Report of the Global Injection Safety and Infection Control Meeting

23-25 October 2006
Mexico City, Mexico
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Executive Summary

The 2006 SIGN Annual Meeting on Injection Safety and Global Infection Control strategies held in Mexico City, the first time in the Americas, was well attended and contained a substantial volume of presented material. Reduction of unnecessary injections was a theme for the meeting and a session on alternative injection and drug delivery technologies was included.

Infection Prevention and Control Strategies in Healthcare Settings

SIGN has developed “Standard Precautions for Injection Safety” guidelines. WHO is developing indicators for intravenous injections and infusions, phlebotomy and lancet procedures to be included with indicators for injections in a methodology called Tool C – revised, which will permit countries to perform assessments on different health services and sectors. The WHO World Alliance for Patient Safety (WAPS) has selected health care-associated infections as the first global challenge. Its theme "Clean Care is Safer Care" has hand hygiene promotion as its cornerstone, and is a good WHO umbrella for SIGN to promote injection safety. Equipment reprocessing risks were identified for patients and providers. The burden of disease associated with unsafe use of sharps in dental procedures should be assessed to determine its priority as a future focus of SIGN.

Health Care Worker Safety

Various tools exist to estimate the burden of disease at national or local levels from sharps injuries to health care workers. Data generated can be used to assess the distribution of disease burden by category of health care worker, ward or activity, leading to better targeting of interventions.

Reduction of health care worker injuries requires collaborative multifaceted approaches. Phlebotomy is a higher risk procedure, but use of the syringe and needle for purposes for which they are not designed is a risk by equipment category. All health workers would benefit from Hepatitis B vaccination; however, the need for those who handle health care waste and inexperienced providers including students to be vaccinated are priorities. Health care providers should be sensitized to the importance of waste segregation to reduce the exposure of waste handlers to sharps injuries. Waste handlers should also be provided adequate Post Exposure Prophylaxis (PEP).

Injection Safety Strategies

Collaborative approaches with multiple partners and multiple interventions are bringing success. Injection safety training should be part of curricula of students in health programmes and education for health workers.

Rational Use of Injections

The overuse of curative injections is still a serious problem worldwide. Patients have low awareness of the risks of injections, retain a strong demand for them, and are unwilling to question health workers' use of injections. Analyses of overuse of injections by disease can engage professional associations and health system administrators. A strategy called Monitoring-Training-Planning (MTP) includes serial small-group discussions among managers and

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prescribers in health facilities having particular problems with medicine use. Periodic revision of treatment guidelines are necessary to change prescribers behaviors and encourage the rational use of injections. Strategies to reduce unnecessary injections must address obstacles and enabling factors that influence alternative desired behaviors.

**Quality and Access to Safe Injection Devices**

In partnership with the International Organization for Standards (ISO) and the International association of Safe Injection Technologies (IASIT) which is the umbrella organization of injection devices manufacturers, the World Health Organization (WHO) has developed specification standards for AD syringes for immunization and curative injections and for syringes with reuse prevention features (RPF syringes). These standards are currently being used in the prequalification process in which WHO is involved. All Ministries, procurement bodies, International Organizations, and NGOs should follow WHO’s lead and only supply devices that meet these standards. UNICEF has fully endorsed and implemented the Use of Auto-Disable Syringes in Immunization Services and is now planning to provide RPF syringes for reconstitution of vaccines. The demand for AD syringes has increased substantially to over 600 million pieces per year since the implementation of AD syringes with GAVI being the driving force, but some countries are still using sterilizable syringes in routine immunization. The Making Medical Injections Safer (MMIS) project has introduced safety syringes into 10 countries in Africa and the Caribbean.

Disposable cartridge jet injectors (DCJIs) can be a safer alternative for vaccine delivery and should be explored. Plastic hypodermic needles are easily disabled and disposed of compared to metal needles.

**Health Care Waste Management**

There is no empirical evidence demonstrating that needle removers prevent needlestick injuries. Results of two studies are positive, but another study, planned for 2007 in Bangladesh that is randomized and using a WHO protocol is required before WHO will be in a position to have a policy on needle removers.

Resources should be systematically made available in all health care activities for the management of waste. The Global Environmental Facility project (GEF) on Health Care Waste Management is to demonstrate and promote best techniques and practices for reducing health care waste to avoid environmental release of dioxins and mercury. Alternative technologies identified include large-scale centralized autoclaves, small autoclaves, microwave technologies, advanced steam treatment systems, and alkaline hydrolysis technology for anatomical and cytotoxic wastes.

**Conclusions and the way forward**

Collaborative in-country partnerships are essential to improving injection safety and for sustainability. Strategies used to improve the safety of injections should be implemented with the consent, commitment, involvement and participation of many agents including governments, health system administrators, health care workers and partners outside of health systems who represent the community. Broadening the injection safety initiative to include other procedures highlights the need to synergize with other patient and health care worker safety initiatives and to ensure device standards and waste management processes encompass these developments.
Waste handlers and inexperienced health workers are two priority categories of health care workers to target for health care worker safety interventions.

Incremental rationalization of injection use is possible through various evaluative processes. Alternative injections technologies show promise and should be explored further.

Further expansion of the initiative to include dentistry should be considered. Alternative technologies for waste management require further development.
SIGN Openings - 23 October 2006

PWR Mexico
Dr. Jacobo Finkelman

The Region of the Americas was the first region to eliminate a number of vaccine preventable diseases. This is a great achievement and it leads populations to become used to changes and expecting of changes in area of health services including technological areas.

Injection safety is one area of technology that populations expect will be met. It is laudable that the curative and preventive sectors in Mexico have indicated their willingness to improve practices. On behalf of WHO Mexico, I welcome you to Mexico for the SIGN annual meeting on injection safety.

Welcome address from WHO
Dr. Steffen Groth

Mister Chair, Mr. Roberto Tapia Conyer, Vice Minister of Health, distinguished ladies and gentlemen, colleagues.

It is a great pleasure for me to welcome you to the Annual Global Meeting on Injection Safety and Infection Prevention and Control in Mexico City, Mexico on behalf of the Department of Essential Health Technologies of the World Health Organization. WHO continues to give high priority and support to injection safety and the prevention and control of bloodborne infections. I would like also to express the Organization's appreciation to the Government of Mexico for hosting us.

WHO also expresses its appreciation to the Ministry of Health, our partner, in the planning and implementation of this meeting.

It is with pleasure that I open these 3 days of presentations, discussions and exchange of experience for the following reasons:

First, it is a unique annual event. Since the launch of the SIGN alliance in 1999, experts, programme managers, policy makers, industry partners and NGOs from all over the world have come together every year to share their experiences, exchange ideas and discuss recent initiatives aimed at making injection practices safer and preventing bloodborne infections, particularly HIV/AIDS and Hepatitis B and C

Second, building on the successful initiative at the 2003 ,2004 and 2005 meetings in Nairobi, Kenya, Cape Town, South Africa and Hanoi, Viet Nam where injection safety and the broader infection prevention and control issues were addressed, this year's meeting, yet again brings together injection safety and HIV/AIDS programmes on infection prevention and control.

Third, new initiatives have been launched in the period since the last meeting to scale up injection safety. The President’s Emergency Plan for AIDS Relief (PEPFAR) identified improving Injection safety as one of the five key interventions that could reverse the tide of the HIV/AIDS epidemic in 14 countries in Africa and the Caribbean. The global infection prevention and
control, and injection safety meeting is the appropriate opportunity to report on these projects, their achievements and their challenges.

Lastly, but very importantly, we must acknowledge the significance of having our global meeting held in the PAHO region and specifically in Mexico, where national authorities, health professionals and partners are committed to addressing infection prevention and control including the safe and appropriate use of injections in their prevention and care initiatives.

**Poor injection practices remain a major challenge.**

According to the latest estimates produced for the 2003 Global Burden of Disease Study, unsafe injections are responsible every year worldwide for 21 million new hepatitis B cases (HBV), 2 million hepatitis C infections (HCV) and 260,000 HIV infections. While significant success has been achieved with immunizations, there is still much to be done to improve the safety of curative injections. Safe and appropriate use of injections has gained international visibility. SIGN members have moved the agenda forward with country-level achievements. However, increased public awareness about injections as a risk for HIV transmission could support efforts for safer injections. Many of the objectives formulated at the SIGN meeting in 2001 in New Delhi, India have been attained, and the international environment is favourable to the injection safety initiative. We have now solid evidence to document poor injection practices, their determinants and their consequences; the SIGN alliance has a strong focus towards countries, and tools are now available to help in the formulation of policy and guidance in development of sound management practices for policy management. The experience in pilot countries is showing us the way forward.

We know that interventions to achieve safe and appropriate use of injections are effective, although the impact on safety is usually greater than the impact on reducing unnecessary use. While communication with providers and patients is key to reducing injection overuse, successful interventions to improve safety combine the provision of safe injection equipment together with the education of health care providers.

Two decades into the HIV pandemic, the use of unnecessary injections and unsafe practices are still common in both developing and transitional countries. There is an urgent need to use injections safely and appropriately to prevent nosocomial and HIV infections worldwide.

I would strongly encourage SIGN participants to:

1. Facilitate the use of data for local decision-making;
2. Disseminate WHO policy management tools within countries;
3. Continue to educate health care providers and the general public about the risks associated with unsafe injections particularly through HIV prevention and care programmes; and
4. Scale up the infection prevention and control culture.

**What further contribution should the World Health Organization be making to improve safe health care for patients, health care workers and communities?**

Based on evidence, WHO will continue its support at country, regional and global level for operational research and for the implementation of programmes, and it will maintain its normative role in a broader infection control approach which includes injection safety, blood safety, patient safety, safe sharps waste management and health care worker protection.
Medical treatments, including injections are intended to save lives and improve health. The Department of Essential Health Technologies has identified the prevention of health care associated HIV, Hepatitis B and C infections as a key initiative that cuts across the work of the department and which supports the work of other departments and other UN agencies such as UNICEF, UNFPA among others. EHT, with the support of the United States Centres for Disease Control and Prevention and the United States Agency for International Development (USAID), will continue to host the SIGN Secretariat in close collaboration with other WHO departments involved in the global efforts to prevent HIV and other bloodborne pathogen infections and to extend its activities to a more comprehensive approach towards infection prevention and control.

I am heartened by the broad, global interest for this meeting, both in participation and in the presentation of country reports. I wish you a successful meeting, and look forward to continue working with you in the future in this critical area of public health.

Welcome address from UNICEF
Dr Edward Hoekstra, Representative for UNICEF New York

Ladies and gentleman,

It is a great pleasure for UNICEF to be here in one of the oldest cities in the world with a wealth on history going back to the Aztec culture. As well organized and sophisticated the Aztec’s were in there time, we seem to be poorly organized and now, in 2006, are lagging behind in ensuring safety for our children and our health care workers while performing basic interventions such as giving an injection. An estimated 250,000 people go home each year after medical treatment that resulted in the person contracting HIV/AIDS. Half of these 250,000 persons are children. All of these 250,000 persons trusted their provider to do the right thing. And all of these medical induced infections are preventable, if health care workers had only used and handled their medical equipment the way it was meant to be handled, … sterile!

UNICEF has been working closely with WHO and other partners to improve injection safety around the world in all their programs. Joint assessments have been carried out in many countries and UNICEF has advocated change of country programs to promote policies that ensure we do no harm to children.

UNICEF has fully endorsed and implemented the Use of Auto-Disable Syringes in Immunization Services as recommended in the WHO-UNICEF-UNFPA Joint Statement of 1999. The bundling policy has resulted in, that for each vaccine dose, sufficient numbers of AD syringes, reconstitution syringes and Safety boxes is ensured.

Now UNICEF will go one step further. Observations world wide have shown that the bundling concept is not always ensured all the way down to end destination. Instead, in the field we often find one reconstitution syringe available for every 2-6 vials, if that. These practices are unacceptable. Reconstitution syringe are re-used and hence represent a risk for contamination. To avoid this risk of contamination during the reconstitution process UNICEF will start fading out regular disposable reconstitution syringes and replace them with RPF syringes. In the initial stage, UNICEF opt to offer RPF syringes as an option to countries with the objective to only provide RPF re-constitution syringes by end 2010.
We are here together in Mexico City to talk about our next steps. And although the main challenge is syringe use in the curative sector, I urge you to stop and realize that although we have now 69% of the countries using bundled vaccines, that means that 1 out of every 3 countries still doesn’t. We need to implement this essential program everywhere to ensure that the trust given to the providers by parents and children is kept by those who practice medicine. So we have still a long way to go, but seeing the overwhelming participation today, I have no doubt that we will succeed to make this a safer world for all. Thank you.
Day 1, Theme 1:

Integrated Infection Control Strategies in Health Care Settings

WHO & SIGN Activities on Injection Safety and Related Infection Control

Selma Khamassi, MD,
WHO Injection Safety
SIGN Secretariat

Many of the objectives set by the Safe Injection Global Network since its launch in 1999 have been reached. The international environment is favourable to the injection safety initiative. We now have a solid evidence base to document poor injection practices, their determinants and their consequences; advocacy efforts have resulted in a high level of awareness; the SIGN alliance has a stronger focus towards countries; and tools now available for policy management and experience in pilot countries indicate the way forward.

Despite all these achievements, injections are still unsafe in developing and transitional countries. The capacity to use assessment data to make decisions is still limited; there is a limited consumer demand for safety in many countries; and the WHO tools are not yet widely available and used in countries.

SIGN participants must facilitate the use of data for local decision-making; educate about the risks associated with unsafe injections through HIV prevention and care programmes; build up a broader infection control culture; disseminate the WHO policy management tools in countries and identify the steps and processes of scaling up injection safety activities. They also should identify ways to implement activities at country level and engage all stakeholders in injection safety activities.

WHO and SIGN are developing Standard Precautions for Injection Safety and are reviewing the injection safety assessment tool (Tool C) based on its field use to broaden its scope to assess the safety of other injection routes, i.e. phlebotomy, intravenous injections and lancets.

Report on last SIGN Meeting Recommendations

Selma Khamassi, MD,
WHO Injection Safety
SIGN Secretariat

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<tr>
<th>Action point</th>
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<tbody>
<tr>
<td>SIGN Meeting 2006 to be held in the region</td>
<td>Americas</td>
<td>Achieved</td>
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### Reduction of unnecessary injections as a theme for the meeting

Achieved  
Entire session planned- Day 2

### Alternative injection and drug delivery technologies should be included in the meeting

Achieved  
Session Day 2

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<tr>
<th>Action point</th>
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<tbody>
<tr>
<td>Pharmacists and pharmaceutical manufacturers to participate</td>
<td>Partially achieved</td>
<td>Contact with pharmaceutical manufacturers ongoing</td>
</tr>
<tr>
<td>Health workers from developing countries as meeting speakers enlarged</td>
<td>Achieved</td>
<td>Could still be improved</td>
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<tr>
<td>Maintain SIGN post as it is a useful resource for the network</td>
<td>Achieved</td>
<td></td>
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<tr>
<td>Continue to publish the post in plain text format</td>
<td>Achieved</td>
<td></td>
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<tr>
<td>Develop guidelines on referencing postings and conducting archive searches</td>
<td>Being developed</td>
<td></td>
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<tr>
<td>Keep the focus on Injection safety</td>
<td>Achieved</td>
<td></td>
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<tr>
<td>SIGN to cover Lancets and phlebotomy</td>
<td>Ass tool under development</td>
<td>Presentation on Day 2</td>
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<tr>
<td>SIGN to address the role of the private and informal injection providers</td>
<td>Not achieved</td>
<td>Unmet need</td>
</tr>
<tr>
<td>SIGN to address other key population groups such as IDU since their role in HIV transmission is very clear</td>
<td>Not achieved</td>
<td>Collaboration with HIV department started</td>
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<tr>
<td>SIGN working groups in WHO regional offices</td>
<td>Partially achieved</td>
<td>Focal points in PAHO, WPRO, AFRO, EMRO, EURO. SEARO in the process of being organized</td>
</tr>
<tr>
<td>National SIGN coalitions</td>
<td>Achieved</td>
<td>New coalitions in several countries. The latest in Vietnam following last SIGN meeting</td>
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SIGN should address health care associated infections for HCWs and patients prioritized by the level of risk, frequency of exposure, effectiveness of interventions and identified hierarchy of controls

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<tr>
<td>More data about injection use in the curative sector is needed: IV versus IM or SC</td>
<td>In progress</td>
<td>Assessment tool being developed</td>
</tr>
<tr>
<td>Working group on lancets is needed</td>
<td>Not achieved</td>
<td>Assessment tool being developed</td>
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<th>Action point</th>
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<tbody>
<tr>
<td>More systematic approach to HCWM to address cost, develop solutions and facilitate interdisciplinary action</td>
<td>In progress</td>
<td>Presentation on day 3</td>
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<tr>
<td>Establish a working group of users and producers of inj devices with safety features to develop tender specifications</td>
<td>Not achieved</td>
<td></td>
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<tr>
<td>Priority to identify ways to implement SIGN recommendations, to get action at the lower level of the health system, to achieve behavioral change and improve practices of front line HWs</td>
<td>In progress</td>
<td>Should be discussed during the meeting</td>
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**Plenary:**

- Should the safety of injection equipment use during injection drug use be a priority for SIGN?
- SIGN has to find a way to work with organizations at field level. SIGN is at risk of developing tools and guidelines that have little impact.
- Many issues with which the initiative is concerned are far broader in the curative sector.
- A policy on needle cutters is urgently needed.
- The pros and cons of estimating the rate of HIV infections due to unsafe injections were considered. There is no acceptable level of infections transmitted by this route, but an estimate is important for advocacy purposes.
- A national injection safety day was held in India and was useful for raising awareness about injection safety.
- From the U.S. there is data that indicates syringes are used in 32 different ways. These data should be explored before development of tools and specifications.

**Injection Safety And Blood Borne Pathogens Transmission In Latin American Countries: A Literature Review**

César Javier Calderón
Safe Injection Global Network
WHO Geneva
The aim of the present work is to have a general vision of the injection safety situation in Latin American countries (LAC). Most research on injection safety is related to clinical and technical aspects, qualification, adverse effects and sequelae. These emphasize the necessity of qualification and monitoring.

Evaluations of national Expanded Programs on Immunization (EPI) have been promoted by PAHO since 25 years ago, and since 1993, there is a permanent recommendation to promote safe vaccination practices (handling of syringes and needles, particularly to change behaviour regarding the two hand recapping of used needles, safe injection practices, administration technique, handling and final disposal of used equipment), as well as the appropriate supply of needles, syringes and safety boxes. A survey was conducted in 2003, in which EPI managers responded to a questionnaire on vaccination safety components used in their respective countries (Venezuela, Uruguay, Honduras, Guatemala, El Salvador, Colombia, Bolivia, and Peru), results were: Auto-disable syringes use, 30%; Safety boxes (SB) use, 30%; Disposable plastic receptacles (DPR) use, 40%; Both SB & DPR use, 30%; No two hands recapping of needles, 75%.

An overview of immunization safety practices conducted in 2004 by UNICEF 1+TACRO in 27 countries. Results were presented during the SIGN meeting in October 2004, in Cape Town, South Africa. Out of the 27 countries, 16 (59%) reported having updated policies (revised within the last five years) on immunization safety, but only 7 (26%) reported having a rational coordinating structure that addresses immunization safety issues on a regular basis. Only four (15%) make exclusive use of auto disables syringes during supplementary immunization activities and one country still uses reusable syringes for routine and supplementary immunization activities.

Although 21 (78%) of the 27 governments polled finance injection equipment on their own, only 13 (48%) reported allocating specific resources to sharps waste management. Of the 27 countries, 19 (79%) report the use of other waste disposal practices (such as burn and burial) in addition to the use of incinerators or as the only option available for final disposal of sharps.

Three nongovernmental projects related to Injection safety were identified through this revision:

- The INCLEN's Model Injection Center. Based in the findings of "Assessment of Injection Practices in India" the International Clinical Epidemiology Network's Program to Improve Injection Practices in Low & Middle Income Countries, established a chain of Model Injection Centers at Medical College Hospitals in Argentina, Bolivia, Brazil, Chile, Colombia, Mexico and Peru to improve injections safety and reduce transmission of blood borne pathogens.
- The PEPFAR (President's Emergency Plan for AIDS Relief) Making Medical Injections Safer Project (2004-2009) is implemented in Haiti and Guyana, and is aiming to reduce the risk of HIV transmission through injections given in health care settings.

Vaccination programs have been central in promoting safe injections. According to PAHO, "National teams that investigate adverse events supposedly attributable to vaccination or immunization (ESAVI) have improved the quality and speed of investigations, and have also improved management of ESAVI from a clinical, laboratory, epidemiological, and communications standpoint"
Nurses, surgeons and resident physicians are the most exposed personnel to suffer accidents. The most frequent type of exposure is the hypodermic or surgical needle accidental puncture. Accidents occur frequently during the accomplishment of procedures, but an important number of accidental needle punctures affect personnel who is not member of the staff providing care due to unsafe disposal of needles.

According to this context and despite activities already implemented in Latin American countries:

- There is a need to further improve injection safety in immunization services.
- There is a need to implement national programmes on injection safety and prevention of bloodborne pathogens transmission in healthcare settings.
- More information about injection safety in Latin American Countries and the Caribbean is needed (surveys, assessment, etc).
- More information about syringe use in therapeutic injections is required.
- There is an urgent need to revise the recommendations for medical waste management and their implementation at local levels.

**Highlights of WHO global efforts and progress in blood safety**

*Neelam Dhingra*

Dr S. Khamassi, on behalf of Dr. Dhingra, reviewed WHO global efforts and progress in blood safety (presentation available on CD). The strategic objectives of WHO in delivery of blood transfusion services is to promote development of nationally coordinated blood transfusion services, collect data for decision making and enhance international collaboration and partnership, promote quality and safety by developing national quality systems, recruiting VNRBDs and testing all donations for HIV, HBV and HCV and blood groups. WHO promotes development of disaster management, training, access to suitable functioning equipment and use of new cost-effective technologies, safe and appropriate use of blood and implementation of good transfusion practice. Policy development is carried out by advocacy and global strategies, publishing recommendations and guidelines on organization and management of BTSs and gathering and publishing data (WHO Global Database 2001-2002, Global Database questionnaire 2004 and assessment tool for situation analysis of BTSs) for decision making and by building collaboration and partnership such as GCBS, bilateral and multilateral collaborative activities, World Blood Donor Day, WHO expert panel on Blood Transfusion and WHO Collaborating Centres. Capacity is build by technical cooperation in assessment, planning, implementation and evaluation for establishing a national blood programme and providing training and materials for training and learning.

14 June 2005 WHO organized in liaison with other organizations related to blood transfusion services or transfusion medicine World Blood Donor Day. WHO and IFRC have developed strategies to reach 100 % VNRBD by year 2015 as part of the 2015 Millennium Development Goals.

Future priorities of include WHO Global Strategic Plan on Blood Safety and Availability for 2008 – 2015, development of evidence based donor selection guidelines, safe and appropriate use of blood, impact of evaluation of blood programmes and expanding of the expert panel on Blood Transfusion into a Committee of 60 members. Dr. Dhingra requested GCBS members to recommend experts to the future committee.
The WHO World Alliance for Patient Safety (WAPS) has chosen the topic of health care-associated infections (HAI) as the first global challenge, covering the period of 2005-2006. It has the theme "Clean Care is Safer Care" with hand hygiene promotion as the cornerstone. Newly developed and evidence-based *Guidelines on Hand Hygiene in Health Care (Advanced Draft)* have been issued. The use of a multimodal strategy is recommended for the implementation of the guideline. At the heart of the strategy is a recommendation for a system change - making *alcohol-based handrubs* available at the *point of patient care*. The strategy includes 5 different phases: facility preparedness, baseline assessment, hand hygiene improvement, follow up assessment, and review.

WHO has prepared a Pilot Implementation Pack (PIP) to facilitate the local implementation of the hand hygiene improvement strategy around the world. The PIP enables local adaptation of the strategy and recommends that health-care facilities develop their own action plans based on the multimodal approach.

**Pilot test Sites**
Following the WHO framework, 6 health-care facilities in 6 countries have been selected as Pilot Test Sites to work closely with WHO in the testing and evaluation of the WHO Guidelines on Hand Hygiene in Health Care (Advanced Draft). The aim of this testing phase is to evaluate the feasibility and acceptability of the recommendations expressed in the guidelines in a wide range of different healthcare settings and learn from the successes and shortcomings.

**Complementary Test Sites**
A large number of sites have volunteered to actively participate in the implementation and evaluation of the WHO Guidelines by using all or some of the implementation tools available in the Pilot Implementation Pack. These sites have been established as Complementary Test Sites. Becoming a Complementary Test Site is open to all health-care facilities around the world. The WAPS is keen to work in a targeted capacity with Complementary Test Sites and will establish a formal partnership with each site. The status of Complementary Test Site requires: signature and submission of an application form; submission of a basic information form; assessment of a limited set of parameters before and after the implementation; and a short written report at the end of the implementation, as formal feedback to the WAPS. Results and feedback from the Complementary Test Sites will form part of the overall global feedback on the Clean Care is Safer Care initiative and will feed into a final report about the achievements of the first GPSC. The request of becoming a Complementary Test Site should be submitted to: patientsafety@who.int. You will then receive the application form together with the basic information form.

**Risk factors for BBP transmission in healthcare settings**

*Prof Shaheen Mehtar,*
*Head, Academic Unit for Infection Prevention & Control,*
Tygerberg Hospital and Stellenbosch University, Cape Town, South Africa

Healthcare facilities fundamentally treat the sick who place their trust in the hands of healthcare workers. In some developing countries, the burden of disease is high; HIV infected population of 30%, TB prevalence of 380/100 000 population as well as nosocomial bacterial infections. Areas of risk associated with health care facilities are mainly associated with clinical practice. IV injections make up 25 to 30% of clinical interventions in hospitals. The other aspects which require attention are sterilization and decontamination of clinical equipment particularly surgical procedures. Endoscopy related transmissions of infection particularly of blood borne viruses are well documented. Finally, the generation and disposal of clinical waste is another important risk. Needle stick injuries are high in poorly organized waste management systems.

In conclusion, the lack of effective systems for establishing and ensuring safe IPC are inversely related to the risk of transmission of BBP.

Plenary:

• The design of clinical spaces has so far been neglected by SIGN. Clinical space design is often inconvenient design and therefore unsafe.
• Moving injection safety outside of the immunization domain is a fundamental challenge, and the fact that public health and clinical departments aren’t administratively related is an obstacle to success. WHO is traditionally a public health organization, but due to SARS and other issues, it is increasingly being realized that curative sector interventions need development.
• In some studies rates of unsafe practices decreased when single interventions, such as proper placement of safety boxes, were implemented. There is a need to identify what interventions that are going to be the most effective in certain situations.
• Retraining of health care providers may be necessary in some settings.
• Affordability is an important issue for equipment, but if equipment doesn’t substantially meet needs then why use it at all?

Standard Precautions for Injection Safety

Dr. Una V. Reid, WHO Consultant

While the importance of safe and appropriate use of injections is recognized, there are many challenges, including the use of unprocessed syringes and needles due in part to inadequate supplies particularly in developing countries resulting in increasing health care costs and deaths; improper injection activities waste management resulting in increased rates of infectious disease, especially among children and health workers, with the community at-large at risk.

The WHO/SIGN strategy for the safe and appropriate use of injections worldwide has four objectives: (1) formulating national policies and plans for the safe and appropriate use of injections, (2) ensuring quality and safety of injection equipment, (3) facilitating equitable access to injection equipment and (4) achieving appropriate, rational and cost effective use of injections.
In keeping with these goals, and in recognition of the important role of infection prevention and control in injection safety, SIGN has developed “Standard Precautions for Injection Safety” guidelines. These Guidelines extend SIGN’s “Toolkit on Injection Safety”.

The Guidelines are consistent with Standard Precautions for infection prevention and control as recommended by the Centers for Disease Control and Prevention (CDC). The scope is limited to elements of Standard Precautions relevant to the transmission of bloodborne pathogens through unsafe injection practices at the workplace. While they are intended to increase the awareness of all health care workers of the importance of Standard Precautions relevant to injection safety, their primary target however, is health care workers actively engaged in the administration of the various types of injections in all health care facilities, particularly at the peripheral level. The main areas of coverage include bloodborne pathogens, relevant elements of Standard Precautions and associated barrier protections, best injection and related infection prevention and control practices, occupational risk factors and their management.

A practical method of design is used to illustrate the Guidelines resulting in a series of Flash Cards and Spreadsheets, which makes it an easy source of reference for the user.

An Aide Memoire, whose purpose is to sensitise the reader to the subject, is also provided.

**Integrating phlebotomy into the Making Medical Injection Safety (MMIS) project**

Dejana Selenic, Robert T. Chen,
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Phlebotomy is one of the most common invasive medical procedures. With the global transition towards increased HIV testing as a part of routine medical care and regular monitoring associated with increased antiretroviral therapy, demand for blood tests and trained phlebotomists will also increase. HIV and other blood-borne pathogens can be transmitted during phlebotomy if the phlebotomist uses incorrect techniques or if reusable equipment is inadequately reprocessed. The Hippocratic maxim "First, do no harm" also applies to phlebotomists. In the US, phlebotomy has been associated with up to 62% of percutaneous injuries (PI) reported to hospital occupational health services. Of the 51 documented cases of occupationally-acquired HIV infections associated with PI in the US from the early 1990 through the 2000, 22 (43%) occurred during phlebotomy or blood sampling procedures. Similar data for developing countries are unavailable due to limited reporting systems for PI. However, based on our present knowledge, the risks should be equal to or greater than those seen in the US. At the 2005 Safe Injection Global Network (SIGN) meeting, stakeholders concluded that phlebotomy is a particularly high risk procedure.

The Making medical Injections Safer (MMIS) project is part of an initiative funded by the President Emergency Plan for AIDS Relief (PEPFAR) to improve medical injection safety by implementing SIGN strategies. During the annual MMIS country directors meeting in July 2006, MMIS began to explore how safe phlebotomy practices might be integrated into the existing project. The following 7 key steps were identified:

1. Assess existing phlebotomy practices in the 11 PEPFAR focus countries. These assessments will include the collecting of information on the types of health facilities performing phlebotomy; the percentage of blood drawn by laboratory staff vs. non-laboratory staff in each of these
facilities; and the areas of greatest technical need (e.g. training to use vacutainers and other devices).

2. Amend the MMIS Facilitators’ Guide to include information/training for phlebotomists.

3. Ensure that current training in injection safety does not make practices worse. For example, emphasize the importance of not recapping needles; if recapping is needed, safe recapping methods should be used (e.g. the single handed scoop technique).

4. Include training on the safe use of rapid test-lancets, especially for non-laboratory personnel.

5. Identify opportunities to provide pre-service training in sharps handling safety for phlebotomists, nurses, and physicians.


7. Gather information on broader HIV prevention efforts (e.g. consider how to integrate MMIS expertise into those programs).

To achieve these goals, the MMIS team and its partners from the Centers for Disease Control and Prevention and USAID will form a working group to develop a phlebotomy action plan. MMIS also plans to collaborate with SIGN to develop assessment tools to explore the role of hollow-bore needles in the transmission of blood borne pathogens. The MMIS working group will engage other stakeholders, such as the WHO Department of Essential Health Technologies, to discuss opportunities for collaboration. Finally, the MMIS team will develop closer working relationships with other projects that have involved consideration of a phlebotomy risk such as PEPFAR’s blood safety initiative.

Developing indicators and methodology for intravenous procedures and phlebotomy - Tool C – revised

Mark McLean
WHO Consultant, Injection Safety

Tool C was used for the assessment of intramuscular, intradermal and subcutaneous injections. The development of indicators for IV and phlebotomy will be included with indicators for injections in a methodology called Tool C – revised. Both venous and capillary types of phlebotomy (the latter of which use lancets), and intravenous infusions and injections can be assessed using the revised tool. Countries will have the option of performing assessments of different procedure types individually or together in the same assessment, and can evaluate a number of different health services settings. The prevention of bloodborne virus transmission remains the focus of assessments.

Because different procedure methods can carry different risks, the method used for each procedure type is itself often an indicator. Proper procedure performance may decrease the frequency of procedures by increasing both their effectiveness and that of the health services they compose. We know from our work on injections that one way of reducing bloodborne virus transmission is to reduce the number of procedures. For phlebotomy procedures, in addition to some tests being unnecessary when first ordered, a substantial proportion of phlebotomies may need to be repeated because ineffective technique has caused hemolysis or contamination of the sample.

Tool C - revised will include equipment sterility indicators for all procedures, whether disposable or sterilizable equipment is used. Indicators for disposable equipment sterility include observation of appropriate packaging upon selection and whether any unpackaged equipment is available. Sterilizable equipment indicators include observation of selection from a sterilizer, or an
apparently sterile packet or receptacle, as well as sterilization indicators similar to those found in Tool C. Indicators of sterile technique during intravenous procedures include skin and injection port preparation and performance of injections only at injection ports. Although the primary aim of some practices is reduction of bacterial contamination, inadequate skin or IV port preparation before IV injections or phlebotomy can cause contamination or even sepsis and lead to the occurrence of more procedures, some of which may be unsafe.

Phlebotomy procedures include lancet procedures and venous phlebotomy. Many safety indicators for venous phlebotomy are in common with those of intravenous infusions and injections. Venous phlebotomy can be performed in a number of ways. The most common way is by using vacuum tubes with a holder and two-ended needle, but winged collection sets, needle and syringe either directly accessing a vein or via an intravenous system, and luer-lok access of IV ports are all used at various times depending on what test is being performed, what equipment is available, provider preference and other factors. Sometimes venous phlebotomy requires an additional step after blood withdrawal that involves use of a blood transfer device, or in less than ideal circumstances, a direct syringe injection transfer of blood to a vacuum tube or some other vessel.

The assessment tool will also include venous phlebotomy indicators of the substantial risks for providers due to the handling of hollow-bore needles containing whole blood. In some countries the restricted range of equipment used for these procedures may increase risks. When venous phlebotomy involves use of a vacuum tube and holder, risks for providers are associated with the two-ended needle that screws into the holder. If the holder is disposable, safe practice includes the immediate disposal of the needle and holder without dismantling; however, reusable holders are still in use in many countries, so indicators for safe dismantling are being developed. Safe removal of the phlebotomy needle can occur after one-handed recapping of the needle followed by manual unscrewing, or with the use of forceps. Other methods draw blood using a needle and syringe, and transfer the syringe contents to a tube by direct injection, the latter action being similar to two-handed recapping if the syringe and needle are held in one hand and the tube is held in the other. The transfer of blood from the syringe to a tube may otherwise occur using a blood transfer device, which requires that the needle be removed from the syringe using forceps or one-handed recapping before attaching the syringe to the transfer device. Indicators of safety for the provider include the absence of two-handed recapping before removing any needle and the absence of uncapped needle removal using only fingers. Another action having the potential for two-handed recapping occurs when a phlebotomy needle is removed from its holder and the needle that was inside the holder is exposed. If blood is directly injected into a vacuum tube using a needle and syringe, an indicator of safer practice is whether the tube is supported upright by a rack or holder and a one-handed technique is used. A venous blood sample also may be taken from an IV port using a syringe with or without a needle, and subsequent blood transfer might occur with or without a transfer device. Indicators of the procedure methods used and key actions associated with each will be included.

Lancet procedures obtain a drop of blood for diagnostic or clinical monitoring purposes, often with the blood sample collected in a capillary tube or applied against a reagent strip. Lancets carry risks for recipients analogous to those for IV and venous phlebotomy procedures. Indicators of effective procedure performance will address the impact fraction of procedure frequency. These include whether the body part to be punctured is checked for capillary refill and prepared by warming if necessary to increase the likelihood of obtaining a sample; appropriate skin preparation with antiseptic; checking expiry dates on reagent strips and following the manufacturer’s instructions for their use; and, whether a capillary tube is used to scoop a sample or blood is smeared against a reagent strip, both of which can cause hemolysis. Appropriate skin
preparation before using a lancet will reduce mainly bacterial infection, but such an infection could lead to the occurrence of injections and other procedures, some of which may be unsafe.

Intravenous infusions and injections are administered directly into a vein or into an existing intravenous system. Indicators for these different routes of venous access are equally relevant for the recipient since an intravenous system is confluent with the vascular compartment. Some risks for recipients associated with intravenous procedures are high due to the complexity of both the work environment. Patients with IV infusions are often located together, and sometimes receive multiple procedures over time. Moreover, health care providers are often responsible for the care of a number of patients in the same vicinity. All of these factors put patients with IV infusions at higher risk of nosocomial infection due to mental errors or short-cuts taken by providers.

Finally, the use of gloves for many of these procedures and the use of IV sets requires that indicators pertaining to the management of non-sharps infectious waste and waste segregation are also included.

The Columbian Experience on Reuse of Single Use Medical Devices

Maria Latorre

A study was performed to identify more frequently used medical devices across institutions and to determine if Single Use Medical Devices (SUD) were reused and, if so, under what conditions. Two data collection instruments were designed in coordination with the National Regulatory Authority (NRA) INVIMA, College of Pharmaceutical Chemists and PAHO. The instruments were piloted in 22 clinics and hospitals having a high level of complexity.

The 146 more common SUD were identified, with 9 of these accounting for 90% of devices used. The proportion of institutions in which reuse was identified was 71%. Only 25% of the institutions make periodic internal audits; 50% have neither reprocessing orders nor reprocessing procedures; 75% of institutions identify products that will be reprocessed.

Other findings included:

-100% had methods of cleaning and sterilization 100%
-94% had special methods of disinfection and precautions
-56% of SUD to be reprocessed were subjected to Quality Control
-50% of the institutions had an adequate area for reprocessing
-75% had the required equipment for reprocessing
-56% of institutions validated the reprocessing of devices
-87.5% had procedures to clean areas
-81.25% had procedures to clean and disinfect the equipment
-94% of staff had suitable clothes
-70% had had training programs on reusing, reprocessing and sterilization
-68.8% of facilities had staff responsible to attend to complaints

Conclusions: Reuse of SUD is a common practice in the surveyed institutions. In general there is a lack of protocols, procedures and quality control mechanisms for reprocessing SUDs.
Injection and Needle Safety in Mexico: Current Policies - Future Goals

Dr. Javier Barroso Aguirre, Mtra. Diana Pimentel Nieto, Dr. Francisco Morales Carmona, Dra. María de Lourdes Cornu Gómez, Ginger B. Parker, MBA, Jane L. Perry, M. A., Janine Jagger, MD, PhD

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Mexico's population is around 106 millions of habitants, there are almost 4000 hospitals, most of these hospitals are privates, and there are 109 000 hospital beds. Most of the beds are in the public health sector. According to syringe manufacturers, the Ministry of Health, and the National Federation of Diabetes, approximately 586 million injections are administered annually in Mexico. Most are for therapeutic use.

The sale of syringes in Mexico is bigger than the number of administered injections, which may be an indicator of low reutilization. Single use disposable syringes are mainly used, except for diabetic patients for whom one syringe may be used up to 6 times. In Mexico a low percentage of safety syringes have been sold, which may be associated with misconceptions of their high cost and poverty.

During 6 weeks in 2006 we interviewed nurses of preventive medicine services from hospitals of a large Mexican oil company, who always have been unaware of the existence of skin puncture devices with safety features.

Nearly 50 per cent of the injections are applied in public and private hospitals, 37 per cent of these injections are applied in the house of the patient. There is adequate management of syringe disposition in hospitals and during vaccination campaigns. In the home setting, they are often put in the common waste.

In Mexico two relevant official norms exist: the norm for Infectious and Hazardous Biological Garbage requires use of specific containers for penetrating-cutting material in hospitals, and the norm for the prevention and control of nosocomial infections emphasizes the application of standard precautions while attending all patients.

At the present time hospitals are being certified by specialized national bodies and some of them, especially important private hospitals, are requiring certifications from international bodies. These certifications focus on the pursuit of safety measures for the patient, and the control of nosocomial infections.

Special syringes have been introduced in the vaccination program in Mexico to protect children against pathogen transmission from patient to patient. There also is an aggressive program for the safe management hazardous biological waste to protect waste handlers and the community.

More action to protect the health workers against sanitary risks in their work places is required - e.g., education related to the importance of the workers' health, and the implementation of obligatory training on the application of standard precautions. It is necessary to promote active epidemiologic surveillance and the voluntary reporting of sharps injuries, as well as Hepatitis B vaccination among health workers.
Finally, it is important to spread knowledge and use of skin puncture devices with safety features, and to put the health of the health workers at the same level of importance as our patients.

**Plenary:**

- A driving force for change is missing from the injection safety initiative.
- A working committee on clinical areas should be developed.
- One participant stated that the initiative shouldn’t move on to other procedures until injections are safe.
Day 1, Theme 2:

**Health Care Workers Safety**

**Assessing the burden of disease from sharps injuries to health workers**

This session outlines a method for estimating the burden of disease at national or local levels from sharps injuries to health care workers and provides the estimates from the Global Burden of Disease study. Sharps include syringe needles, scalpels, broken glass and other objects contaminated with blood from a source patient. Health outcomes from percutaneous injuries include infections with hepatitis B virus (HBV), hepatitis C virus (HCV) or HIV. Exposure is assessed from the number of sharps injuries in health care workers each year, and from the infection prevalence in source patients. The immunization rate against HBV and the post-exposure prophylaxis (PEP) coverage are also needed to assess the disease burden. The assessment provides the incidence of HBV, HCV, and HIV infections caused by sharps injuries to healthcare workers and the fraction of infections attributable to sharps injuries. The number of infections that could be prevented by PEP can also be estimated. The data can be used to assess the distribution of disease burden by category of health care worker, by ward or by activity, which would allow protection measures to be more specifically targeted. A guide is available to help countries assess the national or local disease burden from sharps injuries in health-care workers (Rapiti et al., 2003). The guide provides a practical step-by-step approach, using numerical examples, and can be adapted to local circumstances and data availability. The guide and a Microsoft Excel worksheet are available at the WHO web site to assist with the calculations (EBDassessment@who.int).

**Needlestick injury surveillance: using data for prevention**

**Susan Wilburn**  
**Gerry Eijkemans**  
**WHO Occupational Health Programme**

The purpose of surveillance is to determine the nature and severity of health care worker exposure to bloodborne pathogens and monitor trends over time. Data elements include those needed for risk identification for the purpose of determination of post-exposure follow-up and need for prophylaxis with anti-retroviral therapy as well as data elements to identify preventable hazards and needs for product, policy, and/or practice changes. The analysis of injury data on a regular basis by a facility based needlestick prevention committee (or infection prevention and control or occupational health committee) along with regular walking through the wards to observe practices and products is important to make recommendations and monitor progress for prevention. Every needlestick injury and exposure to bloodborne pathogens should be taken seriously as a failure to prevent the exposure and an opportunity to learn from the situation resulting in the exposure for the purpose of prevention.

The problem of underreporting was described and barriers to reporting including: minimizing the seriousness of the exposure by the worker, uncertainty of confidentiality of the system of reporting, lack of information about to whom to report, no access to PEP (or perceived lack), fear of discipline and job loss, fear of being tested for HIV and of test results, and not being relieved from duty in order to pursue treatment. Eliminating barriers to reporting is necessary in order for health workers to have appropriate follow-up including post exposure prophylaxis and workers
compensation in the case of occupational disease in addition to the accurate record of injuries and use of the data for prevention.

Examples of two available surveillance systems in use globally were shown and additional tools described as available in the surveillance section of the WHO tool kit: Protecting health workers – preventing needlestick injuries found on the web at www.who.int/occupational_health/activities/pnitoollkit/en/index.html.

EPINet: Epidemiologic Surveillance of Needlesticks and Sharp Injuries in Mexican Hospitals

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The Exposure Prevention Information Network (EPINet) is a simple and standard methodology for a sharps injury and blood exposure surveillance system developed by Professor Janine Jagger at the University of Virginia and overseen by a steering committee from la Asociación Mexicana de Infectología y Microbiología Clínica y de la Asociación Mexicana para el Estudio de las Infecciones Nosocomiales.

With the technical assistance of Prof. Janine Jagger and her staff at the International Healthcare Worker Safety Center, University of Virginia, in January of 2005 EPINet was introduced into a national sample of 14 hospitals with the following characteristics:

- > 50 beds
- Existing preventive medicine service
- Existing surveillance of nosocomial infections
- Available testing for HIV, HBV, HCV
- Existing protocol for tracking needlesticks/blood exposures
- Capability to provide educational program to all personnel
- Availability of computers for data entry
- Geographically representative

From April - September 2006 we provided safety awareness education (on DVD) to all at-risk personnel in 7 hospitals selected at random (Group 1). The remaining hospitals (Group 2) did not receive any training during this first phase. In Phase II (October 2006 - March 2007) the 7 hospitals in Group 2 receive the same safety awareness training program. Additionally, in Phase II safety engineered needle devices will be introduced into Group I hospitals. In April 2007 we will analyze our surveillance data and compare injury rates in Group I and Group II hospitals and determine the effects of safety training alone versus safety training in combination with safety-engineered needles on the incidence of needlestick and sharp injuries.

We found that 70% of these high-risk injuries associated with blood-drawing were sustained by the least experienced healthcare workers. More than one-third of injuries were reported by medical students, medical interns and residents, nursing and other students. Forty-five percent of
injuries were reported from patient rooms and the area just outside of patient rooms in cases where needle disposal containers were not located in patient rooms. Sharps disposal is an important issue in Mexico. Twenty-eight percent of injuries occurred in surgery and labor and delivery.

When we looked at the devices causing injuries we found that the disposable syringe is the predominant device involved, accounting for forty-eight percent of injuries. The highest proportion of injuries, thirty-one percent, was associated with blood-drawing procedures. The remaining injuries - almost half – were associated with a wide variety of non-injection uses including fingersticks, the drawing of other types of body fluids and trash-related incidents in which the original purpose could not be determined. The second most common device was the suture needle, accounting for eleven percent of injuries. Eighty-four percent of injuries related to blood drawing were caused by syringes; the figure was only thirty-six percent in U.S. data.

Conclusions:
• Surveillance is an essential prevention tool. With limited resources we must prioritize. To continue to improve sharps disposal systems with puncture-resistant containers and point-of-use placement
• Syringes are used for many other purposes than injection, which is typical in economically-limited countries. Not all types of syringes with safety-engineered features are appropriate for high-risk procedures like blood drawing. A protective feature is needed that can cover the needle BEFORE injecting the blood into a specimen container
• In addition to safer equipment, training and performance standards are needed in medical and nursing schools and hospitals and clinics for performance of procedures involving blood drawing or other vascular access
• We are now addressing the design and placement of sharps disposal containers on a national level and we can monitor the impact of these measures with our surveillance program. This is an area where the introduction of one device - the blunt suture needle – can potentially prevent a significant proportion of injuries
• Blunt-tip suture needles should be introduced for use in surgical settings
• HCW hepatitis B vaccination rates require improvement

Health Care Worker Safety in Botswana

Jamu, S.; Tamocha, J.; Mgeni, A.

1 Styn Jamu, Dip PH., MPA, is the Country Director for the Making Medical Injections Safer (MMIS) project under JSI Research and Training Institute, Inc.
2 Joyce Tamocha, R.N., MSc, is the presiding President of the Nurses Association of Botswana.
3 Dr. A. Mgeni is the head of Occupation Health Unit in the Ministry of Health, and the MMIS Coordinator in the Botswana Ministry of Health.

Health care workers are exposed to infectious pathogens everyday through unsafe medical practices and contaminated sharps waste, which are a conduit for HIV and viral hepatitis transmission. Data indicate that 1,720 to 2,400 sharps object injuries with contaminated blood occur annually in public health facilities. Botswana’s health care system currently faces
unprecedented challenges due to the HIV/AIDS pandemic,\(^1\) with health care workers bearing a significant psychological and physical burden due to the risk of infection, work overload and inadequate safety measures in health care facilities.

Most occupational infections in health care settings are caused by injuries sustained from sharps contaminated with blood through accidents, unsafe medical practices and inappropriate sharps disposal. Transmission of bloodborne diseases is dependent upon health care worker practices, disease prevalence, and frequency and extent of exposures. Assessments conducted in health care facilities in Botswana in 2003 and 2004 found that: 26% of nurses sustained needlestick injuries annually; 23% of injections administered for curative care were unnecessary; and unsafe injection practices, such as recapping, were observed. Studies also showed that health care facilities were understaffed, resulting in a heavy workload in major facilities. Because HIV and AIDS patients make up over 50% of the patient population, promoting health care worker safety is one of the government’s core strategies to improve health care delivery services.

National efforts have been made to eliminate unsafe working conditions and their associated risks of infection among health care through:

- A collaborative approach to health care worker safety from pertinent stakeholders [i.e. the Ministry of Health\(^2\) is working in collaboration with the Making Medical Injections Safer (MMIS) project, a HHS/CDC-funded initiative to promote injection safety, and the Nurses Association’s Care for Carers project];
- A task force made up of medical and public health professionals guides the national effort to promote health care worker safety and injection safety;
- Development of infection prevention and control policy, national guidelines, and norms for promoting health care worker and patient safety;
- Implementation of integrated strategies to include behavior change communication, capacity building training for health care workers, availability of adequate and appropriate injection safety supplies and appropriate and sustained health care waste management to ensure safe working environments; and
- Use of safer medical devices that reduce accidental injuries to create a psychological sense of safety.

The fear of acquiring infections and poor working conditions encourage health care workers to switch employers, provide poor services, or discriminate against sick patients. Consequently, this further strains the health care system. Recommendations to improve the situation include:

- **Implement Holistic Health Care Worker Safety Programs**: Holistic approaches must involve all stakeholders and partners. Health care workers must be involved in the development and formation of policies, guidelines, implementation strategies, and monitoring and evaluation plans;
- **Promote Policy Implementation, and Best Practices for Health Care Worker Safety**: Policies must have clear implementation plans. Achieving best practices in health care worker safety

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\(^1\) Botswana has one of the highest prevalence of HIV in the world. Current data estimate that 17.1% of the total population aged 18 months and over are infected with the virus.

\(^2\) The following departments and units are involved in healthcare worker safety initiatives: Occupational health Unit, The Wellness Program for Healthcare Workers, Environmental Health Unit, Botswana Essential Drug Action Programme, Expanded Program on Immunization, and Central Medical Stores. Ministries of Local Government (Local Government Management Services – Health), and Environment [Department of Wildlife and Tourism] are involved in the overall healthcare worker safety initiative.
programs requires commitment and participation of MOH senior level managers, health care institutions, and pertinent partners; and

- *Establish Continued Health Care Worker Safety Capacity Building*: Capacity building must be tailored to strengthen health care workers’ competency, knowledge and skills to create a social and professional norm where safety is observed.

**Hepatitis B immunization care workers in LAC**

Prof Assunção, Ada Ávila (NESCON, UFMG, Brasil)
Tennessee, Maritza (SDE/RA, OPAS)

Hepatitis B (HB) is an infection of worldwide distribution and its epidemiologic importance has been demonstrated in many studies. The prevalence of the surface antigen (HbsAg) in the general population is 0.3 - 13% in Latin American countries, and 3.2% in the USA. Hepatitis B virus is able to remain in a proportion of infected peoples producing chronic hepatic disease at long term. Health care workers are one of the groups with higher risk to have the infection (0.3% to HbsAg, and 3 - 10%, if any Hepatitis marker is considered). The risk is highest for health care workers having contact with blood and others body fluids. There is a consensus on the necessity of vaccination to the groups at risk of HB infection.

HB vaccine is safe and its effectiveness is well-known. More than the 95% of vaccinated peoples have protective levels of antibodies. Vaccination is indicated for the exposed groups. Based on this, a vaccination campaign is programmed into the Plan for the Security and Health of Health Sector Workers in Latin American and Caribbean Countries 2006-2007. The approach would be to reunite a group of experts to elaborate the consensus on the period, vaccine providers, doses, monitoring of undesired effects, and the assessment of the immunologic answer in vaccinated population. After, it would be possible to prepare the campaign and to constitute an operational group that will multiply the actions.

**Epidemiology of Needle-Stick Injuries and Injection Practices in the Dominican Republic**

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**Background:** Injection practices and sharps injuries (SIs) in healthcare facilities in the Dominican Republic were assessed in cross-sectional surveys to identify areas where preventive efforts might be directed to make them safer. **Material and Methods:** Observation of facilities and injections and questionnaire-guided interviews were conducted in 2005 among health care workers (HCWs) in two Santo Domingo public hospitals and 137 public immunization clinics throughout the country. **Results:** Of the 441 HCWs interviewed, 98 (22.2%) reported ≥1 SIs during the previous 12 months. Immunization clinics (ICs) had a lower incidence (13 per 100 person-years) of SIs than hospitals (65 per 100 p-y) (p < 0.0001). Unsafe needle recapping was observed in 98.5% of all injections at hospitals, but in only 11.7% of all injections at ICs (p
Disposed sharps were observed in regular waste containers in 24 (92%) of 26 areas where injections are prepared at the hospitals, but in only 11 (8%) of 137 ICs (p < 0.0001). Training in injection safety was received by 4% of HCWs in hospitals but by 78% in ICs (p < 0.001). Of 429 HCWs, 253 (59%) were fully immunized against Hepatitis B. Logistic regression analysis showed a higher risk of SIs among staff dentists (OR=7.9; 95% CI=1.9 – 33.7), resident physicians (OR=3.6; 95% CI=1.9 – 6.8), and those who gave >10 injections per day (OR=2.6; 95% CI=1.5 – 4.3). Those who attended ≥2 safe injection training sessions had lower risk (OR=0.4; 95% CI=0.2-0.9).

Conclusions: Injection practices at ICs were safer than those found at public hospitals. Preventive strategies to lower SIs in public hospitals should include regular training of hospital staff to minimize needle recapping and improper disposal.

Plenary:

- In many countries Hepatitis B vaccination of health care workers is deficient. What are the barriers to Hepatitis B vaccination in health workers?
- Better staffing is associated with lower rates of needlestick injuries.
- In many countries there is high rate of health care provider turnover associated with unsafe practices.
Day 2, Theme 3:

Injection Safety Strategies

Review of WHO / BASICS Injection Safety Assessment Tool and Revision of the methodology to enable assessment of other procedures in a number of services and sectors

Mark McLean
WHO Consultant – Injection Safety

A review of Tool C was performed in July 2006, during which the strengths and weaknesses of Tool C were identified, and revisions necessary to accommodate the increased scope of assessments due to inclusion of indicators for phlebotomy and intravenous procedures and the ability of assessments to examine other sectors were discussed.

Problems encountered during performance of Injection Safety Assessments:
- Country organization and logistics planning were often major problems, some of which caused additional problems during other parts of an assessment. The number of fieldworkers was often insufficient and their recruitment not timely
- Countries often misunderstood the need to conduct the sampling process as described
- The low number of injections observed in some assessments may have affected data validity
- The analysis of equipment inventories was complex and prone to error. Fieldworkers complained that some equipment inventories were too tedious
- Assessment cost - in the past this was 12 to 15 thousand U.S. dollars median cost, and ranged up to $40,000 dollars excluding the cost of external consultants

Features of Tool C-revised methodology:
- The revised methodology will include the ability to evaluate injections, phlebotomy and intravenous procedures
- A secondary cluster sampling method was described, which will enable assessment of many services and the curative and private sectors. For these assessments each selected facility will be used as a base to identify a number of unlisted facilities or service sites for evaluation. The unit of analysis will be the health facility service area, which can be defined as an area limited by distance from the base facility
- The interview of the provider will include a focus on health care worker protection. Providers will be asked their Hepatitis B vaccination status, the number of sharps injuries they experienced in the previous 6 months and whether they reported any of these. If the provider reported a sharps injury they will be asked whether HIV and HBV testing was offered to them, whether the source patient was asked to provide a blood sample for disease testing, whether HIV post-exposure prophylaxis was made available, and whether completion of the Hepatitis B vaccination series was offered to them
- A comprehensive toolbox for distribution to countries that will provide instructions for start-to-finish step-by-step conduct of an assessment will be provided, including provision of data entry templates, and instructions on analysis. Prepared indicator report tables will facilitate presentation of results
Limitations and potential problems with Tool C-revised:

- The complexity of the assessment methodology has increased at the same time as a decrease in visible technical support
- There are a number of ways that deviating from the assessment methodology could bias the results, and enough of these combined could substantially affect data quality
- The basis for determining the adequacy of the disposable equipment supply is susceptible to bias. More objective ways of determining rates of equipment require development, but these may ultimately be country-specific
- Sterilization policies and practices may vary across services and nations in the curative and private sectors, resulting in an inability of the assessment tool to assess different practice standards

Lessons learned and the way forward for sustainable injection safety programs in Africa and the Caribbean

Jules Millogo
John Snow Inc.

Thanks to the continued efforts of the Safe Injection Global Network (SIGN), the global community has a greater awareness about the role of unsafe injections in the transmission of HIV and other bloodborne pathogens in the medical setting. The US Government, recognizing the cost-effective impact of HIV prevention in clinical settings, decided to fund an injection safety and blood safety program as part of its response to the HIV/AIDS pandemic in Africa and the Caribbean.

Over the last two years, the Making Medical Injections Safer (MMIS) project has been working with 11 host country governments and partners to implement interventions to prevent the spread of bloodborne disease through unsafe injections. The project’s interventions have yielded significant improvements in injection practices in all implementation countries.

All countries have developed revised policies that emphasize health worker safety, and health workers have been trained to administer safer injections. Safe injection commodities procured through MMIS cover about 15% of the countries’ needs, while efforts are being made to ensure a sustainable plan that encourages countries to continue procurement of injection devices beyond the life of the project. Sharps waste management practices have dramatically improved in intervention districts, and evidence suggests that some countries are experiencing a reduction of unnecessary injections.

Promoting collaboration and synergy among stakeholders under the leadership of host governments is one of the key elements that MMIS is using to achieve nationwide coverage and ensure the sustainability of its interventions. As a result of this collaborative approach, the Japanese International Cooperative Agency (JICA) in Haiti and the World Bank’s Multi-Sectoral AIDS Program (MAP) in Rwanda have provided funds for the construction of small scale incinerators to serve these countries’ health facilities.

The MMIS project continually refines its technical approach based on the results of assessments conducted in all countries. Lessons learned from the implementation of this injection safety project are applied to ongoing and future efforts and to the broader context of infection prevention and control. Collaboration with host nations is central to the project’s strategic
Forging partnerships for injection safety in Haiti

Jean Antoine Alceus

In Haiti, the injection safety situation presents many significant challenges. A WHO/SIGN Tool C assessment and a qualitative assessment on safe injection knowledge, attitudes and practices conducted in 2004 found that unsafe injection practices were prevalent in health care settings, medical staff and the population prefer injections to alternatives, and that sharps and medical waste are not safely managed posing a risk to staff, patients and the community. To address this critical issue, the Ministry of Public Health and Population (MSPP) is engaged in partnership to improve injection safety practices and management of waste produced by injection and health care activities.

In June 2004, the MSPP created a task force to assess, document and understand the problem and take steps to change the situation. Members of the task force are staff of key MSPP directorates working along with PAHO/WHO, UNICEF, private sector entities involved in waste management and professional associations. The task force meets monthly in the MSPP and was instrumental in elaborating a strategic plan national policy and norms and standards for Injection Safety and Waste management, and in overseeing training of staff in health facilities.

As a result of this broad and active partnership, the MSPP is working with GHESKIO, University Hospitals, and other partners to implement safe injection interventions based on the strategy, including elaboration of a needlestick reporting form. UNICEF secured funding for incinerator construction in a number of sites, and a broad waste management plan has been developed in collaboration with MSPP, UNICEF, PAHO, MMIS and other partners. PAHO/WHO will participate by providing waste management equipment to peripheral facilities. MMIS is supporting the MSPP through technical assistance and training of waste handlers and incinerator operators. Training sessions have been conducted in many facilities, behavior change and waste management strategies were elaborated and are being implemented. Safety syringes have been introduced, and both public and private sector partners are being involved to improve supply management and reduce syringe reuse.

This partnership under the MSPP leadership has been very effective: supervision activities have shown improved injection practices by trained personnel. In addition, the use of safety boxes for immediate disposal is leading to dramatic improvements and reduction of risk of needle sticks injuries, making an immediate visible difference.

While initially participants came to the meetings out of deference to the MSPP, they have remained actively engaged beyond this point. A key element in maintaining the participation of partners was to promote the links and complementarities among the activities of the task force and their own activities and action plans. The MSPP is conscious of the importance of ensuring engagement of partners, particularly in light of the difficult environment in Haiti, and is committed to institutionalizing this task force, which through its activities fosters awareness of
injection safety and waste management in Haiti. This collaborative process combining resources and expertise can be a model for other projects.

Strategies for sustaining IP/IS programmes in Zambia

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Authors: Chipukuma, A.; Hughes, R.; Mazimba, C.; Ndhlovu M.; Maitra, K.; Favin, M.; Zyambo. M.; Mtolo, P.

Background: Unsafe and unnecessary medical injections account for a small percentage of HIV transmission in Zambia and are largely preventable. However, implementation of sustainable interventions that result in observance of proper infection prevention and injection safety (IP/IS) practices among healthcare workers is extremely difficult. This is largely due to limited human resources within the health sector, limited availability of injection safety equipment and commodities, and insufficient monitoring and evaluation of provider behavior.

Methods: Project activities are to be implemented in healthcare facilities found in all nine provinces (72 districts) of Zambia. Two districts per province are selected each year for project implementation. The project uses a multi-pronged intervention approach to address issues of injection safety. This approach involves orientation of healthcare administrators on IP/IS issues, training of healthcare providers in IP/IS best practices, procurement of IP/IS commodities and behavior change communication (BCC). After implementation of intervention activities has been completed the project conducts follow-up visits to evaluate the immediate impact of the intervention on provider behavior.

Results: To date, project intervention activities have been implemented in 17 districts. Management support of IP/IS activities appears essential to program sustainability. Active and consistent advocacy for IP/IS by the District Health Management Team has resulted in incorporation of IP/IS activities (such as on-the-job training, clinical demonstration sessions and supportive supervisory visits) and budgeting for IP/IS commodities in district action plans. Active infection prevention committees also characterize districts in which program activities have been sustained. These committees actively participate in health planning activities at both the facility and district level.

Implementing injection safety at country level—can we afford it?

Prof Shaheen Mehtar, Academic Unit for IPC,
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At any one time, approximately 25% of patients admitted to hospital will have an injection, either intravenous or intramuscular, administered to them. The aim to make injections safer at country and healthcare facility level is paramount. It is evident that training in good infection prevention and control (IPC) practices are lacking, particularly in this area, because IPC is a low priority in most developing countries. In order to convince management that IPC is effective, both in the long and short term, cost savings associated with good IPC practice should be considered.
A baseline audit or evaluation of current practice gives a good insight and foundation upon which to build IPC training programmes. This should be followed by short courses for non-IPC practitioners and more in-depth training for IPC specialists (both nurses and doctors) to build capacity and sustain an IPC programme. A follow-up evaluation (audit) would highlight the improvement in clinical care and cost savings.

At Tygerberg Hospital, our IPC Team demonstrated a reduction of sharps injuries by 22 in a month with a saving of R62000 (approx $1000). By rationalising glove usage a saving of R1.2m was noted, while implementation of treatment of MRSA carriers highlighted the difference between treatment and prophylaxis was that the former was 55 times more expensive. These cost savings have been recognised by management and support for the IPC has grown as confidence in the programmes, and the IPC Team, has grown.

**Medical Waste and Injection Safety in Latin America and the Caribbean (LAC): UNICEF TACRO collaboration**

**Paulo Froes, MD, MPH, PgD OH & S, UNICEF TACRO**

**Itzel Hewitt, General EPI Coordination, Panama, MoH**

A brief update on medical waste and injection safety status and activities held in LAC by UNICEF TACRO is presented. The major challenges are discussed and as a case-study, the findings and outcomes of a comprehensive injection safety assessment conducted in Panama by the end of 2005 is presented.

For future accelerated improvement in medical waste and injection safety practices in LAC the key role of broad-based partnerships and the potential for public-private partnerships development is highlighted.

**Injection Safety Experience in Honduras**

**Molina, Ida Berenice**

**Chief, Extended Program of Immunization, Secretary of Health of Honduras**

In Honduras the development of safe vaccination practices, including injection safety began six years ago with the process of updating of the manual of standards of the Expanded Program on Immunization (EPI). Subsequently in the year 2001, with the support of the Pan-American Health Organization (PAHO), a study of safe vaccination was realized, and in the year 2003, the National Plan of Injection Safety was formulated and implemented in vaccination clinics. This plan was presented to the Global Alliance for Vaccines and Immunization (GAVI) and approved for support for US$ 456,000.00 for a period of three years. The national study of safe vaccination of 2001 allowed for the characterization of the problem of insecure handling of injections in vaccination clinics, highlighting among its findings: evidence of syringe reuse (1%), re-capping of needles (90.5%), accidental needle-sticks after administering a vaccination (56%), inadequate discarding (70%), and inadequate final disposal of vaccine paraphernalia (municipal dumping 31%, open field 8%), among others.

Up to the year 2006 important advances have been made in the fulfillment of activities of the National Plan in the areas of political priority and legal bases, planning and programming, equipment and infrastructure, training, mobilization, social marketing and evaluation. The
principal achievements are the formulation of a National Regulation on management of hazardous waste generated by health facilities (a presidential signature is pending), sensitization of the Authorities of the Secretary of Health and Cooperation, procurement with national funds of 100% of AD syringes since 1997 and safety boxes since 2001, provision of portable needle destroyers to 34% (486/1427) of Health Centers for vaccination services, training of 90% of health workers and development of a module for safe vaccination for training school resources. Various limitations have been identified, including: the lack of a national policy, lack of definition of a national technical unit responsible for the comprehensive management of hazardous waste, a diversity of standards among programs, and lack of financing to improve final waste disposal.

The principal lessons learned are that Injection Safety should be a comprehensive part of the health services of a country and not be part of isolated programs that generate changes in practices and behaviors. National technical standards are required for the management of hazardous waste including sharps disposal. Also, the offer of the Revolving Fund of PAHO should be increased to include AD syringes with needle for all EPI vaccines. Use of disposable syringes represents a potential risk for the country.

Based on the current situation several plans of action have been identified: conduct a follow-up study of safe vaccination, advocate for the establishment of national safety policies for vaccinations in health establishments, define a regulatory normative unit for the management of hazardous waste, definitions of standards, formulation and project management for the mobilization of financial resources in coordination with the local governments.

Assessment to intervention: Model injection centres to promote safe injection practices in India

Rukshana Zaman

According to WHO estimates, in the year 2000 almost 12 billion injections were administered worldwide. These injections were also stated as the cause of 80,000 - 1,60,000 new infections of HIV, 8 to 16 million Hepatitis B cases and 23 - 47 million Hepatitis C infections. With this background the study “Assessment of Injection Practices in India (AIPI)” was initiated by IndiaCLEN Program Evaluation Network (IPEN) in the year 2002.

The AIPI study revealed that between 3-6 billion injections are given annually in India; out of these 62.9% are unsafe. Safety profile of injections was worst at immunization clinics under public health system (74%) followed by government health facilities (69%) and private clinics (60%). Type of injection equipment was the dominant determinant of unsafe injections; 90.8% of injections given by glass syringes were unsafe as compared to 53.3% injections administered with plastic syringes. Injections administered with glass syringes are unsafe due to inadequate sterilization and lack of monitoring process.
The findings of the AIPI study was submitted to the Ministry of Health and Family Welfare, Government of India in July, 2004. Based on the report, the Government of India introduced the Auto Disabled (AD) Syringes in the Universal Immunization Program (UIP) in the country since 2005. The introduction of the AD syringes was a landmark policy decision. But intervention was also required for remaining 85% of the injections given in the curative sector; where 63% of the injections are unsafe.

In the above background, an interventional program “Model Injection Centres” was conceived and implemented by 25 Partner Medical Colleges located in 19 states of India with the objective to improve injection practices by promoting: (a) safe injection techniques; (b) rational injection prescription; (c) safe disposal of injection related waste and (d) community awareness through an institutional mechanism.

The Model Injection Centres Program in India has now completed nine months of implementation and till date 982 training sessions have been conducted in which 11,926 participants were trained. This included 3768 doctors, 1675 medical students and 7590 paramedical personnel. Four state governments (Kerala, Gujarat, Orissa and Jammu & Kashmir) expressed interest to expand the program to all medical colleges in their state. MIC program facilitated in establishing waste management system in 4 medical colleges; reviving the waste management system in 6 medical colleges and strengthening the existing system in 15 medical colleges. Monthly teleconferences at regional level helped in sharing experiences and solving operational problems. There were initial hesitations to setup and initiate program activities in rural areas but experience sharing helped to overcome this barrier. A full assessment of the program will be done in February, 2007.

Plenary:

- The PEPFAR MMIS strategy is to focus on affordable interventions first, then adding more expensive strategies.
- The devices market situation should be closely examined. Adequate quantities of equipment, affordable processes and sustainable systems are needed.
- Budget protocols for funding of injection devices in developing countries can be cumbersome and are a problem. In Africa, African Union meetings could be used to get ideas on the table.
- One participant stated that the length of time it takes for the WHO certification process impedes starting a factory and locally producing equipment.
- Concern was expressed about the use of incinerators in some settings.
• Use of medical students and nursing students for Tool C assessments has been successful in the past.
• The opportunity costs of performing injection safety assessments must also be considered.
Day 2, Theme 4:
Rational Use of Injections

MTP to Reduce Overuse of Curative Injections

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Although some countries like Indonesia has been successfully reduce the unnecessary use of injections, the overuse of curative injections is still a serious problem worldwide. Efforts have been paid to improve appropriate use of medicines, including that of injections and injectable antibiotics, and well-proven strategies have been identified. However, they are difficult to implement in a wider scale due to specific research conditions, or health managers may not be interested to conduct interventions or they may be unaware of problems in medicine use. In coping with these difficulties, there is a need of an intervention strategy that can be incorporated in the existing managerial activities, or in other words, intervention that is a part of the quality improvement management cycle.

A strategy called MTP has therefore been developed. MTP is an abbreviation of Monitoring-Training-Planning. In brief, MTP consists of serial small-group discussions in health facilities, involving managers and prescribers who have problems in a particular medicine use. Each serial discussion focuses on one problem (e.g., high injection use in patients undergoing malaria treatment). When the problem has been solved, another serial discussion may follow to address another medicine use problem. The Monitoring component identifies the existing problem and defines its severity by collecting drug use indicators. The Training component concerns why the problem exists and what to do to solve it. The Planning component sets the target of improvement, i.e., to what level to reduce and when data should be collected again, to see if target is being met. Each MTP meeting should not exceed two hours, covering the M, T, and P components. To solve a problem, 3-5 MTP cycles are needed. If the problem is not solved within 5 cycles, it means that the problem-solving may not be effective or does not address the real underlying motives of inappropriate prescribing practices. Evaluation should therefore be made to identify the factors causing the failure.

After a successful pilot-test in Indonesia, MTP has been implemented in Cambodia and Lao PDR, and the country experiences were presented during the International Conference in Improving the Use of Medicine (ICIUM) in Chiang Mai, 2004. A WHO (WPRO-SEARO) Bi-regional Workshop was then organized in December 2005 to further disseminate MTP to other countries in the regions, e.g., Mongolia, PR China, and the Philippines. With the support from SIGN, INRUD groups of Bangladesh and China (Zhuhai) is currently conducting a pilot test to implement MTP to reduce curative antibiotic injections in hospitals.
Reducing unnecessary medical injections: formative research from 10 countries and implications for action

Rebecca Fields

Unsafe and unnecessary medical injections account for an estimated 5% of new HIV infections each year, as well as more than one third of all new hepatitis B and C infections annually. Yet demand for injections among both the general population and health personnel appears high and deeply-ingrained; this results in a surfeit of injections that, in turn, exacerbates the risk of bloodborne pathogen transmission. Efforts to reduce unnecessary injections require first understanding the knowledge, attitudes, and behaviors of not just recipients but also prescribers of injections, so that effective strategies can be developed.

With technical support from the Academy for Educational Development, the country teams of the Making Medical Injections Safer (MMIS) project conducted formative research in 2004 in 10 countries: Botswana, Cote d'Ivoire, Ethiopia, Haiti, Kenya, Nigeria, Rwanda, South Africa, Tanzania, and Uganda. These studies comprised in-depth interviews with prescribers and providers of injections and focus group discussions with waste handlers, patients, and community members. Study instruments were based on SIGN (Safe Injection Global Network) Tool A and adapted to particular country circumstances.

While variations were seen among findings from the ten countries, some common themes included the following:

- Patients have low awareness of the risks of injections and retain a strong demand for them. This is especially true among older, female populations; younger patients are more amenable to oral alternatives.
- Patients have confidence in their health workers in terms of the care and information they provide; however, patients report they are unwilling to question health workers' use of injections or request oral medications as an alternative.
- Prescribers of injections view injections as an effective means of providing patients with a known quantity of a known medication with minimal problems of patient adherence. Prescribers believe that patients strongly prefer injections and have little time to explain the benefits of oral medications over injections to patients. Moreover, prescribers' awareness is generally low regarding the risks that contaminated needles and syringes pose to patients, themselves, other health workers, and the community.

Strategies to reduce unnecessary injections must push beyond messages that simply discourage injections and additionally address the obstacles and enabling factors that influence the alternative desired behaviors. MMIS country teams are using the qualitative data plus results of assessments to develop and implement multi-faceted strategies that incorporate components of communication and advocacy, review of standard treatment guidelines, capacity-building, and logistics management.

Revising STI treatment protocol guidelines to reduce unnecessary injections in Mozambique

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Outdated treatment protocol and guidelines, such as those for treating sexually transmitted infection (STI) in Mozambique, promote the overuse of injections. The Ministry of Health (MOH), in partnership with the Center for Disease Control (CDC), UNICEF, Family Health International (FHI), and the Making Medical Injections Safer (MMIS) project revised the STI treatment protocol by reviewing guidelines and algorithms, field-testing them, and suggesting alternatives to injections in the essential drug list. The training materials, especially for prescribers at health facility level, were also reviewed.

Many Mozambicans are vulnerable to HIV transmission in the medical setting. Data collected in Mozambique in 2004 using WHO’s Tool C revealed unsafe injection practices. One or more needle stick injuries in the prior 12 month period were reported by 43% of health workers providing curative services. Furthermore, 86% of 209 observed injections for curative services were administered with sterilizable metallic needles and glass syringes, even though disposable syringes were found in over half of the visited health units. Furthermore, it was found that adequate sterilization occurred in only 51% of the facilities where procedures were tested. The country’s high prevalence of STIs is most often treated by over-prescription of injectable formulations using these reusable glass syringes, making transmission of bloodborne disease possible. The overuse of injections was a result of both patients’ preference and outdated STI management guidelines.

To reduce the number of unnecessary injections, the MMIS project advocated the MOH and partners for revision of the STI treatment protocol and guidelines and worked closely with the STI Working Group to develop 2,500 training manuals for health workers on syndromic management of STIs, as well as their publication and dissemination at provincial/district and health facility levels. Partner support was obtained in planning and implementing health workers training with FHI supporting 3 regional courses to train 75 health workers as trainers (TOT), and MMIS supporting training for 275 health workers in 11 provinces.

High-level advocacy within the MOH is critical in order to draw attention to a cause, to secure commitment and active involvement in the development or revision of a key policy or documents, and to get partner support in the planning and implementation. Periodic revision and validation of treatment guidelines are necessary to change prescribers behaviors and encourage the rational use of injections.

**Rational use of injections in Uganda**

**Jacintho Amuanda**  
Comisionado de Servicio Clinico  
Uganda

Globally, emerging evidence has shown high rates of transmission of HIV and other blood-borne pathogens in the health sector. Uganda, being one of the countries with high rates of injection use and high prevalence of HIV and hepatitis B, was awarded a USAID-funded project to reduce transmission of the blood-borne pathogens through the rapid reduction of unsafe and unnecessary injections. Reducing the number of unnecessary injections presumably reduces the pressure for re-use of injection equipment and further improves the safety of the fewer medically necessary injections. The objective was to assess the impact of targeted interventions on prevalence of injection use by: district, health facility level, ownership (public, NGO, private for profit), and disease category in four initial project districts.
All prescribers working in facilities in the project areas were trained on rational drug use with emphasis on rational use of injectable medications. Communities in the catchment’s areas of the facilities were targeted in BCC campaigns aimed at reducing demand for unnecessary injections. Data was collected for pre- and post-intervention periods from outpatient registers as well as from a control district.

According to preliminary results, overall there was a more than 15% reduction in injection use in the project districts. This compares to a 36% increase in injection use in the control district.

The reduction in the project districts was demonstrated in all but one district. Lower-level facilities were giving more injections than upper level facilities. The highest number of the injections was being given in the private for-profit sector, followed by the private non-profit (NGO) sector. Patients with infected wounds and trauma were more likely to receive injections than malaria and respiratory cases. For clients that received injections, the average number of doses per injection was close to four and did not differ significantly between the pre- and post-intervention periods.

Kenya’s “Top down approach” to improve rational injections

Robert T. Chen, Jackson Songa, Jane Mwangi, Bill Lore, Fauzia Khan

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4International Network for Rational Use of Drugs (INRUD) - Kenya

The Making Medical Injections Safer (MMIS) project is part of a five-year initiative funded by the President’s Emergency Plan for AIDS Relief (PEPFAR), to prevent medical transmission of HIV. The MMIS project is being carried out in 11 developing countries, 10 of which are in sub-Saharan Africa. To achieve its vision, MMIS has used four of the prevention strategies developed by the World Health Organization’s Safe Injection Global Network (SIGN). These include: 1) increasing the supply of injection commodities to prevent stock outages and the reuse of syringes; 2) educating health care workers on safe injection practices (e.g., avoiding recapping needles); 3) ensuring the appropriate management and disposal of sharps waste; and 4) reducing the demand for unnecessary injections via behavior change and communication (BCC) (i.e., rational injections). To date, the primary intervention for educating patients on rational injections has been via BCC activities with the community (i.e., “bottom up” approach). In Kenya, we piloted a complementary “top down” approach for rational injections, which includes the following steps:

Review of the literature and local surveillance data to identify the most prevalent diseases in Kenya requiring injection (including intravenous) therapy. The diseases included: malaria, tuberculosis, diarrhea, sexually transmitted infections (STI), and acute respiratory infections (ARI).

Review of current and future treatment guidelines for each of these diseases through interviews with disease-specific experts at the Centers for Disease Control and Prevention (CDC). This review served to identify opportunities for minimizing injectable therapy.

Identification of key stakeholders for rational injections from the Kenyan Ministry of Health, Kenyan universities, and the private sector. A one day stakeholders’ meeting was held to
introduce the objectives of the project, and allow the group to brainstorm ideas on enhancing rational injections in Kenya. The stakeholders meeting concluded with agreement among participants to collaborate on a national approach to enhancing rational injections. As a result, the following next steps were recommended:

The Kenyan MOH will update the 1994 National Drug Policy, the 2002 Clinical Guidelines for the Diagnosis and Treatment of Common Conditions in Kenya, and the Essential Drug List. A representative from MMIS was invited to participate in this process.

Mobilizing domestic and donor resources for BCC in local communities was identified as a priority for all stakeholders.

The following targeted evaluations were highlighted as priorities: a) determine methods for improving acceptability of rectal artemisinin combination therapy (ACT) for severe malaria; b) identify the full cost of procuring and administering rectal ACT via a health economic study; c) review medications ordered by the MOH, faith-based organizations, and wholesalers to track usage patterns for injectable medications in Kenya. These surveys may ultimately become a prospective surveillance system for tracking the use of injectable drugs in Kenya. A sample of medication may also be tracked to determine changes in the use of rational injections over time.

Several factors suggest a positive prognosis for advancing rational injections in Kenya:
1) After salaries, pharmaceuticals are the most costly line item in the MOH budget. Rationalizing the pharmaceuticals budget is, therefore, a high priority in the 2005-2010 MOH National Strategic Plan.
2) Anecdotally, the number of injectable medications used in Kenya has been declining over time. This has been attributed to greater awareness of the risks of HIV/AIDS.
3) The new malaria control initiative emphasizing ACT and insecticide-treated bednets introduced in Kenya in May 2006 may lead to a substantial decrease in use of parenteral quinine.
4) Finally, the Kenyan chapter of the International Network for Rational Use of Drugs was established as an NGO in 2004.

We look forward to improving rational injections in Kenya through a combination of top down and bottom up approaches. We also hope to share the lessons learned in Kenya with other countries to inform the interventions to meet country-specific injection safety goals.

Plenary:

- The cost of reprocessing medical devices is often higher than the cost of a new piece of equipment. Cost analyses should include costs of disposal, and for multiple use devices, the cost of reprocessing.
- Strategies should not be implemented without the consent, commitment, involvement and participation of many agents including governments health systems and partners outside health systems.
- Drug procurement lists are an important way of reducing the number of injections.
Day 2, Theme 5:

Quality and Access to Safe Injection Devices

Regional Plan for Syringe Quality Control and Safety

N. Rodríguez, J. Fitzsimmons, A. Hernández

The Pan American Health Organization (PAHO) and its Member States are working to fulfill the Millennium Development Goals (MDGs) in the Americas. One of the goals is to reduce the mortality in children aged <5 years by two-thirds. To reach this objective, one of the Regional strategies promoted by PAHO with Member States is to strengthen the vaccination campaigns. PAHO, through its Revolving Fund (RF) for vaccine, syringe and another supplies procurement, (Unit of Immunization), acquires and distribute this supplies for vaccination campaigns in countries of the Region of the Americas. The Fund places special emphasis on these products being effective, safe, and of good quality. For 2006 the Revolving Fund is acquiring 122,421,000 syringes, both Auto-Disable (AD) and disposable.

To generate the projected impact on vaccination campaigns, PAHO is promoting the immunization safety initiative. This is one of the fundamental components of the injection safety program and requires the use of safe and quality syringes. In this context since 2004, the Unit of Immunization and the Unit of Essential Medicines, Vaccines, and Health Technology have developed a Regional Plan to verify the quality and safety of syringes. The plan was originally based on compliance with international ISO regulations (specific to AD and disposable syringes and needles). This program was extended to include the whole shelf life cycle of the product, from its procurement, including storage, distribution, and use, to its final disposal.

The Regional Plan for Quality Control and Safety of Syringes is structured into three phases. The first phase, Consisted to strengthen RF and PAHO’s capacity. The second phase is focused to develop capacity at national level, establish laboratory layout to verify quality of syringes, and strengthen national immunization programs. The third phase is to transfer the accumulated knowledge, infrastructure and expertise on syringe management to countries and strength National Regulatory Authorities.

The plan has the following objectives:

1. Ensure syringe quality and safety, through the implementation of laboratory testing to verify quality and compliance with standards.
2. Promote and strengthen the use of AD syringes and introducing a transition process for its standardization, established in accordance with syringe presentation and needle caliber, as per the type of vaccine and dose to be administered.
3. Promote safe injection practices and contribute to immunization and patient safety.
4. Train health workers in the use of AD syringes and safe injection practices, include syringe disposal and final waste management.
5. Establish the Regional Laboratory Network for Quality Control of Syringes. The network is currently made up of six countries, trained by PAHO in the administration of quality control tests in verifying syringe quality and compliance with international standards.
6. Establish a Regional incident reporting system to provide a forum for quality and safety issues regarding syringes, and conduct monitoring and investigation of syringe-related incidents.
Quality standards for injection devices

Cecilia Jimenez / Paul Mallins
International Association of Safe Injection Technology (IASIT)

Injection safety is a complex multi-dimensional public health problem. All the factors that affect injection safety need to be addressed if the massive problem of unsafe injections is to be overcome. Government policy and legislation, rational drug use, health worker training, public education, effective health care waste management and the adequate supply of safe equipment are all important elements of injection safety.

IASIT believes that one element of the injection safety puzzle is solved. Internationally agreed product and manufacturing standards exist for injection devices.

In partnership with the World Health Organization (WHO) and the International Organization for Standards (ISO) IASIT has created global standards for safe injection devices.

- ISO 7886-3 auto-disable (AD) immunization devices
- ISO 7886-4 re-use prevention feature (RPF) therapeutic devices

These two product standards (the only type of injection devices pre-qualified by WHO) are supported by a third key standard:

- ISO 13485 medical device quality assurance system

An independent accredited specialist body issues this manufacturing quality assurance certification.

If an injection device meets one of the product standards and has the quality assurance certification the user can be sure that is a quality safe device. These standards are the only guarantee of device quality and safety.

IASIT urges all Ministries, procurement bodies, International Organizations, and NGOs to follow WHO’s lead and only supply devices that meet these standards.

Update on jet injection developments

Darin Zehrung
PATH Technology Solutions

Disposable cartridge jet injectors (DCJIs) can be a safer alternative for vaccine delivery. The technology can be used to delivery intradermal (ID), subcutaneous (SC) and intramuscular (IM) injections. The Biojector 2000, produced by Bioject Medical Technologies, Inc. is being used to successfully deliver immunizations for pediatric and adult populations in the United States. A meeting was recently held by the WHO Initiative for Vaccine Research (Dr. Martin Friede) to discuss DCJIs, with presentations by device developers, regulatory experts, and public health stakeholders. The following points were discussed during the meeting:
Review the current state of development of disposable cartridge jet injectors
To agree on design criteria critical for devices for developing countries
Discuss the vaccine manufacturer's and regulatory agency views on the use of DCJI to deliver vaccines
Review regulatory pathway of needle-free injection devices
Review potential and use of intradermal delivery to permit dose-reduction
Clinical/regulatory pathway to licensure of reduced dose ID delivery of vaccines

Four DCJI developers presented their technologies to the meeting participants (Bioject, DCI, PharmaJet, Eurojet Medical). The following are some draft points from the meeting:

• Bioject is the leader in industry and represented the sole manufacturer with actual devices being used in the marketplace (Biojector 2000)
• Biojector 2000 is successfully being used in US for pediatric to adult immunizations, for all injectable vaccines (millions of injections)
• WHO “design criteria” not finalized – this will be kept general to allow for creative design solutions by device developers.
• National regulatory authority (NRA) review will be required for regulatory pathway determination (standard dose and/or intradermal / reduced dose)
• Technology will be viewed as a “combination product” (drug and device) by regulatory authorities (especially if pre-filled or multiple fill on site design)
• Standard dose “bridging studies” per vaccine and DCJI type may be required for WHO approval (small clinical studies comparing to needle and syringe)
• Intradermal vaccine DCJI delivery pediatric studies underway with Biojector 2000
  o CDC – Dominican Republic (influenza)
  o WHO – Cuba, Oman (IPV)

Fabrication and analysis of plastic hypodermic needles

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2 U.S. Centers for Disease Control and Prevention

Plastic hypodermic needles may help reduce illness and disease due to unsterile re-use, as they may be more easily disabled and disposed of as compared to metal ones. This paper presented the fabrication of plastic hypodermic needles using micro-injection moulding and the analyses of their buckling behaviour. As a needle cannula is a thin-walled column (here 0.7 mm outer diameter with a 0.15 mm wall thickness), it is vulnerable to buckling. The buckling behaviour is characterized by numerical simulation and experiments, which are compared to the penetration forces for rubber skin mimic and human skin.

Plastic needles may also help to rationalize the waste stream by eliminating metal, leading to ease of shredding and reprocessing into other products, such as consumer goods. Simple melting, rather than incineration, can also be used to disable both plastic syringes and hypodermic needles and reduce their waste volumes, leading to a sterile “brick” that can be recycled or disposed of safely.
Use of Safety Syringes in Curative programs

Carib Nelson
PATH

The Making Medical Injections Safer (MMIS) project has introduced safety syringes into 10 countries in Africa and the Caribbean: 64 million syringes with reuse prevention features (RUP) and 25 million syringes with needlestick prevention features over the last 2 years. The project has conducted ongoing monitoring of the use of these syringes, but no formal evaluation.

Curative safety syringes follow separate specifications from immunization syringes. There are important differences: Whereas the WHO-ISO specification for immunization AD syringes requires fixed needles and an automatic disabling mechanism, curative RUP syringes can have fixed or detachable needles, and allow the disabling feature to be user-activated or automatic. These types of features enable more flexible use needed for the variety of procedures found in curative services.

The acceptability and performance of the safety syringes has been very good. Health workers have a high appreciation for the safety features. Most health workers feel the syringes improve safety to themselves, to their patients, and to the community. The majority find the devices easy to use and use them properly.

Training is a critical issue. Training weaknesses are common. Without training on some syringe types, health workers tend to prematurely activate the auto-disable feature. After a few attempts they will learn to use it properly, but sometimes they get frustrated and give up completely. The project has helped the suppliers improve the training materials that come with the syringes, but there is no substitute for hands-on training and supervision.

One of the most important lessons learned from this introduction is the need to match the specific features of safety syringes to the medical procedures they will be used for. Compared to disposable syringes, safety syringes are more limited in how they can be used and cannot replace all disposable syringes. For example, fixed needles and disabling features can make it difficult, or impossible, to perform certain specialized procedures such as connections to IV lines, phlebotomy, or reconstitution. Detachable-needle safety syringes have proven more versatile in curative settings and most MMIS countries are shifting to a greater proportion of these safety syringes.

MMIS has also learned important supply and logistics lessons. Initially most countries had weak forecasting, supply management, and warehousing capacity. This led to distribution problems and stock outs. The project has emphasized improvement of central medical stores capacity and strengthening of logistics monitoring, supervision, and consumption-based forecasting.

The price of syringes supplied by MMIS may be different than what countries have to pay for in-country purchase. MMIS is paying US$.03 for disposable syringes while most countries pay about US$.07 for local procurement. MMIS pays about US$.03–US$.04 for curative RUP syringes with detached needles, while the same syringes, when locally procured, syringes can cost around US$.06 or more. MMIS is paying US$.15 for retractable syringes, while some countries report local prices of around US$.37 or higher. We expect these discrepancies to lessen as local purchase and distribution systems improve.
The policy environment for safety syringes is changing rapidly. Many safety syringes are now included in the revised WHO PQS system. In some countries, local registration is also required. Syringe manufacturers have facilitated this where needed in MMIS countries, and are likely to be willing to do so in other countries if there is local demand. Several countries now have in-country distributors for most of these products which will ensure a more reliable supply.

The introduction of safe injection devices through the MMIS project has generated valuable insight into user acceptability and appropriate application of safety syringes. The experience has illuminated the challenges and opportunities within training, logistics, and policy environments.

Implementation of safe injection – UNICEF perspective

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UNICEF has fully endorsed and implemented the Use of Auto-Disable Syringes in Immunization Services as recommended in the WHO-UNICEF-UNFPA Joint Statement of 1999. The bundling policy has resulted in, that for each vaccine dose, sufficient numbers of AD syringes, reconstitution syringes and Safety boxes is ensured.

The WHO pre-qualifications of re use prevention featured (RPF) syringes and the increased availability of this type of syringes has enabled UNICEF to bring the Injection Safety concept one step further, to also include syringes for reconstitution of vaccines. Observations world wide have shown that the bundling concept is not always ensured all the way down to end destination. Instead, in the field we often find one reconstitution syringe available for every 2-6 vials, if that. These practices are unacceptable. Reconstitution syringe are re used and hence represent a risk for contamination. To avoid this risk of contamination during the reconstitution process UNICEF will start fading out regular disposable reconstitution syringes and replace them with RPF syringes. In the initial stage, UNICEF opt to offer RPF syringes as an option to countries with the objective to only provide RPF re-constitution syringes by end 2010.

In addition to expand the current injection safety policy for immunization purposes, UNICEF is together with WHO working on a joint statement to cover any disposable syringe for which RPF alternative exists regardless of whether purpose of use is for curative or immunization.

Policies facilitate procurement of safety syringes and create awareness of the need for safety devices from a donor point of view. However, it is clear that policies do not suffice alone. There are several elements that imply that there are several areas still needed to be addressed, such as (1) lack of creation of budget lines for safety devices for countries having benefited from the GAVI safe injection support and (2) countries still using sterilizable syringes despite the cessation of the supply of the same by UNICEF.

The demand for AD syringes has increased substantially to over 600 million pieces per year since the implementation of AD syringes with GAVI being the driving force. The supplies meet demand and prices are generally decreasing. The price level is a couple of cents more expensive than regular disposable syringes. This causes implications to country governments in terms of finding a financially sustainable solution. The data from country forecasts for 2007 indicates that as of October 2006, about 20% of GAVI supported countries that have reached the Injection Safety support end, have so far been able to create a budget line for AD syringes and an additional 39% have identified funds.
Although UNICEF ceased supplying sterilizable syringes and sterilization equipment by 2003, there are 7 countries still using sterilizable syringes in routine immunization according to the WHO/UNICEF joint reporting form 2005.

The overall procurement objective of UNICEF is to ensure an uninterrupted supply of affordable quality products – on short as well as long term basis. This is done by establishment of multiple long term arrangements. The procurement process undertaken by UNICEF falls under rules of public procurement with equal treatment and international competitive tender process. The tender process is subject to internal as well as external control mechanisms such as independent review committees and audit. The current arrangements for the supply of AD syringes and Safety boxes expiring 3 quarter of 2007 and hence subject to renewal during course of 2007.

**Plenary:**

- Dentistry is so far not addressed by the initiative. To what extent are safe devices being designed for dentistry?
- The terminology used to describe devices can be misleading.
- Jet injectors can accommodate different tissue thicknesses.
- Tests have not yet been performed to determine the degree of pain associated with injections using plastic needles.
- Occupational health experts should be a part of any device standards meeting.
- ISO standards should be disseminated more widely to better inform people working in health sectors, who are often in a position to advise governments on what equipment to procure.
Day 3, Theme 6:
Health Care Waste Management

Needle Removers in India, Vietnam, and Senegal
Presented by Nancy Muller and Dr. Satish Kaipilyawar, PATH

Needle removers are devices designed to separate the needle from the syringe and isolate the needle in a puncture-proof container. Primary advantages of needle removers are that they prevent syringe reuse, isolate the needle, reduce risk of needle stick injury to waste handlers and the community, reduce volume of syringe waste, simplify waste management and facilitate disposal options, including plastic recycling. Disadvantages of needle removers are the added cost (US$4-55), requirement of needle pit or barrel, added step to injection process, requirement of training and maintenance, and that all syringe sizes may not fit.

Several commercially-available needle removal devices have been recently introduced or evaluated by PATH and Ministries of Health in India, Vietnam, and Senegal. In Andhra Pradesh, India 14,000 BMDi needle removers were introduced as part of a comprehensive, State-wide immunization waste management system. In Vietnam, waste management practices were compared over a six-month period using three different interventions in one district including needle removers and/or safety boxes. In Senegal a low-cost needle remover prototype design was evaluated during a two-week design stage field trial.

Overall findings were that needle removers were well accepted; devices were easy to operate and durable; health workers reported feeling safer and reported the community felt safer; no needle stick injuries were reported by injection providers using the devices; needle removers required regular cleaning and lubrication to work optimally; not all syringes sizes fit; training and supportive supervision resulted in improvements in waste management; needle removers may not add value where good final disposal systems exist; and lack of specifications can result in introduction of low-quality devices. PATH has posted a link on its website to needle remover resource information:
http://www.path.org/projects/health_care_waste_needle_remover_resources.php

The WHO PQS system: standards for safety boxes

Andrew Garnett – WHO Temporary Adviser

PQS (Performance, Quality and safety), is WHO’s replacement for the long-standing Product Information Sheets (PIS). New performance specifications and verification protocols are being prepared to replace the existing PIS specifications and test procedures.

Compared with PIS, the new system is intended to be more transparent: manufacturers are invited to review and comment on draft specifications; many of these comments are being incorporated into the final documents. It is industry-friendly: manufacturers receive clear written guidance on the pre-qualification process. Finally, it is will be more efficient: all pre-qualification documentation will be held on a database; the PQS catalogue will be downloadable
from a PQS website and it will be automatically updated whenever the list of pre-qualified products changes.

Implementation of PQS has unfortunately been delayed. Recent WHO reorganization has re-directed priorities and PQS-specific staff resources have been reduced. The project is designed to be self-funding, but the only current income stream comes from the dossier review fees paid by syringe manufacturers; no development funding is yet available for the PQS database and website.

In the interim, PQS-related material is located on the WHO PQS webpage at: http://www.who.int/immunization_standards/vaccine_quality/pqs/en/index.html

Progress on safety boxes
A draft performance specification and verification protocol has been completed and further amendments are now underway. Circulation of the ‘draft for comment’ to industry and others in will take place in November - December 2006 with final drafts issued in December 2006 – January 2007 and publication scheduled for February 2007.

The main changes from the PIS specifications include: incinerator boxes for un-controlled on-site burning no longer specified; tighter definitions throughout; boxes designed for ISO 7886 – part 1, 3 and 4 syringes and entry port size defined more precisely; bio-hazard markings added; additional materials restrictions, including restrictions on materials which emit pollutants during controlled incineration; pictorial instruction only required on boxes with additional languages on packing inserts.

Discussion in recent SIGN postings suggests there is a problem with the use of under-specified safety boxes. As has been done with syringes, it is suggested that the next step should be an ISO standard for safety boxes.

Plenary:

Regarding the WHO position on needle removers:

Two studies have been done. Results are positive, but another study, planned for 2007 in Bangladesh that is randomized and using a WHO protocol is required. There is no empirical evidence demonstrating that needle removers prevent needlestick injuries.

Points from participants:

- It seems that needle removers are a retrogressive step. They are necessary only in environments that don’t supply safer devices.
- Risks of contamination associated with needle cutters require study.
- Will WHO make resources available to enable PQS [?] to work effectively?
- Perceived safety of needle cutters may be their main advantage. What assurance is there that study results will not be biased? Backsplash is an important issue.
- Needle cutters represent an additional step in the administration of an injection. It is better to position sharps containers properly instead of introducing needle cutters.
- Experience from the field indicates needle-cutters are useful to reduce needlestick injuries in work environments lacking adequate safety boxes.
• Needle-cutters permit recycling of the plastic in syringes.
• Removal of needles condenses waste volume.
• Proper training is needed before operation of a needle-remover to prevent backslash. Current data on contamination of hands of providers is not adequate. Providers report feeling safer when needle removers are in use.
• Needle cutters should be used only for vaccination campaigns. If allowed to enter the curative sector, it will be misused on many other sharps devices.
• Needle removers are controversial technology, and SIGN should not be associated with controversial technology. Taking no position is the best position. It is not a sustainable solution.

WHO response on issue of needle removers:

• WHO cannot promote equipment when it is not sure that it is safe.
• Both occupational and patient safety considerations are required.
• After the Bangladesh study, WHO will be in a position to have a policy on needle removers.

Health and Safety for health care waste workers and update on WHO activities

Yves Chartier
Public Health and Environment
WHO Geneva

What are Hazardous wastes? Hazardous waste refers to any waste that could pose a threat to human health and the environment if managed improperly. Hazardous waste exhibits any of the following characteristics: ignitability, corrosivity, reactivity, infectiosity or toxicity.

In 2002, a WHO assessment in 22 countries showed that the proportion of health-care facilities not using proper waste disposal methods ranges from 18% to 64%. In health-care facilities 12.5% of needle stick injuries occur during garbage disposal by waste workers. Sharps & more specifically needles are considered the most hazardous category of health-care waste. More than 20 blood borne diseases can be transmitted as a result of exposure to blood. Health-care waste workers are at risk!

About "16" billion injections are administrated / year worldwide

Everybody is at risk form health care waste from health-care workers to communities.

Waste management is not the sole responsibility of waste workers. It concerns all and upstream, poor management put waste workers at risk and treatment of waste a real challenge. Links for SAFETY is a necessity and priority to all categories of staff in health-care settings.

The Fifty-Seventh World Health Assembly (May 2004), URGES Member States to develop and implement infection control and prevention strategies, including for the safe and appropriate use of injections and waste management, involving all cadres of health care workers, as well as patients, community representatives, and other stakeholders, in developing these strategies.
Facts: Needle stick injuries are the most common source of occupational exposures to blood. The two most common causes of needle stick injuries are two handed recapping and the unsafe collection and disposal of sharps waste (WHO 2003). Inadequate waste disposal systems extend the problem beyond health workers to cleaners, laundry workers, porters, waste handlers but also outside to rag pickers and the general community including workers. Health care waste workers are not immunized against HBV and poorly if not at all equipped with PPE.

Sound Health Care Waste Management helps in controlling nosocomial diseases; dramatically reduce HIV/AIDS, sepsis and hepatitis transmission from dirty needles and other improperly cleaned/disposed medical items; control zoonoses (rats, insects…); cut cycles of infection, complementing the protective effect of proper hand washing and use of Personal Protective Equipment (PPE); easily and cost-effectively address health care waste workers safety issues, including reducing risk of needle sticks; prevent illegal repackaging and resale of e.g. contaminated needles; avoid long-term health effects; e.g. cancer from environmental release of toxic substances such as dioxin, mercury and others.

Clear guidance, policies, recommendations for safety of health workers and all do exist.

Water, sanitation and hygiene was intentionally not presented at the meeting to keep it focused on waste. But one have to bare in mind that safe water, basic sanitation and hygiene in health-care settings impact on all, staffs, patients and communities and prevent them from catching HAI but also opportunist diseases among immunocompromised patients such as HIV/AIDS patients.

Think positive. Stop presenting waste as an incurable disease. There is still a long way to go but things are slowly changing for better.

Update on WHO activities

GAVI - Objective of the project
By end of 2007 50% countries receiving GAVI support (36 countries) have adopted national policy and developed plans on Health-care waste management. Time frame: 2 years.
AMRO: Bolivia, Honduras, Nicaragua
EMRO: Pakistan, Sudan, Yemen
EURO: Kyrgyzstan, Uzbekistan, Tajikistan, Ukraine
SEARO: Bangladesh, Bhutan, Myanmar, Nepal
WPRO: Cambodia, Lao PDR, Mongolia, Salomon
GAVI Future developments
Mobilize resources for the implementation phase: GAVI, Other stakeholders, Tax based on "polluter pays" principle. Consolidate contacts with operational partners; define priorities for implementation based on resources and develop recommendations.

Global Environmental Facility project - 2006 - 2010
The Global Environmental Facility project (GEF) on Health Care Waste Management is to demonstrate and promote best techniques and practices for reducing health care waste to avoid environmental release of dioxins and mercury. The project involve UNDP as implementing agency, UNOPS as executing agency, WHO and Health Care Without Harm (HCWH) as
principal cooperating agencies. Participating countries are: Argentina, India, Latvia, Lebanon, The Philippines, Senegal and Vietnam (+ Tanzania).

**Promising studies**
Sharps Blaster (melter); Steam steriliser (GEF Tanzania); "WHO position" on needle remover; cost of waste management; added cost on syringes for HCWM.

**WHO Web Site**
Increased number of technical options; soon a section on cost; on process country information; 50 WHO documents available on HCWM. [http://www.healthcarewaste.org](http://www.healthcarewaste.org)

**HCWH/GEF project in Tanzania: steam sterilization of waste**

**Jorge Emmanuel**
**UNDP GEF Global Project Team**

The Tanzania project is part of the larger Global Environmental Facility (GEF) project in eight countries (Argentina, India, Latvia, Philippines, Senegal, Tanzania, Senegal, and Vietnam) to demonstrate and promote best practices and technologies for health-care waste management consistent with the Stockholm Convention on Persistent Organic Pollutants. The 8-country GEF project has involved a broad range of stakeholders on the local, national, and global levels in project planning through national and global steering committees and national working groups. The GEF project models four treatment approaches: on-site treatment, urban centralized treatment, treatment within clusters, and mobile treatment. The alternative technologies identified include large-scale centralized autoclaves, small autoclaves, microwave technologies, advanced steam treatment systems, and alkaline hydrolysis technology for anatomical and cytotoxic wastes.

Among the models for the project is the pilot study at a 340-bed urban hospital by the Swiss Red Cross in Bishkek, Kyrgyzstan. The hospital practiced little segregation and used an on-site incinerator. Infectious waste was inadequately treated by sprinkling with hypochlorite powder then discarded at an open dump. Syringes were soaked in hypochlorite, and needles were removed and bent using pliers. In January 2006, a 54-liter autoclave was installed and 18 mechanical needle cutters were distributed, along with color-coded waste containers. The needles, plastic portions, as well as other infectious waste bags are now treated in the autoclave. The needle pieces are buried in a sharps pit, while the plastic portions are treated and shredded in a mechanical hammer mill to reduce volume by about 30-40%. The plastics are taken to a plastics manufacturer and re-melted to produce clothes hangers, flower pots, yarn spindles, and electrical covers. Improved segregation significantly reduced the quantities of infectious waste from 6000 kg/month to 1200 kg/month. The reduction in hypochlorite use and the revenues from the plastics resulted in a two year return on investment of the autoclave.

The goals of the ongoing Tanzania project are to develop, test, manufacture, and deploy low-cost, small to medium scale waste treatment technologies, such as autoclaves with multiple energy source options, mechanical and electrical shredders, and reusable sharps containers. The work is taking place at the University of Dar es Salaam. The outcomes will include manuals of construction, installation, operation, and training, as well as reports of validation tests, field demonstration, and technology transfer.

A complementary project by Health Care Without Harm (HCWH) is the evaluation and demonstration of small-scale imported autoclave technologies in Tanzania. As a part of that
A model to budget for sharps waste management in resource-scarce settings

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Background: The scale-up of HIV care will generate millions of HIV-contaminated needles, syringes and lancets. Health facilities need a way to estimate the resources needed to manage these sharps wastes. Methods: We created a spreadsheet model to estimate the resources needed to manage sharps waste with different waste systems, including recurring (e.g., labor, fuel) and non-recurring (e.g., incinerator purchase/installation, site preparation) costs annuitized over their lifespan. To test the model, we first entered information available from vendors and field reports to estimate the resources needed to use three types of incinerators (plasma, refractory brick, and commercial) for two waste volume scenarios: a) High: 20 safety boxes/day = 9700kg/year, and b) Low: 1 safety box/day = 485kg/year. To further test the model, we entered actual cost data from a diesel fueled incinerator burning ~10 kilos/hour at Nyanza Provincial Hospital and a De Montfort incinerator that burns ~7 kilos/hour at Bondo District Hospital in Kenya. Costs available included the disposal, collection, storage, transport (by wheelbarrow), and destruction. Results: The results of a model using data from vendors and field reports were presented. Estimated costs to destroy one syringe at Nyanza ($0.03) and Bondo ($0.11) hospital incinerators were generally in the same range. One-time start-up costs, including incinerator purchase, installation and facility preparation were annuitized over their lifespan. For high-volume
operation, these represent 35% of plasma incinerator costs, 25% of costs of brick incinerator, and <1% of costs for contractor services. Labor costs were respectively, 30% (Plasma), 31% (Brick); and <1% (Contractor); transport costs were 5% (Plasma), and 7% (Brick); and 0% (Contractor). Supply costs, including safety boxes, were respectively, 29% (Plasma), 31% (Brick) and 11% (Contractor), of the total costs. The contracts for off-site disposal presented no costs for the plasma and brick incinerators but 88% of the costs of contracted destruction. **Discussion:** Our model suggests that the costs of safe disposal and destruction of a syringe may equal or exceed the purchase price (2 to 9 cents), providing an additional reason to reduce unnecessary injections. The sharps disposal container and fuel to start up the incinerator were key portions of the supply costs. This suggests that costs could be reduced by waiting until boxes were ¾ full. Facilities which use a high portion of 5 and 10 cc syringes could decrease their costs by using the smallest appropriate syringe barrel. Fuel and staff labor could be reduced by running the incinerator for longer hours, but fewer days. Reducing the number of incineration days requires storage space and a leak proof safety boxes that can withstand storage in damp conditions for up to a month. Sites with a low volume of sharps waste may minimize costs by transferring waste to central facility. Central facilities were more cost effective than smaller scale facilities, even if they had larger start up costs. We plan to develop the spreadsheet model and the protocol for collecting appropriate data into more user-friendly tools to help managers budget for safe waste management. Such planning can help HIV programs avoid a common problem of HIV-contaminated sharps dumped in community living areas.

**Plenary:**

- Safety boxes should be not more than ¾ full.
- More data on economies of scale for different waste management strategies is required.
- Alternative technologies for HCWM require development.
- Stockholm convention should be examined and paid more attention.
- Better data on injuries that occur during vaccination campaigns, especially healthcare worker injuries is needed. Also, data on cost analyses regarding different waste management strategies during immunization campaigns is needed.
- When will blood services waste management guidelines be available? Answer: 2007
Conclusions and Recommendations of the meeting

1. General recommendations:

1. SIGN should continue to focus on the rational use of injections.

2. Since it is a public health initiative with limited resources, SIGN should prioritize its activities by factors such as magnitude of risk reduction, cost effectiveness, sustainability and interest to potential donors.

3. Since the risk of transmission of blood borne pathogens have been demonstrated to be proportional to the volume of residual blood in medical devices at the time of sharps injury, SIGN should include medical procedures such as phlebotomy and intra venous procedures in the above prioritized process.

4. The experience of a national Injection Safety day in India was useful for raising awareness about the importance of injection safety. SIGN acknowledges the value of holding National Injection Safety Days and recommends that countries consider their implementation to raise awareness about the importance of injection safety.

5. SIGN will continue advocacy among countries on the strategic importance of a national injection safety policy to build political will, engage key partners and identify resources necessary to implement successful strategies that will substantially impact the safety of injections in health care systems.

6. SIGN recommends that countries develop and implement communication/advocacy strategies that specify objectives, target audiences, appropriate messages and appropriate channels to reach those target audiences.

7. SIGN recognizes that collaborative in-country partnerships are essential to improving injection safety and for sustainability. Strategies used to improve the safety of injections should be implemented with the consent, commitment, involvement and participation of many agents including governments, health system administrators, health care workers and partners outside of health systems who represent the community.

8. Injection safety including health care waste management is a cross cutting area of work among several health programmes in the ministries of health ministries of environment and ministries of local development at country level and among WHO departments. SIGN should identify a mechanism to engage all these programmes and departments in the injection safety initiative.

9. SIGN meetings: Future SIGN meetings should:
   * Contain fewer presentations. This could be achieved by
     - having country updates as poster sessions and using session time for in-depth, small group technical discussions.
     - have the sessions structured to focus on key interventions rather than providing project overviews.
   * Consider offering concurrent sessions.
   * Build-in time in the schedule to develop, discuss, and reach consensus on SIGN meeting recommendations.
* Identify ways to increase the participation and attendance from countries where SIGN strategies are being implemented, including developing countries.

10. SIGN should develop ways of encouraging greater participation of fieldworkers within SIGN meetings

11. SIGN should improve strategies to work with WHO regional offices, country offices and organizations at this level, in order to achieve greater impact with SIGN recommendations at the field level

12. SIGN should advise WHO that specifications and a position statement on needle removers are urgently needed when field trial data becomes available.

13. In order to reduce the cost of injection safety assessments, SIGN/WHO should consider recommending that SIGN/WHO should encourage collaboration among agencies when conducting injection safety assessments to maximize use of resources and eliminate any duplication of efforts. Students in health programmes are a logical source of fieldworkers for these assessments, however these workers must be trained and supervised by well qualified people

14. SIGN is beginning to hit the limits of its effectiveness working through traditional public health stakeholders. As the clinical domain in most countries have a different set of stakeholders (that only partially intersects with that of public health), it’ll be important in each country to find ways for SIGN to extend to the clinical domain. The India model of using the International Clinical Epidemiology Network (INCLEN) is a promising one that is worth exploring in other countries.

2. Integrated infection control strategies:

1. SIGN should assess the burden of disease associated with the unsafe use of sharps in dental procedures in order to determine the priority that dentistry should have as a future focus of SIGN. Consider including dentistry in injection safety assessments

2. Patient Safety with its current programme "Clean Care is Safer Care" targeting health care associated infections provides a good WHO umbrella for SIGN to promote injection safety.

3. SIGN should incorporate work done by Patient Safety within its existing training material and promote core messages on hand hygiene developed by the Patient Safety Team.

3. Health care workers safety:

1. SIGN should advise IASIT and other bodies involved in standard-setting that occupational health and safety experts should be a part of any device standards meeting having an aim related to injection safety or other invasive health care procedures.

2. Given that the wide availability and proximal accessibility of sharps containers to end users combined with training is the most cost effective determinant of the rate of needle stick injuries within health services work sites, SIGN should prioritize this strategy which is already in the SIGN Best Practice Tool Kit and Standard Precautions for Injection safety

3. Given that there often are high needlestick injury rates in inexperienced providers, SIGN should recommend that students in health care provider programs should be immunized against
Hepatitis B and trained in injection safety. Countries should develop policies, implement worker vaccination policies and monitor coverage in these populations.

4. waste handlers should be immunized against HBV and provided with adequate Post Exposure Prophylaxis (PEP)

5. Health care providers should be sensitized on the importance of waste segregation to prevent waste handlers from high risk of exposure from needle stick injuries and blood borne pathogens

4. **Injection safety**

1. Instead of trying to demonstrate the burden of disease attributable to unsafe injections SIGN should actively promote safe injections as a quality indicator for health services

2. SIGN recommends that a task of the injection safety technical working groups should include reviewing specifications and planning issues related to the supply of injectable medications and injectable equipment and means for sound waste management

3. The effects of clinical work space structure and function are areas affecting injection safety that have not yet been adequately addressed by SIGN. SIGN should advice countries and partners having expertise and responsibility for safe provision of health services to ensure that injection safety considerations are incorporated into the structural design and logistics management of health care service sites planning, design and logistics management of health care facilities

4. SIGN should develop resource materials for providers that focus on identifying the correct site for injections and also using the proper technique

5. SIGN should continue to advocate for the inclusion of injection safety including waste management into the training curricula of students in health programmes. This would have a 2-fold effect: assure that new healthcare workers are provided the basic injection safety messages as a part of their training and also ensure the sustainability of these messages. SIGN should also advocate regular on the job refresher training for all clinical staff as a way to prevent them getting into bad habits.

5. **Rational use of injections**:

1. SIGN should facilitate the dissemination of existing cost-effectiveness studies that look specifically at rational prescribing of Injections. This would enable countries without the financial resources for their own study to benefit from lessons learned from studies in similar country settings

2. Since unnecessary injections related to over-prescription and inappropriate prescription within health services remains a problem area in many countries, SIGN will examine strategies to identify practices that can be modified to result in more rational use of medicines and decrease unnecessary injections. SIGN will encourage exploration of various strategies, including MTP (Monitoring-Training-Planning) and BCC strategies.

3. Reviewing the list of Essential Medicines at country level is an important way of reducing the number of injections and making injections more appropriate.
4. The MTP (Monitoring-Training-Planning) strategy is a cost and time-efficient strategy to identify opportunities to implement more rational use of medicines that can decrease unnecessary use of injections.

6. **Quality and access to safe injection devices:**

1. A working group to make technical recommendations on adoption of new safe injection devices and to work on tendering specifications should be formed. UNICEF will procure only reuse prevention syringes for reconstitution of vaccines by 2010.

2. Strategies to identify a country’s balance point between the affordability and safety benefits of safe injection devices should be developed. Matching different safety syringes to their most appropriate setting will help control costs and maximize safety benefits.

3. SIGN should advise IASIT and other bodies involved in standard-setting that wider dissemination of ISO standards for devices as well as information about their availability, price and safety features will better enable health care providers and others working in health systems to advise their governments and procurement agencies on what equipment to procure for injections, phlebotomies and other common intravenous procedures.

4. Since industry is a critical contributor in ensuring the availability of affordable devices, SIGN should study the market in terms of cost trend analysis, life cycle of current products, and their willingness and ability to support global needs in the future and disseminate this information to countries and procuring bodies.

5. SIGN/WHO should consider ways to increase the speed of the WHO Quality/Standards and pre-qualification processes.

6. Medical device cost analyses should include the cost of purchasing a new piece of equipment, as well as either the cost of disposal for single-use equipment or the cost of reprocessing for multiple-use equipment. This is a way to incorporate funding of injection safety into the process of procuring equipment.

8. SIGN to actively support the promotion, the availability and affordability of Jet injectors of the type shown for mass campaigns.

7. **Waste management:**

1. SIGN in line with global initiatives such as GAVI should advocate for waste management and ensure that waste management remains high on the agenda.

2. There are diverse needs both within and among countries with regards to medical waste disposal methods including waste handling, air pollution, land fill capacity and location of people in relation to waste processing and disposal. SIGN with relevant partners will develop a range of policy and financing/leveraging options for health care waste handling and disposal.
3. What is important and in the pipe is the development of a concept paper to ensure that resources will be systematically made available in all health care activities for the management of waste. This concept should be approved by the time of the next SIGN