take twenty years to evolve from infection to symptomatic chronic liver disease (cirrhosis and liver cancer).

Depending on the age at which infection occurs, 10% to 70% of persons infected with HBV develop a chronic infection. The younger the age at which infection occurs, the higher the risk of chronic disease. Of the 370 million people chronically infected with hepatitis B virus worldwide, more than one million die each year because of their infection; overall, 25% will eventually die of chronic liver disease. Hepatitis B is the fifth leading cause of death from infectious diseases in the world.

The proportion of individuals contracting HCV who develop chronic infection is even higher than for HBV. With 170 million people infected with HCV throughout the world, the burden of chronic liver disease and death associated with HCV infection is increasingly recognized, although no estimate is yet available.

Taken together, hepatitis B and C account for 75% of all cases of chronic liver disease worldwide and, while no estimate is available for the whole world, the annual cost of hepatitis B and hepatitis C in the United States alone has been estimated at \$1.3 billion (medical and work loss) ††. As the diseases progress and symptoms become more acute, loss of health incurs absence from work, inability to support family, and loss of social position. Every carrier of the disease, whether symptomatic or asymptomatic, is a potential source of infection to others.

* Stoica A et al. Abstract, annual meeting of the Society for Healthcare Epidemiology of America, San Francisco, CA, April 1999.

† The Statesman (India), Thursday, July 29th 1999 (via NewsEdge Corporation).

‡ Ko YC et al. Am J Epidemiol 1990; 133: 1015-23.

§ Hutin et al. Int. J. Epidemiol 1999; 28: 782-786.

** El-Sakka H. Field Epidemiology Training Program Cairo, Egypt, personal communication.

†† Hepatitis Foundation International.

In addition to hepatitis B and hepatitis C, unsafe injections may cause HIV infection. However, because HIV is less efficiently transmitted through injections than the hepatitis viruses, unsafe injections account for far less infections than unprotected sexual intercourse in countries where HIV infection is highly endemic.

Improving public health through safe and appropriate injection practice

To prevent the transmission of bloodborne pathogens that results from unsafe injections, injection use must be reduced and injection safety must be achieved. To move populations away from injection overuse and toward oral medications, behavioural change of patients and healthcare workers should be encouraged through the combination of a supportive environment and Information, Education, and Communication (IEC) activities. Health infrastructures must be adapted and the issue of negative incentive (e.g., higher fee for services when an injection is prescribed) must be addressed, bearing in mind that oral treatment is less labour-intensive (requiring less health workers) and often more cost-effective (cheaper drugs, less staff involved). In addition, to achieve injection safety, a combined strategy to improve awareness and healthcare worker performance, provide injection supplies, and strengthen disposal infrastructure must be developed. The medical device industry should also be encouraged to develop safer technology that is adapted to national public health requirements and government budget capabilities.

To prevent the adverse effects of unsafe injection practices, United Nations organizations, non-governmental organizations, governments, donors, and universities sharing a common interest in a safe and appropriate use of injections joined their forces in a Safe Injection Global Network (SIGN). Because of the complexity of the problem, assistance from different types of professionals will be needed (e.g. public health officers, infection control practitioners, epidemiologists, anthropologists, specialists in behaviour development, researchers in administration technology, environmentalists). Because little experience is available regarding integrated programs that link the community with the health system to aim at safe and appropriate use of injections, the Safe Injection Global Network plans to co-ordinate the launch of pilot projects in five countries. Results of the evaluation of these pilot projects should be available by 2002, and will enable the Safe Injection Global Network to identify strategies that work to develop a large-scale initiative to ensure that safe and appropriate use of injections is a priority for all.

Fact and figures

Total number of injections per annum	12 billion (prophylactic and curative)
Ratio of therapeutic to vaccination injections	20:1 (95% of all injections are therapeutic)
Diseases most frequently contracted through unsafe injection practices	Hepatitis B, Hepatitis C, HIV/AIDS.
Estimated proportion of viral hepatitis due to unsafe injection practices in selected countries where information is available:	
Hepatitis B:	Moldova: 50% (1994-1995) * Romania: 30% (1997) † India: 60% ‡ Taiwan: 60% (1977) §
Hepatitis C:	Egypt: >40% (1996) **
Estimated total burden of infection per annum attributable to unsafe injection practices ††	8-16 million hepatitis B cases 2-4.5 million hepatitis C cases 75,000 – 150,000 HIV infection cases
Main factors contributing to transmission of bloodborne pathogens through injections	Overuse of therapeutic injections Lack of awareness of risk Lack of syringe and needle supplies leading to syringe and needle reuse Lack of safe disposal infrastructures
Estimated annual public health cost generated by unsafe injection practice	26 million of years of life lost †† Direct medical cost of US\$535 million
Estimated annual deaths due to unsafe injection practices	1.3 million deaths ††
Countries where unsafe injection practices have been reported	World-wide
Countries where syringe/needle re-use is most often reported	Africa, Asia, and former Eastern bloc countries
Estimated proportion of syringe and needle re-use by geographical area††	Former eastern European block: 15% Middle East: 15% India: 50% China: 50% Sub-Saharan Africa: 50% Central and South America: N/A East Asia, Pacific Islands: 50%

* Hutin et al. Int. J. Epidemiol 1999; 28: 782-786.

† Hutin et al. Abstract, annual meeting of the Infectious Diseases Society of America, Denver, CO, November 1999.

‡ Narendranathan M et al. Trop Doct 1993; 23:64-6.

§ Ko YC et al. Am J Epidemiol 1990; 133: 1015-23.

** El-Sakka H. Field Epidemiology Training Program Cairo, Egypt, personal communication.

†† Kane, A. et al. Bull. World Health Organ. 1999; in press.

‡‡ Miller M et al. Bull. World Health Organ. 1999; in press.

Costs to achieve a safe and appropriate use of injections

Cost of information, education, and communication / behavior change campaigns.
Cost of providing sufficient injection equipment.
Cost of waste disposal infrastructure.

Savings generated by a safe and appropriate use of injections

Savings generated by appropriate use of medications.
Savings generated by using oral medication rather than injection, including staffing costs.
Savings generated by the prevention of chronic viral infections.

Glossary of terms

<i>Abscess</i>	A focal collection of pus resulting from necrosis of tissue, sometimes observed at the site of an injection.
<i>Antigen</i>	Any substance which can generate the formation of a specific antibody (a protein created by the immune system to protect the body). For vaccines, the term antigen refers to a vaccine component that induces protection for one single disease (e.g., the measles antigen induces protection against measles).
<i>Auto-disable (A-D) * syringe</i>	A specially modified disposable syringe with a fixed needle which is automatically disabled by plunger blocking after a single use.
<i>Burden of disease</i>	The health and socio-economic cost of a given medical condition on a society.
<i>Bloodborne pathogens</i>	Infectious agents transmitted through exposure to blood or blood products.
<i>Cirrhosis</i>	A chronic scarring of the liver that can result in hepatic failure, jaundice, and death.
<i>Combination vaccine</i>	A vaccine that combines several antigens to induce protection against several diseases.
<i>Cost effectiveness</i>	Ratio comparing the results of a healthcare programme or procedure to the direct and indirect net costs of this programme or procedure.
<i>Disposable syringe</i>	An all-plastic syringe designed for a single use, with a separate, steel needle. Because there is no mechanism to prevent re-use, this type of syringe may be used more than once.
<i>Disposal</i>	The collection, storage, and subsequent destruction of all syringes and needles to avoid any accidents.
<i>Hepatitis B</i>	Hepatitis caused by a virus and transmitted by exposure to blood or blood products or during sexual intercourse. It causes acute and chronic hepatitis. Chronic hepatitis B can cause liver disease, cirrhosis, and liver cancer.
<i>Hepatitis C</i>	Hepatitis caused by a virus and transmitted by exposure to blood or blood products. Hepatitis C is usually chronic and can cause cirrhosis and primary liver cancer.

* Often referred to as "Auto-Destruct"

<i>HIV/AIDS</i>	Human Immunodeficiency Virus, a virus transmitted through exposure to blood or blood products or during sexual intercourse. HIV causes the Acquired Immunodeficiency Syndrome (AIDS).
<i>Infection control</i>	The activities aiming at the prevention of the spread of pathogens between patients, from healthcare workers to patients, and from patients to healthcare workers in the healthcare setting.
<i>Injection</i>	The administration of a substance into the skin, subcutaneous tissue, muscle tissue, or veins.
<i>Intramuscular injection</i>	An injection made into the body of a muscle.
<i>Intravenous injection</i>	An injection made into a vein.
<i>Jet injector</i>	Needleless device that allows the injection of a substance under pressure through the skin without a needle.
<i>Pathogen</i>	A microorganism capable of causing disease.
<i>Safe injection</i>	An injection that does not harm to the recipient, does not expose the health worker to any risk, and does not result in waste that puts the community at risk.
<i>Safety (Sharps) Box</i>	A puncture proof/liquid proof container designed to hold used sharps safely during disposal and destruction.
<i>Safety syringe</i>	Modified, disposable plastic syringe designed so that the healthcare worker can disable it in such a way that the needle is protected and cannot be re-used.
<i>Septicaemia</i>	Severe generalised infection resulting from dissemination of pathogenic microorganisms and their toxins.
<i>Sharps</i>	Equipment that is used in skin piercing procedures, such as needles and lancets.
<i>Sterile</i>	Free from living micro-organisms, aseptic.
<i>Sterilizable syringe</i>	Either all plastic or all glass syringe with steel needle. This type of syringe is designed for re-use after proper cleaning and sterilisation in a steam sterilizer or autoclave.
<i>Subcutaneous injection</i>	An injection delivered under the skin.

Toxic shock syndrome

An acute, sometimes fatal, intoxication by an infectious agent during which organ activity is blocked causing severe shock and hypotension.

Vaccination

The administration of vaccine either orally or by injection to produce active immunity to a disease.

Questions and answers

What are the risks associated with injections?

Bloodborne diseases such as hepatitis B, hepatitis C and HIV/AIDS are transmitted through injections due to unsafe injection practices and injection overuse.

Can you explain what the differences between safe and unsafe injection practices are?

A safe injection does no harm to the recipient, does not expose the health worker to any risk, and does not result in waste that is dangerous for the community. To achieve this, the injection needs to be prepared with clean hands in a clean area, using medication drawn from a sterile vial. The injection must be administered using a sterile syringe and needle. After administration, sharp equipment needs to be discarded in a puncture-proof container for appropriate disposal. Any break or departure from this procedure represents a risk, rendering the injection unsafe.

Among unsafe practices, syringe or needle re-use between patients without sterilisation is associated with the highest risk of bloodborne pathogen transmission.

What diseases can be contracted through unsafe injection practices?

The diseases most frequently transmitted through unsafe injection practice are hepatitis B, hepatitis C, and HIV/AIDS. Hepatitis B and C represent the highest burden of disease associated with unsafe injection practice. Contrary to public perceptions, hepatitis B and hepatitis C are transmitted respectively 100 and 10 times more through unsafe injection practices than HIV/AIDS. In addition, unsafe injections can cause abscesses and lead to septicaemia. Less frequently, haemorrhagic fevers and malaria can also be transmitted.

How many people become infected each year due to unsafe injection practice?

Mathematical models have been developed suggesting that annually 8-16 million hepatitis B infections, 2-4.5 million hepatitis C infections, and 75,000-150,000 HIV/AIDS cases may be caused by re-use of syringes and needles without sterilisation^{*}. Because the viruses that can be transmitted through unsafe injections can remain “silent” in the body for a long time before they cause symptoms, precise estimates of the number of people who become infected each year because of unsafe injection practices are not available.

How many injections are administered annually world-wide?

About 12 billion preventive and curative injections are given each year, signifying that everyday 40 million injections are administered world-wide. Over 95% of all injections given are curative (therapeutic): for every vaccination given, 20 therapeutic injections are administered.

How does overuse of injections lead to the transmission of blood-borne pathogens?

The more injections are given, the more people are exposed to needles and syringes. In addition, if the use of injections exceeds the availability of injection equipment allows, re-use of syringes and needles is likely to occur. Therefore the greater the use, the higher the risk.

What are the reasons for injection overuse?

- In the case of curative injections, patients and healthcare workers often believe that injections are more effective and act faster than oral medication. In addition, injections

^{*} Kane A. et al. Bull. World Health Organ. 1999; in press.

allow healthcare workers to control the intake of a given medication (better compliance with treatment regimens), and sometimes, to charge an increased fee for service.

- In the case of vaccination injections, there is a lack of combination and oral vaccines to be used to decrease the number of vaccination injections.

Are healthcare workers not aware of the risks of unsafe injection practices?

In many cases trained healthcare workers such as physicians, nurses, and paramedical staff have not been trained to safe injections practices. Often, they lack the awareness of the risks associated with unsafe practices. In addition, in some communities, untrained lay persons administer injections outside the formal healthcare sector.

Is it difficult to make injections safe?

Yes. Improvement of injection practices is difficult because it requires behaviour change that needs to be induced through Information, Education, and Communication (IEC) activities in a supportive environment. Awareness of healthcare workers and patients regarding the risks associated with unsafe practices must be increased, adequate injection equipment must be provided in sufficient quantities, and a reliable waste disposal infrastructure must be made available. Strong political and economic support is needed to achieve such changes and establish community norms for safe injections.

Why are syringes re-used in the developing world?

Widespread re-use of syringes and needles in the developing world is due to several factors:

- a lack of awareness regarding the risks associated with syringe re-use associated with a cultural resistance to waste in countries where resources are scarce;
- a lack of supplies of syringes and needles;
- the absence of infrastructure for the safe collection and destruction of used injection equipment, allowing for scavenging and parallel market development.

What constitutes safe syringe disposal?

Safe syringe disposal requires that syringes and needles be placed in puncture-proof containers (safety box) immediately after use. These boxes must then be collected for incineration or other forms of destruction.

What is the annual cost of unsafe injections to healthcare systems?

In the United States where HBV and HCV infection are not common, the overall cost of HBV and HCV is estimated at US \$1.3 billion. In many developing countries, the proportion of the population infected with HBV and HCV exceeds 10 times the prevalence seen in the USA, and in many of these countries, unsafe injections account for a large proportion of new cases of HBV and HCV infection. Thus, the cost of unsafe injection practices in developing countries is high.

What are the WHO recommendations for a safe and appropriate use of injections?

Education: A safe and appropriate use of injections should be promoted among healthcare workers and in the population by Information, Education, and Communication (IEC) activities. These activities should be based on an initial assessment of the situation.

Medical practice: Incentives against overuse of injection should be put into place. Recommendations for increased use of oral medication should be made at all levels of society so that healthcare workers and consumers alike can request alternatives to injections.

Waste disposal infrastructure: Syringe disposal systems should be re-examined and disposal infrastructures put into place and supervised.

Politically: Governments should provide the strong political and financial support needed to achieve a safe and appropriate use of injections. They should support Information, Education, and Communication (IEC) activities, purchase safe injection equipment in sufficient supplies, and set-up appropriate waste disposal systems.

Private sector: Industry should consider technology transfers to allow companies within countries to develop cheaper, safer technology accessible to local health budgets. Injection technology should evolve, with ever safer technology being developed. Combination and oral vaccines should be developed to reduce the number of injections in the case of immunization campaigns.

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