Safe Injection Global Network

Report of the Global Injection Safety and Infection Control Meeting

13-15 October 2008
Moscow, Russian Federation
Injection safety is a must in the HIV era

The annual Meeting of the Safe Injection Global network was held in Moscow, Russian Federation 13-15 October 2008.

More than 100 experts from SIGN member organizations worked to reach consensus in plenary and in three thematic groups and two satellite sessions:

- From evidence to action: review of strategies to improve implementation of injection safety and related infection control programmes at country level
- Injection Safety contribution to Achieving MDGs
- Advocacy and communication activities on injection safety and related infection control including fund raising
- Health care waste management
- Occupational health - needle stick injury surveillance systems and the use of data for prevention

The consensus produced 43 recommendations to WHO, to countries, to SIGN network members, to the medical device industry, and to the SIGN Secretariat to guide efforts towards increased injection safety through to 2010.

Safe Injection Global Network Annual Meeting

Day 1: Monday, 13 October 2008  Plenary

Welcome and Introductory Notes

Dr Steffen Groth, Director, Essential Health Technologies (EHT), WHO/HQ

Mister Chair, Dr Onischenko, Chief State Sanitary Doctor, distinguished ladies and gentlemen, colleagues.

It is a great pleasure for me to welcome you to the Annual Meeting on Injection Safety and Infection Prevention and Control in Moscow, Russian Federation 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 the Russian Federation for hosting us. WHO also expresses its appreciation to the Open Health Institute, Moscow, 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:
Firstly because the Annual SIGN meeting 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.

Secondly, but very importantly, we must acknowledge the significance of having our global meeting held in the WHO Europe region and specifically in the Russian Federation, 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.

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 (CDC) 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.

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. Furthermore, unsafe injection practices are not any more an issue in developing countries only.

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. 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 and are an issue even in developed countries. There is an urgent need to use injections safely and appropriately to prevent nosocomial and HIV infections worldwide.

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.

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.

Session 1: Updates on Injection safety and Infection Control activities

Chair: Steffen Groth Rapporteur: Allan Bass

The meaning of syringes: history, culture and use practices

Associate Professor John L Fitzgerald, School of Population Health, University of Melbourne, Victoria, Australia

Syringes inspire hope, fear, pleasure, pain and confidence. Like any technology, what we do with syringes and how we use them give them meaning. Since their inception, syringes have represented different things to different segments of the community. For some, syringes are the source of healing and remedy. For others, they represent the risk of infectious disease and the existence of illicit drug use. The syringe in this sense carries great weight as a symbol. In the face of often negative symbolism we often forget the multiple cultural dimensions to syringes. Syringes are a part of life, health and culture.

In this paper I will review the changing fortunes of syringes over time. The syringe has undergone significant technical developments from designs by Pravaz and Wood in the 1800s to the nanosyringes in development this century. In some parts of the globe, the cultural meaning of syringes has changed from being an essential drug delivery technology to a symbol of illicit behaviour. I will draw on two digital stories to illustrate global variation in the meaning of syringe use. The paper concludes with a discussion of how understanding the meaning of syringes may help inform social marketing and health promotion campaigns to facilitate safe injecting practices.
Update on WHO/HQ Injection safety & SIGN Injection safety and Integrated Infection Control Strategies in Health Care Settings

Dr Selma Khamassi, MD, MSc, Injection safety and Related Infection Control, SIGN Secretariat

There is more recognition than ever before that injection safety represents a very cost effective intervention in preventing the transmission of blood borne pathogens, mainly Hepatitis B, hepatitis C and HIV to patients through reuse of injection equipment and mishandling of multi dose vials, to health care workers through needle stick injuries and to the community at large through improper sharps waste management.

The WHO injection safety programme and the Safe Injection Global Network were launched in 1999 following major studies that documented the magnitude of unsafe injection practices worldwide and the burden of diseases transmitted by them.

The presentation reviewed major achievements in terms of tools and guidelines developed by WHO to assist Member States assess injection practices, identify safety breaches, and to plan and implement national injection safety programmes and strategies.

The second part of the presentation reviewed the latest developments in terms of injection safety activities, innovation in safe injection technologies as well as new funding opportunities for injection safety through GAVI for immunization injections and the Global Fund for therapeutic injections and health care waste management.

The last part of the presentation discussed future collaborative activities between SIGN and WHO Regional Offices based on country needs and programme needs.

Ensuring injection safety in the Russian Federation

Albina Melnikova, Russian Federation Federal Service for Surveillance on Consumer Rights Protection and Wellbeing) and Irina Mikheeva, Central Research Institute of Epidemiology of Rospotrebnadzor

The administration of injections is subject to legislation and regulation. At least 20 federal laws have some provisions on injection safety and more than 120 regulations set rules for administering injections.

In 2005 an assessment of the medical waste management system in 65,415 HFs in 52 territories identified that chemical disinfection with prior disassembling and washing of the needles and syringes was used in 98% of facilities, safety boxes were in use in only 5.7% of facilities and 61.2% of facilities used plastic bottles for collection of syringes, only 1.4% of HFs used needle cutters, more than 40% of HFs used centralized disposal of syringes and needles including 14% of HFs that sent used syringes for recycling, while in
19.2% of facilities syringes and needles were disposed of by open burning and in 37% of facilities sharps were disposed of in regular garbage. In 2006 a pilot project on the use of AD syringes at two children's polyclinics and 51 educational institutions with a total average of 2,310 injections per month showed that 70.4% of health care workers noted the advantages of AD syringes and 100% identified the safety and convenience of disposal into safety boxes. In the 2007 assessment of injection safety, 1,683 health care workers in two regions of Russia were interviewed; 47.5% had history of trauma at the workplace while 46.2% of traumas were registered, 37.1% of traumas were due to the used needles with 7.3% after the prohibition of recapping. Of 389 health workers that had trauma during the last year, 18% had more than 5 traumas and 2.8% had more than 10 traumas.

Management decisions were made on the basis of these data to change current instructions and to introduce new guidelines and rules that prohibit manipulations of non-decontaminated syringes; recommend physical decontamination (autoclaving, microwaving and high temperature incineration) for AD syringes; regulate collection of used syringes and needles into the safety boxes with transportation and final disposal by high temperature incineration; set requirements for the training of health workers; strictly regulate the measures in case of emergency.

Challenges related to the financing of disposal and decontamination of medical waste should be overcome to enable implementation: consumables costs included into the budgets of health facilities; funding for transportation of wastes; provision of capital equipment; technologies for materials reclamation.

Overcoming noncompliance of medical workers safety techniques requires the recognition of the emergency situation and the use of up-to-date methods of injection safety.

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**Session 2 Integrating Injection safety into Health Systems**

Chair: Steffen Groth   Rapporteur: Allan Bass

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**Innovative Financing Approaches to Outsourced Services in the Health Sector**

Terrence Hart, CEO, IT Power India Pvt. Ltd

The WHO/Path initiated Project Optimize seeks to apply “state-of-the-art and innovative systems and practices for the management, distribution, and use of vaccines and health products; and to optimize the characteristics of high-priority products for use in low and middle income countries.” Under this Project, IT Power India recently compiled and analysed information on innovative financing approaches to outsourced services in the health sector.

A review of the models and experiences revealed that considerable diverse instances of outsourced health service provision exist, some successful, others less so. However, little use of innovative financing mechanisms to fund outsourcing is evident. A number of
impediments, including shortcomings in Government procedures; limited involvement of private financiers; un-developed regulatory frameworks; apprehensions of bankers and insurers; etc. all contribute to inhibiting the introduction of innovative financial instruments for health service provision.

Three financial structures are proposed to stimulate the adoption of outsourced services: (1) Leasing, (2) Revolving or subsidized funds, and (3) Fee for service, and the operating modalities explained. Regardless of the financial structures, certain accompanying measures are required, which include assured quality services, prompt payments, guarantees against financial default and risk mitigation to all parties through insurers. Well-structured financial instruments, with good commercial returns and high service quality are mandatory. Any outsourced service should provide these assurances along with securities and a full commitment by all parties. The way forward to ensure growth and success with outsourced services is to adopt a fee-for-service approach, where services are paid for based upon performance. To encourage adoption of this approach requires: (1) development of business plans and financial modeling for business ventures; (2) an assessment of value addition from a dedicated fund; and (3) dialogue with networks of consumer durable networks and financial service networks to benefit from the experiences of success in other business sectors. Project Optimize would be an excellent vehicle to trigger this process.

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**Evaluating the contribution of injection safety towards achieving the Millennium Development Goal(s)**

George Schmid, HIV Department, WHO

The eight Millennium Development Goals (MDGs) were adopted by the 189 countries at the Millennium Summit, 2000, signed by 147, and are goals intended to be met by 2015 that address the world's greatest development challenges. Most pertinent to injection safety is Goal 6: Combat HIV/AIDS, malaria and other infectious diseases, and its attendant target 6A, to halt and begin to reverse the spread of HIV/AIDS. Goals #4 and #6, to reduce child mortality and improve maternal health, respectively, are also pertinent. HIV, blood-borne hepatitis viruses, and other infectious agents transmitted through blood contribute to the unhealthy conditions targeted by each goal.

In 2004, Hauri and colleagues (Hauri AM, Armstrong GL, Hutin YJF. Int J STD AIDS 2004;15:7-16) estimated that unsafe injections caused 260,000 cases of HIV (5.4% of global incidence), 21 million cases of hepatitis B (31.9% of global incidence), and 2 million cases of hepatitis C (39.9% of global incidence) annually. Modeling and its attendant assumptions that produce such estimates are always subject to contention and even disagreement. For instance, whether it is reasonable to assume that all injections that by definition are unsafe are equally capable of transmitting these agents, as the models assume, is contestable. Unsafe injections that have been washed, or heated to temperatures that may destroy virus, may arguably be assumed to be less likely to transmit virus than injections that have not been subject to such efforts. Similarly, using the efficiency of transmission of virus determined when the source of contamination of the source-needle was intravascular may not apply to needles that were used intramuscularly,
which are far less likely to contain blood. It can be argued that the assumptions used in modeling have overestimated the numbers of cases of HIV, hepatitis B, and hepatitis C caused by unsafe injections.

Accurate estimations of the magnitude of HIV, hepatitis B virus, and hepatitis C virus transmission globally due to unsafe injections are important to understand the epidemiology of these infections, to understand their relative importance and magnitude in contributing to the disease states targeted by the MDGs, and towards measuring progress towards achieving the MDGs as programs to end unsafe injections become increasingly successful. Whatever their proportion and magnitude are, the elimination of unsafe injections is morally correct and vital. Health care systems should not harm, and the elimination of unsafe injections is mandatory to help achieve this goal.

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**Integrating Injection safety into Health Systems for sustainability in 11 countries**

Ousmane Dia, JSI, Making Medical Injections Safer Project

The achievements, challenges and lessons learned in integrating injection safety into health systems in 11 countries were presented. The 11 countries are those where HIV/AIDS prevalence is high, and where there is a USAID-funded Making Medical Injections Safer (MMIS) project (ten in Africa and one in Haiti).

According to WHO, sharps injury contribute to 2.5% of annual infections among healthcare workers. MMIS adapted and refined WHO/SIGN approaches to address the IS needs in the provision of curative care. The key objectives were to 1) eliminate reuse, 2) reduce needle stick injuries, 3) rational use of injections and 4) proper sharp waste management.

The key technical approach is to work across the health sector (e.g. preventive and curative services, lab services and reproductive health) in order to: 1) focus on country ownership and ensure that policies are driven by local authorities, 2) strengthen training and capacity building, 3) ensure injection device availability, 4) behavior change and better communication, 5) improve sharps waste management, and 6) strengthen monitoring and evaluation.

MMIS provided commodity support, which served as a leveraging factor in working with MOH structures on budgeting, planning and effective distribution of devices. MMIS also developed pooled procurement to bring economy of scale to the 11 countries. MMIS worked with countries on financing, including cost models and mobilizing resources from other sources. MMIS also addressed the quality of care, through the introduction of safety syringes, the safe administration of necessary injections, the reduction of unnecessary injections and through health worker safety.

The challenges to effective integration were numerous: Competition among health programs for limited resources, turnover among MOH and partner staff, long policy development and implementation processes, securing budget allocations for a continuous
supply of safe injection and waste management commodities, and building partnerships and addressing private and informal sectors.

Sustaining achievements will be accomplished by developing national policies for continuous, country-driven injection safety initiatives; through capacity building by strengthening areas such as the central medical stores, updating pre- and in-service curricula, and by establishing a pool of trainers to continue the IS training on an ongoing basis. HCWM will also need to be more sufficiently addressed with the involvement of more donors, as well as to raise the awareness of health workers and communities about the importance of injection safety and HCWM.

Day 2: Tuesday 14 October 2008

Session 4: Updates on novel injection safety technologies and future perspectives

Chair: Alexey Bobrik   Rapporteur: Allan Bass

User based design in healthcare: a case study in sharps prevention devices

June Fisher, Training for Development of Innovative Control Technologies (TDICT) Project

The Training for Development of Innovative Control Technology (TDICT) project was formed in 1990 to promote the development and use of engineering controls to prevent occupational exposure to blood. It has been funded primarily by US NIOSH. It is a unique program that from the beginning brought together frontline healthcare workers (HCWs), industrial hygienists (IHs) and product design engineers (PDEs). The project is based at the Trauma Foundation, San Francisco General Hospital and the original frontline healthcare worker participants were primarily from there. When the program started there were no safety sharps devices on the market. Initial efforts were directed towards articulating user based criteria for effective devices.

Collaborative methods to develop these criteria included: Review of data on needlestick injuries; HCWs appraisal of devices currently in use and their recommendations to decrease risk (focus groups, interviews); Observational studies on how devices are used; Failure analysis of devices; Simulation studies of devices with safety features; Joint brainstorming sessions with HCWs, product designers, industrial hygienists; Multi-center HCW testing, in simulated settings, of safety evaluation forms; Design course for HCWs.

The criteria developed for several categories of sharps devices as well as for protective equipment have been included in the revised OSHA Bloodborne Pathogen Standard and have been included in the British, Scottish and European Union directives in regard to engineering devices to prevent occupational sharps injuries and have been included in the manuals that the American Nurses Association and WHO/ICN have developed for training nurses in the evaluation and selection of appropriate devices both in the US and worldwide. They have also become the de facto benchmarks for the device
manufacturers. Thus promoting used based design in the later generations of sharps devices.

The TDICT program has emphasized systematic frontline healthcare worker evaluation of devices which includes use of the above criteria but also methods for clinical based task analysis as well strategies for simulation efforts to assess new technologies prior to selection and pilot testing. These methods are being used widely not only in the US but worldwide.

The presentation discusses the collaborative process for development of user based design as well as systematic methods for frontline user evaluation and selection of medical devices to prevent occupational exposure to blood. The utility of such collaborations for developing countries were presented as well as a recommendation that regional programs be developed in such areas.

Eucomed - Private Sector Opportunities for Collaboration in Support of Health Technology and Injection Safety

William Dierick, EUCOMED Europe

Eucomed has worked along with WHO-SIGN on topics related to injection safety and within a broader context of health systems. The WHO collaboration with the private sector has resulted in a number of achievements and milestones, addressing ToR’s, Quality Systems and the creation of new ISO international standards for injection devices. Future collaboration opportunities can support WHO in implementing World Health Assembly resolutions (WHA60.29) and the Global Initiative on Health Technologies (GIHT).

Health Care Waste in GAVI Euro Counties

Ute Pieper, ETLog Health GmbH, Germany

WHO EURO provided financial support to Eastern Europe countries for technical support to establish national level health care waste management policy and management plans. Target countries are Azerbaijan, Kyrgyzstan, Ukraine, Uzbekistan, Tajikistan and additional non GAVI countries like Turkmenistan and the Russian Federation.

Every supported country has its own special constraints and requirements to establish a national health care waste management plan. Kyrgyzstan, for example, has already established a national working group and developed with support of the WHO consultant a national strategy. Currently financing tools and possibilities were evaluated in order to cover the investment costs of the system. A pilot project is envisaged for testing and assessing the best solution.

To ensure successful development and implementation it is a fundamental need that the different ministries work together in a steering committee in order to supervise the
activities of the official national working group. This intersectoral approach is needed because of the overlapping working areas in the health care waste management sector, like handling of health care waste within the health care establishment, emission from incinerators, transport on public streets, financing, etc. The collaboration between Ministry of Health, Ministry of Environment and Ministry of Finance is an important indicator for a successful system.

It is important to address many areas from political and legal directions to standard operation procedures at implementation level. Financing, including the yearly budget needed for maintenance and repair, and new investments should be taken into consideration as well as the need of improvement of the health and environment situation of the people living in the countries.

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**Safe Injection Technologies: An Update on Current PATH Activities**

Darin Zehrung, PATH

PATH continues, through the USAID-funded HealthTech program and other funding sources, to explore technologies for increasing the safety of immunization delivery. PATH is currently evaluating a number of prototype and/or commercially available technologies.

Jet injectors are a needle-free technology, designed to safely deliver intradermal, subcutaneous, and intramuscular injections. Intended for use in developing-country clinics or large immunization campaigns, these jet injectors are hand wound or spring powered, generating a high-pressure stream so that the vaccine penetrates the skin. PATH has worked with several jet injector companies over the years to advance “second-generation” jet injectors and improve ease of use of existing products. An assessment and pilot introduction study of this technology class is scheduled in Brazil for 2008–2011. Ultimately, WHO prequalification of the technology is a key goal for this work.

To decrease the risk of disease transmission through unsafe injection practices such as syringe reuse and needlestick injuries, PATH has been exploring a number of technologies aimed at reducing the use of sharps. The plastic spike syringe is one of such technologies, designed for use as a reconstitution device and potentially to be compatible with IV fittings. This device is currently in the design phase—initial clinical trials are scheduled in India for early 2009.

PATH is working on the introduction of injection devices—such as retractable syringes—that will protect health workers from needlestick injuries and simplify sharps waste management. Evaluations completed to date show high acceptability of these devices, but cost continues to be prohibitive for developing-world markets. Manually retractable syringes may be one option—they are lower cost, and there are multiple designs available on the market. Since the user has to initiate the retraction of the needle, concerns exist about risks associated with noncompliant use. PATH is currently conducting bench testing to evaluate some of these technologies and identify areas for design improvement. Pending outcomes of the bench testing, field evaluations may be planned.
Concerns for the well-being of health workers, communities, and the environment grow, non-incineration options for final disposal of medical waste have become increasingly important. Current options for non-incineration include the use of autoclaves, shredders, hydroclaves, microwaves, chemical disinfection, segregation, and protected pits. While facing the challenges of cost, power requirements, maintenance, level of training, and resupply, PATH is focusing on identifying and developing lower-cost, robust technologies appropriate in lower-level infrastructure settings.

PQS prequalification status of autodisable (E08) and reuse prevention syringes (E13)

Umit Kartoglu, WHO Immunization, Vaccines and Biologicals (IVB)

Performance, Quality and Safety (PQS) project has been active for injection devices since 30 June 2005. In 2007 and 2008 there were two annual reviews and today PQS has a list of 19 AD syringes for immunization (E08 category) and 25 with reuse prevention feature devices (E13 category). Safety boxes under the E10 category has been active since 31 May 2008 and has 3 products prequalified. Performance specifications and a verification protocol for needle remover devices under the E10 category is under development and is expected to be announced towards the end of the year.

One issue that was brought to PQS secretariat attention by UNICEF is the auto disable mechanism in AD syringes. Auto disable feature is defined as follows in the ISO 7886-3:

**Auto-disable feature:** The syringe and needle shall be passively and automatically rendered unusable by the delivery of the intended fixed dose. No secondary or additional action on the part of the user shall be required. The timing of the activation of the auto-disable feature may vary by design, typically within the ranges described below:

- the auto-disable feature is automatically activated and remains effective from the time that the injection is commenced;
- the auto-disable feature is automatically activated and remains effective from the point when 50% of the intended fixed dose has been delivered;
- the auto-disable feature is automatically activated on completion of the delivery of the intended fixed dose.

In all cases, once the auto-disable feature has been activated it shall not be possible to re-use the syringe and the needle under the normal conditions of use.

UNICEF preference was indicated to PQS secretariat as the first option that the mechanism is automatically activated from the time that the injection is commenced. PQS secretariat suggested several approaches to move towards having this preferred option as prequalification and underlined the importance of involving all key players, including the industry, to agree upon a phasing out plan for all other options. PQS secretariat suggested organizing a consultation with all involved parties in 2009 to this effect.
Overview of Injection Safety in Immunization Services In WHO Europe

Denis Maire, Immunization Quality and Safety, WHO EURO

In the context of its Immunization Quality and Safety programme (IQS), the European office of the WHO aimed at optimizing the safety of immunizations in bringing support to countries for better identification and response to the risks attributable to injections for vaccinations.

This support included the provision of guidance in developing policies and plan of actions, advocacy and communication activities for the introduction and sustained use of auto-disable syringes and safety boxes. Assessments using the tool C of the SIGN toolbox were used to document the risks to patient, injection providers and the community. Support was also offered for training activities aiming at increasing injection providers' awareness and knowledge on "good injection practices". This work could be achieved through mainly three opportunities, the global WHO Injection Safety Priority Project, the GAVI windows on injection safety, and the measles elimination initiative.

The regional situation on the safety of injections for immunization can be drawn from two sets of data, the WHO/UNICEF "Joint reporting form" and the results of countries' assessments completed these past years. The first set highlights the lack of policies on injection safety in 60% of upper middle income countries as well as the still low uptake in the use of AD syringes especially in upper and high income countries. While incineration is the first waste treatment method, it is clear that open burning is the method used in low income countries.

Results of the 25 assessments completed between 2003 and 2008 show a risk to patient that is low to moderate, but highlight some practices, although uncommon, that should have been corrected since long such as the use of hard alcohol to disinfect the skin and injections at improper sites. The risks to providers remain not negligible because of the several sharps manipulations for their disinfection before disposal. The use of needle cutters has proved to be promising in avoiding manipulations in Ukraine. The risks to the community at large are found to be moderate to significant. Open burning in non-supervised areas as well as the dumping in communal bins is still practiced.

Much progress is noted when comparing the results from the first and second assessments after several years of interval in 4 GAVI eligible countries. It demonstrates that partners' support in the field of injection safety has increased awareness and allowed
the development of appropriate policies. Countries are still in a transitional period after the end of this support provided by the vaccine fund. It seems, however, that the use of AD syringes and safety boxes will be sustained. Concerns linger in middle income countries, which have not been as sensitized as those countries with low income.

Strengthening injection safety through HIV control programmes: example from Russia

Alexey Bobrik, Open Health Institute, Moscow

Being an implementer of several substantial international and national health programs, Open Health Institute (OHI) is responsible for the support of about 100 regional projects on harm reduction, antiretroviral therapy and other aspects of AIDS control in Russia. We gradually understood that these projects often miss a very important thing – the health and safety of the people who work in our projects. Several OHI field studies demonstrated a widespread non-compliance of the project staff with universal precautions, unsafe collection and disposal of sharps waste, inefficient injury surveillance system, unexpectedly high rate of occupational traumas, lack of awareness of hazard, and generally weak corporate culture of safety.

Based on this data, in 2007 OHI launched a program on occupational safety that included awareness raising activities, trainings on safe practices, and provision of all OHI supported HIV prevention and treatment projects with the supplies necessary for safe working environment. A separate activity was development and introduction of special software called RUSONET that helps answer key epidemiological questions on needlestick injury: who, when, how, and why.

Additional outcomes such as the deep gratitude of health workers who felt that somebody at last paid attention to their own needs and closer collaboration between AIDS centers and general health services. As an innovative intervention the OHI program also attracted a lot of attention from the medical professional community in Russia and resulted in the rapidly growing interest in the issues of occupational and patient safety.

Healthcare workers are a crucial element for the success of AIDS projects, but often they are a forgotten group themselves and their health is neglected. Given that injection safety can be radically improved by simple and inexpensive measures, it should be considered as indispensable component of current ambitious AIDS projects in the world.

Surveillance of Healthcare Workers’ Blood Exposures: Foundation for Prevention

Janine Jagger, International Healthcare Worker Safety Center, University of Virginia USA

Needlesticks became an issue of serious concern in 1984 when the first case of needlestick- transmitted AIDS was reported in the Lancet. Historically, needlesticks were attributed to the carelessness of healthcare workers. In 1986, at the University of Virginia,
we pursued a different perspective. We identified devices causing sharps injuries and the mechanisms of injuries. We analyzed the extensive device/mechanism matrix and reduced it to a coherent classification system that has become widely adopted. In 1988 we published the first study showing that devices requiring disassembly after use have higher injury risk, illustrating that injury risk is inherent to the devices.

We classified devices by product categories that manufacturers could recognize. Conventional devices were distinguished from devices safety features such as shielding, retracting or blunting mechanisms. We also identified the procedures that devices were used for which is essential for assessing the risk level of injuries; injuries from devices having venous or arterial access hold the highest risk. Also, unnecessary needles (such as those used for accessing IV equipment) were identified and targeted for elimination.

The interrelated parameters of device/mechanism/procedure are used in an algorithm to calculate the “preventable fraction;” including injuries caused by unnecessary needles or injuries occurring “after use” when a protective feature could have prevented contact with the needle. Using the algorithm, 87% of injuries from hollow-bore needles were identified as preventable in 1988, before the availability of safety-engineered needles.

When devices are further categorized as conventional or safety-engineered the efficacy of safety devices can be evaluated. Device evaluations of safety-engineered needles have shown injury reductions in the range predicted by the “preventable fraction” algorithm.

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**Surveillance of occupational sharps injuries in operating rooms of 87 US hospitals: patterns and prevention**

Ahmed Gomaa, Division of Surveillance Hazard Evaluation and Health Studies US Centers for Disease Control and Prevention, The National Institute for Occupational Safety and Health

Operating Room (OR) is known for the high frequency for occupational sharps injuries. It is important to investigate specific sharps injuries surveillance database to implement practical preventive tools to OR setting.

We performed analysis of an Exposure Prevention Information Network (EPINet) database which tracked percutaneous injuries among OR workers in a total of 87 hospitals from 1993 to 2004.

From January 1 1993 to December 2004 there were 7,272 sharp injury cases reported from the surgical setting in participating hospitals. More than half of these injuries were classified as moderate or severe. Surgeons (29%), nurses (28%), and surgical technicians (28%) account for 85% of total injuries. More than 70% of injuries were caused by three devices. Suture needles were at the top the list, accounting for more than 42%, followed by scalpel blades (17%), and syringes (13%). More than 75% of injuries occurred during use and during passing sharps. More than 90% of injuries caused by needles have no “safety design”. A 32.5% drop in injury rates was observed in non-surgical settings, but was unchanged in surgical settings.
After the passage of OSHA BBP law in 2000 the PI rates in the OR are unchanged despite
the significant reduction in other departments in the hospital setting. Surgeons and other
operating room staff have to implement the available preventive tools to reduce their risk
from serious and sometimes fatal exposure to bloodborne pathogens.

**Phlebotomy: Promising Practices and Lessons Learned**

Jackson Songa, JSI Making Medical Injections Safer Project, Kenya,

Collection of blood for diagnostic purposes is a common practice in health facilities. This
puts health workers at high risk of infection with blood borne diseases such as HIV and
Hepatitis B and C because of handling big volumes of blood.

Many developing countries do not have standard procedures that ensure that blood
collection (phlebotomy) for diagnostic purposes is done in a manner that minimizes the
risk of medical transmission of infection during this process. In many countries blood
drawing is often done using inappropriate equipment. There is inadequate knowledge
among health care workers on the risks of medical transmission of infection during
phlebotomy procedures. Disposal of the blood drawing equipment is likewise
unsatisfactory leading to high risks of infection transmission.

MMIS working in Kenya, Tanzania and South Africa has tried to address the challenges in
ensuring safe phlebotomy practices. In South Africa, only health workers registered with
Health Professional Council of South Africa (HPCSA) are allowed to draw blood.
Phlebotomists have been trained as a separate cadre of health workers for the purposes
of blood drawing procedures. This has taken away pressure from nurses. South Africa
mainly uses closed system blood collection equipment (vacutainers).

In Kenya and Tanzania, blood drawing procedures are done with inappropriate equipment.
Inadequate knowledge leads to risky practices and poor quality samples. There is a need
to quantify blood drawing procedures at various health service delivery levels in these
countries. This would enable MOH to determine realistic phlebotomy procurement needs.
It also will help determine phlebotomy work load at various Health service delivery points
as well as to monitor and evaluate phlebotomy services.

It is important for countries to invest in the development of policy guidelines on
phlebotomy services. Countries should be supported to develop evidence based strategies
that prioritize improved phlebotomy practices. Pre-service and in-service training programs
should be based on equipment that reduces the risk of infection transmission.

**WHO guidelines on drawing blood- best practice in phlebotomy**

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

WHO and the Safe Injection Global Network (SIGN) have recognized the need for best
practices in all aspects of injection safety. These guidelines recommend best practices for
all levels of healthcare where phlebotomy is practiced and extend the scope of the existing WHO/SIGN guidelines on Policies and Infection Control Standards Guidelines for Injection Safety and Best Infection Control Practices for Skin-Piercing, Intradermal, Subcutaneous, and Intramuscular Needle Injections.

A team of experts evaluated the existing published evidence, taking cognisance of the fact that there was a dearth of information from low resourced countries. Current practices were evaluated and these draft guidelines address the minimum standard of good infection prevention and control (IPC) practice applicable in healthcare facilities across the globe. Where there was no clear evidence, recommendations were based on phlebotomy practices yielding the best outcome (least adverse events).

The draft guidelines cover the practice of both drawing blood for diagnostic or medical purposes and blood collection for transfusion. Blood drawing from adult, paediatric and elderly patients also reflects the different methods used for such purposes resulting in best practice for patients, staff and laboratory results—quality assurance has been paramount. Some areas of differing practice, such as skin disinfection, have emerged—here recommendations are based on a consensus opinion from the team. Overall, good IPC practices, appropriate use of protective clothing for healthcare workers and establishing patient confidence during the procedure have been given a high priority.

Recommendations on improving current practice have been addressed comprehensively. While the cost of improving phlebotomy could not be documented directly, since these costs differ from country to country, improved disposal of sharps and injection safety have been prioritised and will require some reorganisation. Practices for blood collection for transfusion purposes follow a more rigorous regime. Only the procedure of blood drawing has been addressed—other aspects will be dealt with elsewhere. It is envisaged that supporting documentation such as flow-charts and aide memoires will follow as soon as the guidelines have been finalized.

**Theme 2: Injection Safety contribution to Achieving MDGs**

Chair and Rapporteur: Allan Bass

**Update on the Global Burden of Disease Study Estimates of Unsafe Injection Practices**

Steven Wiersma, WHO IVB Geneva

This talk provided an update on the process of updating the unsafe injection prevalence estimates as part of the Global Burden of Disease Study. The GBD collaborators, aims, steps and process were reviewed. Terms of reference were discussed for a systematic review of the prevalence of unsafe injections throughout the world. These estimates will be summarized by country/GBD region, age, and sex using criteria from the GBD Operations Manual. The prevalence data will be used to generate burden estimates using models.
Issues discussed were how to identify the relevant data sources using the SIGN network, how to account for risk of transmission in hospital settings where prevalence of blood-borne pathogens may be higher than in the general population, how to account for different transmission dynamics between different types of injections (e.g. IM, IV, SC, ID), and how to maintain a transparent process.

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**Post-Exposure Prophylaxis To Prevent HIV Infection: Joint WHO/ILO guidelines on post-exposure prophylaxis (PEP) to prevent HIV infection**

Micheline Diepart, WHO Anti-retroviral Treatment and HIV Care (ATC)

Worldwide, in 2007, an estimated 33.2 million people were infected with HIV. Post-exposure prophylaxis, which by definition includes the prevention of mother-to-child transmission, is currently the only way of reducing the risk of development of HIV infection in an individual who has been exposed to the virus, and as such, is widely considered to be an integral part of the overall strategy for preventing the transmission of HIV.

Strong ethical arguments support providing PEP for HIV infection. Each day, thousands of people around the world experience accidental exposure to blood and other body fluids or tissues while performing their work duties. Health care workers are especially vulnerable. Moreover, in many parts of the world, the potential for workplace accidents that may expose workers to HIV-infected blood and other body fluids is increasing. Several factors are contributing to the increased risk of occupational HIV exposure. First, more people are living with HIV infection. At the same time, antiretroviral medicines are becoming increasingly available for treating AIDS, including in many resource-constrained settings, with the result that more people with HIV are coming into contact with health care services. Second, as people receiving antiretroviral therapy accrue its benefits and live longer, they are more likely to survive, and the numbers of people living with HIV in contact with health services is increasing, both as health care providers and as people receiving treatment.

Although data on the efficacy of HIV PEP are fairly limited, good evidence suggests that a short course of antiretroviral therapy effectively reduces HIV transmission rates following needle stick exposure. Prospective, randomized studies to evaluate the efficacy of PEP in preventing HIV are unlikely to ever be conducted because the generally supportive data described above create difficulty in withholding PEP for ethical reasons. In addition, evaluating the efficacy of an intervention aimed at reducing the risk of single incidents of exposure associated with low-risk transmission would require an extremely large sample size. Several case reports and cohort studies document some failures of PEP to prevent HIV infection, and PEP may never be considered 100% effective. It is therefore imperative that HIV post-exposure prophylaxis policies reinforce the importance of primary prevention and risk prevention counselling in all settings where HIV could be transmitted. PEP should never be provided in isolation, but should always form a part of a wider strategy for preventing exposure to HIV. It is also associated with measures to prevent other bloodborne diseases, such as hepatitis B and C.
The guidelines and the meeting presentation outlines the guidelines and recommendations made from a public health perspective, with a simplified and accessible regimen focusing on risk assessment, adherence support and programme monitoring. Although this publication aims to provide a unified framework to guide both PEP policy development and the implementation of services for situations of occupational and non-occupational exposure, it is recognized that service provision - both nationally and locally - needs to be context specific. The users of these guidelines are thus encouraged to adapt these guidelines to suit their own circumstances.

The document is being printed and could be consulted on the web at:


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**Blood borne viruses in an occupational setting - The UK National Perspective**

F M Ncube, S E Tomkins, S Cliffe, UK Health Protection Agency

Blood borne viruses (BBVs) are a significant risk to healthcare workers (HCWs) in the occupational setting. The first documented case in the UK of a HCW who seroconverted to HIV following an occupational exposure was in 1984 and in total there are now five documented cases of occupationally acquired HIV infections in HCWs in the UK. A further 16 HCWs with probable occupational HIV acquisition have also been diagnosed in the UK. In a case control study in Europe involving the UK, France, Switzerland, Spain and Italy, there have been 60 documented cases of HCWs who have seroconverted to hepatitis C virus (HCV) following occupational exposure. Robust data on hepatitis B seroconversions in HCWs are not currently available.

In the UK, the Health Protection Agency Centre for Infections co-ordinates the enhanced surveillance of occupational exposures to BBVs in HCWs. Initiated in 1997, the scheme covers England, Wales and Northern Ireland. It includes reports of exposures to blood or other body fluids of patients infected with HIV, HCV and/or hepatitis B surface antigen (HBsAg). All reports where a HCW initiated HIV post-exposure prophylaxis (PEP) are also included.

This talk presents the latest national surveillance data, describing the number of HCWs exposed to patients infected with BBVs, by specialty, staff groups involved, location and timing of the exposure and the type of exposures sustained. The use of PEP for HIV was presented, reviewing adherence to the UK National HIV Post-Exposure Prophylaxis Guidelines and outcome of exposures where PEP has been used.

Occupational exposure to HCV presents a more difficult management scenario. There is currently no PEP available and there is no HCV vaccine as yet. This presentation will explore the management issues involved in looking after HCWs exposed to HCV-infected source patients, including the impact of early treatment. Prevention strategies will be reviewed including strategies for improving our knowledge on the risks surrounding the exposure of HCWs to BBVs in an occupational setting.
Injection safety and related procedures training package

Dejena Selenic, US Centers for Disease Control and Prevention

We present progress to date on development of the Injection Safety and Related Procedure Training materials packet that we are developing based on lessons learned during PEPFAR I. We hope it might be a user friendly set of self contained training materials in injection safety that could be a companion to the WHO SIGN Toolkit in development. We are examining all of the materials developed by PEPFAR technical assistance providers to date in addition to the proposed or revised or updated SIGN Toolkit.

The goal is to develop a template that can be circulated to a review panel of representatives of all of the PEPFAR technical assistance providers, country directors, and HQ staff; we would hope to also have SIGN network or representatives of SIGN as a part of that group. We began development in May 2008, and now have a curriculum specialist who will be devoted to this project.

The product would be structured so that it could be adapted to the local circumstance and a person familiar with the content might easily conduct training with consistent messages by following the outlined procedure.

Energy, Injection Safety and the Millennium Development Goals

Terrence Hart, CEO, IT Power India Pvt. Ltd

The 8 Millennium Development Goals (MDG’s) endorsed by member Governments at the UN in 2000 aims to improve human well-being by reducing poverty, hunger, child and maternal mortality, ensuring education for all, controlling and managing diseases, tackling gender disparity, ensuring sustainable development and pursuing global partnerships. Its target for achievement of these goals is 2015.

Injection Safety contributes directly to 3 of the MDG’s (Goal 4,5 and 6), but adversely impacts Goal 7 (Environmental sustainability.) Measures to improve injection safety have resulted in the production and disposal of large quantities of plastic which means a substantial increase in requirements for energy for injectables and syringe production, transportation, distribution, cold storage, waste handling and waste disposal.

This primary energy requirement to facilitate production, disposal, transport, cold storage, distribution etc is estimated to be equivalent to 8 million MWh/yr or production from a 1000MW power plant. (UK capacity is approx 43,000MW, and India 150,000MW.) Environmental sustainability is contingent upon there being a minimum impact on climate change. CO2 emissions are one of the primary contributors to climate change and massive international initiatives are being put in place through the Kyoto protocol to curb CO2 emissions. The energy consumed to enhance injection safety produces approx 11 million
Tons of CO2 p.a. with an equivalent environmental cost of $345 million/yr when traded as carbon emission reduction certificates (CER’s).

Recommendations to address this adverse impact on Goal No 7 of the MDGs are:
- Introduce measures/incentives and awareness to reduce CO2 emissions (Rational use of syringes for example);
- Improved transportations and distribution efficiency, and health services outsourced to the private sector to enhance efficiency of operations;
- A landscape analysis to evaluate the environmental impact of injection safety and to evaluate the potential commercial returns to countries eligible to earn revenue from CO2 emission reductions.

Theme 3: Advocacy and communication activities on injection safety and related infection control including fund raising

Chair: Jorge Mancillas      Rapporteur: John Fitzgerald

Legal system as advocacy tool for injection safety

Professor Sviatoslav Plavinsky, Dean, College of Public Health and Chair, Department of Pedagogic, Philosophy and Law, Medical Academy for Postgraduate Studies, St.Petersburg, Russia. School of Public Health
St. Petersburg Medical Academy for Postgraduate Studies

Unsafe injections are important concern for the public health community. It is a relatively new threat as the mass spread of medication injections took place only in the second half of the 20th century when cheap disposable syringes became available. Unlike the old public health enemies such as communicable diseases spread through food, water or close personal contact, the diseases spreading through unsafe injections have no body of traditional laws regulating health interventions such as quarantine or food inspection. Needles and syringes are frequently viewed as symbols of the medical profession and it is difficult for people to believe that injections could be hazardous. In Russia and other countries more attention is paid to preventing environment contamination from used syringes and needles than to the protection of health care personnel and patients from unsafe injections.

Nosocomial infection is a clear case of personal damage that is preventable and so remedies, including legal, should be used to prevent it from happening. This could be based on passing amendments to existing public health laws calling for more strict control of injection safety, by demanding appropriate training and using engineered devices. Unfortunately it is unlikely that laws clearly increasing cost of health care will be passed quickly in the absence of a demonstrable public health emergency. Private litigation can draw the attention of legislators to the fact that unsafe injections do transmit diseases and that this leads to costly treatments and loss of health. Private suits against health care institutions will draw attention to the unsafe injections and the damage it does. Accidents with needles and other sharps should be viewed as negligence on the part of hospitals to
provide safe workplace or malpractice if the patient was infected. Courts should recognize that there are limits to engineered solutions to safety problems.

In the absence of clear legal mandates for public health agencies oversight of injection safety, it is important that personal legal actions be taken to mitigate effects of unsafe injections and recover damages at the maximum possible extent under national legislation. At the same time personal responsibility for safe behavior should be not overlooked. Public health specialists should use legal instruments to decrease threats of unsafe injections to the public health.

Massachusetts Sharps Injury Surveillance System: Findings from 2002-2005

Angela K. Laramie, MPH

US Federal and state regulations require use of devices with safety features as well as recording of detailed data on each percutaneous exposure incident. In addition, Massachusetts regulations require hospitals to report sharps injuries to MDPH annually. The Massachusetts Department of Public Health (MDPH) Massachusetts Sharps Injury Surveillance System is intended to provide information regarding the magnitude of the problem in the state, to identify devices, procedures, and departments most frequently associated with sharps injuries, as well as to facilitate sharing of best practices among healthcare facilities. It has also served as a model for other healthcare settings, such as homcare.

Since 2002, MDPH has been collecting data from licensed hospitals regarding sharps injuries among hospital workers. Utilizing the MDPH Annual Summary of Sharps Injuries reporting form, 100% of the hospitals have submitted data each year. Findings based on data collected during 2002-2005 have been analyzed, with a focus on devices associated with percutaneous injuries.

Injuries occurred most often to nurses (39%, 5,165), followed by physicians (33%, 4,357). The greatest number of injuries was reported in operating and procedure rooms (43%, 5,668). Most injuries occurred while administering injections (23%, 3,013), followed by suturing (21%, 2,839) and blood drawing (19%, 2,523). In this four year period, 58% of sharps injuries involved devices lacking safety features. While the number of injuries over time has remained relatively steady, the proportion of injuries involving devices without safety features has decreased from 62% to 54%. Of 3,953 injuries with hypodermic needles, 46% were with needles lacking safety features. In contrast, 82% of the 1,296 injuries involving winged-steel needles involved needles with safety features.

The data provide answers to questions about who is getting injured where, and with what. At the same time, the data raise questions about why devices without safety features are still in use and how this can be best addressed. The data indicate a need to emphasize replacement of devices lacking safety features, especially those involving hypodermic needles.
Advocacy and Communication for Injection Safety: What works and what doesn’t - Experience from MMIS

Rebecca Fields, AED, Making Medical Injections Safer (MMIS) Project

Since 2004, the Making Medical Injections Safer (MMIS) project has designed and implemented behavior change, communication, and advocacy strategies in 11 African and Caribbean countries. Advocacy, broadly defined as “putting a problem on the agenda, providing a solution, and building support to act on both problem and solution,” has been a critical element of project activities and key to long-term sustainability of injection safety efforts. MMIS has supported host governments in defining advocacy objectives that are more specific than broad fund-raising; these include promoting the development and adoption of policies and guidelines, incorporating injection safety content into training curricula, promoting decision-making on injection technologies, and promoting the use of indicators to measure progress and foster accountability.

MMIS has used a phased approach in which early advocacy and communication efforts focused on securing government commitment, launching health worker training to improve the quality of services, and assuring that the needed injection supplies were available. The next phase focused on increasing community demand and broadening the base of support for injection safety. A third phase has concentrated on sustaining and institutionalizing progress.

For advocacy, what has worked well is to identify “champions” to help launch work, establish an evidence base to describe risks of unsafe injections, build a coalition of supporters (including professional associations and unions) and demonstrate the relevance of injection safety to existing programs and health priorities.

For communication, what has worked well is to segment different target audiences, develop and test messages that state the desired actions and the personal benefits of taking them, and disseminate and reinforce the messages through multiple channels. MMIS has avoided the use of scare tactics, which tend to produce unpredictable and short-term changes and which may deter community members from seeking those injections that are indeed safe and necessary.

A hallmark of MMIS’ approach has been to synchronize communication and advocacy activities to create demand with improvements in supplies management, training, and health care waste management to assure the supply of high quality services.

Recent U.S. Outbreak Experiences and Prevention Initiatives

Joseph F. Perz, US Centers for Disease Control and Prevention, Division of Healthcare Quality Promotion

The contribution of unsafe injection practices to the transmission of infections is believed to be greatest in resource-poor countries where overt reuse of injection equipment
remains an issue. However, increasing numbers of outbreaks in countries like the United States indicate that unsafe injections, particularly those involving intravenous administration, represent a more widespread problem.

The recent outbreak of hepatitis C virus infections in a Las Vegas, Nevada endoscopy clinic showed that even highly trained healthcare providers do not always understand or adhere to aseptic technique and safe injection practices. In that outbreak, healthcare personnel did not reuse syringes for multiple patients but did reuse them to withdraw additional doses of an anesthetic agent (propofol) from a vial that was then reused for subsequent patients. The impact of this outbreak was amplified by the resulting public health notification that advised tens of thousands of potentially exposed patients of the need to seek testing for HBV, HCV, and HIV.

During 2007-2008, at least a half dozen similar outbreaks and incidents involving syringe reuse have resulted in large patient notifications in the United States and other countries. The challenge of assuring safe therapeutic injections requires diverse strategies and approaches.

Improvements in medical devices and medication packaging may reduce opportunities for reuse and cross-contamination of injection equipment and vials. Public health surveillance and outbreak investigation are vital to recognize and contain transmission and to provide an evidence base to guide prevention activities. Healthcare provider education and training should be based on defined expectations and standards that protect both workers and patients from harm. For example, in the United States, Standard Precautions* includes safe injection practices and is intended as the foundation for infection prevention in any setting where medical care is delivered. Finally, oversight, licensing and public awareness are all needed to drive change, foster a culture of safety, and assure that safe practices are followed.

* Available at: http://www.cdc.gov/ncidod/dhqp/gl_isolation.html

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**Day 3: Wednesday, 15 October 2008**

*Satellite Session : Health Care Waste Management*

Chair: Yves Chartier, Rapporteur: Ute Pieper

**WHO/ PATH Framework to Monitor National Progress in Injection Waste Management**

Nancy Muller, PATH

While there are several in-depth assessment tools that evaluate injection safety and health care waste management (HCWM), none of these tools directly connects district- and facility-level knowledge and practices with influencing factors at the national level. There is a need for a simple, efficient, “snapshot” tool that enables countries to quickly identify progress and gaps in HCWM policy and planning and clearly illustrate the
necessary steps and responsible parties to address those gaps. In April 2007 WHO requested PATH to develop a standardized tool to measure progress in national planning for injection waste management. In response, PATH developed The Framework for Conducting a Self-Assessment of National Progress in Injection Waste Management.

The Framework provides standardized evaluation indicators for measuring progress in injection waste planning on a country-by-country basis, while remaining relevant to each country’s unique HCWM situation. It is structured so that at the completion of the self-assessment process, the country will have generated a set quantifiable outcomes as well as qualitative guidance for national action planning. By collecting data on key achievements, knowledge, and practices at the district and national levels, programs can use the Framework to quickly aggregate data, highlight trends, and identify gaps. An action-oriented national-level workshop with key stakeholders then provides the opportunity to assess the implementation status of HCWM plans and policies, record evidence of the impact of improvement, and outline plans of action and responsible parties for moving the revised HCWM planning agenda forward. This approach ensures that national-level changes have immediate support and momentum.

The Framework consists of the following components:

2. Questionnaires intended to provide a “snapshot” of facility- and/or regional-level progress toward implementing standards for safe injection waste management. These questionnaires are intended to be modified to be country specific and would be used to inform the direction and agenda of the self-assessment workshop.

3. Workshop materials such as a suggested agenda and a matrix to structure dialogue and center strategic discussion around concrete indicators. These materials are intended to be modified to be country specific.

PATH piloted the Framework in Uganda in September 2007 and revised the tool based on feedback from expert researchers involved in the pilot process. PATH also participated in the subsequent national workshop held in Uganda in March 2008, during which a set of national action items was drafted. Future activities include adaptation of the Framework to be used for monitoring and evaluation and further piloting in additional countries.

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Report on a prototype syringe melter evaluation in Andhra Pradesh, India

Satish Kaipilyawar, PATH

In 2006 PATH evaluated three different syringe melters in Indonesia. Based on feedback from this study, one of the syringe melter companies, New Paradigm of Vermont, USA, modified their device to address specific shortcomings. The modified melter was tested in Andhra Pradesh, India in February of 2008. The primary objective of this study was to assess the acceptability and performance of the melter. Training, ease of use, prototype
performance, and acceptability were all evaluated. In addition, an assessment of the fit of this device within the existing waste management systems for both curative and immunization was made.

Study results: In general the melters performed well; Operators of different genders and backgrounds were able to successfully operate the unit after less than 30 minutes of training; The success of the melters generally increased as users gained experience; Fuel quantities decreased as the trials progressed—one melt generally required a handful of sticks or ~12 coconut shells; With experience, operators were able to vary the amount of fuel added in order to match the quantity of syringes and obtain a successful melt; Data indicates that very little partially-burned fuel was left, suggesting that the burn performance of the units was good; With the exception of the PP unit in Khammam, full containers were rarely used, suggesting adequate capacity for both rural and small urban clinics; Smoke was reduced and controlled better than during the 2006 trial—generally 5-15 minutes until the exhaust burned clear; Container emptying was easy when the burn was successful, but became difficult when over-melting resulted in rubber stoppers sticking to containers; Equipment failure included two partial melts (successfully remelted), and one ignition malfunction that resulted in a loss of the melt material; Although used in conjunction with needle removers, some needles were present. The round containers used in this trial seemed to produce fewer protruding needles than the rectangular containers used in the 2006 trial; No injuries were reported during this trial.

In summary, observations in the field suggest that use of this unit in conjunction with needle removers works well and is a good practice. In particular, use of this melter reduced the amount of pre-processing required to recycle the materials. More work could be done to better quantify and understand the environmental impact of this method on air quality.

Satellite Session: Occupational Health: Needle stick injury Surveillance systems - use of data for prevention

Co-chairs: Susan Wilburn and Ahmed Gomaa

EPI Net: History and use of EPI Net

Janine Jagger, International Healthcare Worker Safety Center, University of Virginia USA

The EPI Net (Exposure Prevention Information Network) surveillance system was formalized for distribution in the US in 1992 with support from BD. EPI Net has been adopted by more than 1,500 U.S. hospitals. In 1994 the CDC incorporated EPI Net into the NaSH surveillance system, and from there the core elements of EPI Net were further incorporated into state surveillance systems in California and Massachusetts. Italy was the first country to adopt EPI Net in 1993 and has since been adopted in more than 55 countries and 17 languages.

International comparisons have raised our understanding of healthcare worker safety to a new level. In 2000 the U.S. passed a national law mandating safety-engineered needles
and sharp devices. The law resulted in the rapid adoption of safety devices. EPI-Net data in 2001 showed a sudden drop in injuries of about 30% in all areas of the hospital except the OR. Encouragingly, the greatest reductions were associated with the highest risk devices - blood drawing (~50%) and vascular access (~60%).

Safer devices should be standard equipment for healthcare workers everywhere. Standardized surveillance is an essential tool for promoting effective prevention.


Joseph F. Perz, US Centers for Disease Control and Prevention, Division of Healthcare Quality Promotion

The Centers for Disease Control and Prevention (CDC) has developed a new healthcare personnel (HCP) safety component within its existing web-based surveillance system, the National Healthcare Safety Network (NHSN) which supersedes the National Surveillance System for Health Care Workers (NaSH). The HCP Safety component allows participating facilities to enter data about individual occupational blood/body fluid exposure events and exposure management (e.g., post-exposure prophylaxis, adverse side effects and laboratory test results).

Through an annual survey, baseline data will be collected including use of safety devices, implemented strategies to increase immunization, and denominator data regarding the numbers of HCP stratified by occupational group. Training materials are available online to assist facilities and institutions with successful enrolment in and implementation of this new surveillance system for healthcare personnel.

The NHSN HCP Safety component will assist participating U.S. facilities in developing surveillance and analysis methods that permit timely recognition of healthcare personnel safety problems and prompt intervention with appropriate measures. At the national level, the system will aid in monitoring rates and trends, identifying emerging hazards for HCP, assessing risk of occupational infection, and evaluating preventive measures, including engineering controls, work practices, protective equipment, post-exposure prophylaxis, and immunization uptake strategies.

Plenary Session: Summary Reports and Recommendations

Chair: Christie Reed Rapporteur: Allan Bass

SIGN 2008 Meeting Recommendations

Guidance to The World Health Organization
1. In the current GBD revision process, WHO should provide scientific data on the level of risk and Global Burden of Disease from unsafe medical injections and needle stick injury.

**Guidance to Countries**

2. Countries should establish and support national SIGN networks to enhance organizational change and the adoption of safe injection throughout the health system.

3. Countries should contribute to reaching the millennium development goals 4, 5, and 6 by reducing unsafe injections by 50% by 2015.

**Reduced Injections**
4. Countries should use and review standard treatment protocols for diseases and conditions, and essential drug lists, aiming for greater use of oral medications and reduced use of parenterals.

**Devices**
5. Countries should identify their needs for safe injection devices and health care waste management technology and share information with industry to enable public-private partnerships.

6. Countries should engage field staff in injection safety policy and strategic planning to assure best practice user compliance. Health worker participation in the selection of technologies used in healthcare settings is an essential component.

**Infection Control and Surveillance**
7. Countries should recognize that healthcare workers are a crucial element for the success of health programs. Health managers must make clear to health care workers that the purpose of reporting of blood exposures is for continuous surveillance of sharps use and to help protect health workers through the identification of areas for intervention. Health managers must address the need for action on Hepatitis B immunization, post exposure prophylaxis, stigma, and HIV prevention.

8. Countries that contract health services face additional infection control risks. These key issues must be addressed: outsourced contract management and reduced institutional capacity, competency of staff, timeliness of response to need, and future sustainability.

9. Countries should recognize and inform all health workers that once used, needles and sharps devices should not be manipulated and should be disposed of immediately at point of use.

10. Countries should use the phlebotomy equipment indicated in its health worker training and maintain national supply availability.

**Health Care Waste Management**
11. Countries HCWM interventions should be developed in the context of national plans and regulatory frameworks and be supported with the necessary human and financial resources and implementation tools. Countries must ensure that funding for the realistic costs of injection safety are routinely included in health service delivery budgets.
12. Countries should develop and implement national HCWM plans. HCWM policy, planning, and funding should be comprehensive rather than program specific to avoid duplication. HCWM should be integrated into health systems strengthening planning and funding.

13. Countries should develop and implement standards for hospital HCWM and equipment. HCWM practices should reflect cultural and national definitions and use appropriate options.

**Guidance to SIGN Members**

**Secretariat Support**
14. SIGN member organizations should support funding additional secretariat staff and greater SIGN Member collaboration.

**Evidence: Global Burden of Disease**
15. SIGN Members should identify published and especially unpublished reports on the: Prevalence & frequency of injections (sc, im, iv) in countries and studies of the proportion of injections that involve the re-use of unsterile equipment, and share with the GBD team for the review of scientific evidence.

16. SIGN Members should identify published and especially unpublished data on the burden of disease from occupational sharps injury disaggregated by occupation, device used and procedure performed, and disease or pathogen, in countries, and share with the GBD team for the review of scientific evidence.

**Reduced Injections**
17. SIGN Members should identify disease control programs where injections may be potentially reduced and conduct joint monitoring, reporting, and quantify reductions achieved. Examples include Malaria programs and Home based care.

**Surveillance**
18. SIGN members should assist and facilitate the implementation of NSI surveillance systems for use at country and facility level for the logging of blood exposure and sharps injuries

**Devices**
19. SIGN Members should use these terms for improved injection devices: Re-use Prevention Syringes and Sharps Injury Protection Devices. The term Auto-disable (AD) syringe should not be used.

20. SIGN members proposed ISO standards for new devices with built-in safety engineering controls for sharps injury protection should include health worker usability aspects to avoid problems in use.

21. SIGN member organizations should support countries use of safety boxes to improve uptake and usage.
22. SIGN Members should review jet injectors, sharps free systems, and new innovations in drug delivery devices and alternative routes of administration in each SIGN meeting, leading to evidence based recommendations. Seeking funding for appropriate device development and introduction should be a high priority in 2010.

*Health Care Waste Management*

23. SIGN members should investigate and provide scientific data on the environmental impacts of injections, injection waste, and injection safety and report to the SIGN Secretariat.

24. SIGN Members should investigate and identify acceptable methods for implementing safe syringe material reclamation and transformation into secondary products and report to the SIGN Secretariat.

25. SIGN members should demonstrate that good HCWM is environmentally sound and cost efficient in reducing health impacts on health workers and communities, and report to the SIGN Secretariat.

*Guidance to the Medical Device Manufacturing Industry*

26. Industry should participate in the SIGN Injection safety and device standards working group to address issues and user needs.

27. Industry should work with countries to ensure coordination and communications to avoid supply problems at an early stage.

*Guidance to the SIGN Secretariat*

Near Term: 2009 - 2010

*Global Policy*

28. The SIGN Secretariat should convene a working group on injection safety to prepare a background paper for a 2010 WHA resolution on injection safety and HCWM.

29. The SIGN Secretariat, supported by a working group, should develop a joint policy statement on therapeutic injection safety, including healthcare waste management, to be signed by all partner organizations.

*Change Management*

30. The SIGN Secretariat should seek and support SIGN focal points in all regions and encourage the establishment of national SIGN networks in each country.

*Action*

31. The SIGN Secretariat, recognizing that 2009 is the 10th anniversary of SIGN, should conduct a thorough review of SIGN strategies and the role and membership of the SIGN coalition.

32. The SIGN Secretariat should develop core common injection safety training modules for all health worker cadres.
33. The SIGN Secretariat should advocate for more action on reducing unnecessary injections through improved standard treatment protocols.

34. The SIGN secretariat should actively disseminate the new phlebotomy guidelines and web resources to health workers, teachers, trainers, procurement and government officials and others in the health community. The new phlebotomy guidelines should be translated into the official United Nations languages.

35. The SIGN secretariat should provide guidance and support for the development, implementation, and monitoring of blood exposure and sharps injuries surveillance and reporting systems for the prevention of exposures and prevention of occupational transmission of HIV, hepatitis B and C through the application of the prevention hierarchy and post-exposure follow-up, prophylaxis and treatment. Attention to the elimination of barriers to reporting, a blame-free performance improvement approach with feedback, is key to improving data quality for prevention and treatment.

36. The SIGN secretariat and member states should advocate for a minimum set of data elements to be collected for sharps injury surveillance, including a field to identify the involvement of a device with sharps injury prevention features or re-use prevention features.

37. The SIGN secretariat should advocate to funders and member states for comprehensive funding packages that include waste management up to final disposal. Specific resource support should be sought for the demonstration and replication of successful and sustainable healthcare waste management programs.

**Working Groups**

38. The SIGN Secretariat should convene a communications working group responsible for communications, education, BCC and cultural change strategies, to meet the demands of the SIGN 10th anniversary activities. The role of communities must be emphasized and education and involvement of the public through sustained education campaigns is essential. Responsibilities will include media briefing materials, strategies for communication on outbreak incidents to help establish evidence base and define issues and problems, campaigns to raise awareness of issues and successes among funders and other potential partners.

39. The SIGN Secretariat should convene a HCWM working group to establish an expert network in health care waste management to support SIGN objectives in the safe handling and management of sharps and injection waste. Key issues are safe materials reclamation procedures, technologies, measurement of cost effectiveness and impacts, and the formation of the HCWM Alliance to identify sources of funding for implementing effective waste management in countries.

40. The SIGN Secretariat should convene and coordinate a working group to develop a targeted approach, templates and checklists to assist countries injection safety proposals to the Global Fund and other agencies.

41. The SIGN Secretariat should convene a working group to propose ISO standards for safety boxes for disposing of phlebotomy sharps and other non-immunization injection
blood drawing devices. The working group in collaboration with the WHO IVB Immunization standards PQS performance specification process should develop a proposal for ISO standards for safety boxes for injection and sharps waste.

Alliances
42. The SIGN secretariat should support consideration of occupational health issues as a priority among health care programs through a World Health day.

Topics proposed for the next SIGN meeting:

- Thorough review of SIGN strategies and the role and membership of the SIGN coalition.
- Reduction of injections with oral preparations
- ISO standards for injection safety devices

SIGN Collaborative Working Groups

The SIGN Secretariat will coordinate the work of these proposed working groups:
- Injection safety WHA resolution Working Group
- Joint Statement in Therapeutic Injection Safety Working Group
- Communications Working Group
- Tools for funding proposals Working Group
- The SIGN HWCM Working Group and the HCWM Alliance
- Blood Exposure Surveillance Working Group
Annual Meeting of the Safe Injection Global Network (SIGN)
Injection Safety and Infection Prevention and Control
13-15 October 2008, Moscow, Russian Federation

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