Safe Injection Global Network (SIGN)

Annual Meeting Report

30-31 August 2001

Includes the report of the Joint TechNet – SIGN Injection and Waste Management Technology Day 29 August 2001
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Grand Hyatt, New Delhi, India

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Joint TechNet – SIGN
Injection and Waste Management
Technology Day
29 August 2001
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Executive summary

Background

The Safe Injection Global Network (SIGN) met for the third time on 29-31 August 2001 in New Delhi, India, to review progress and identify how the network participants could best facilitate safe and appropriate use of injections worldwide.

Organization of the meeting

The Ministry of Health of India and the Director of the WHO regional office for South East Asia jointly opened the meeting. Three days of work allowed 120 participants to share their experiences. The WHO South East Asia region was particularly well represented as unsafe injections spread bloodborne pathogens on a large scale in this area of the world. The first day was specially dedicated to injection and waste management technologies. The remaining two days were dedicated to broader public health issues, including national policy and plans for the safe and appropriate use of injections, quality and safety of injection equipment, access to injection equipment and safe, cost-effective, rational and appropriate use of injections.

Reviewing progress in 2000-2001

Progress made since the SIGN meeting 2000 was reviewed. First, a number of countries reported having taken steps to formulate national policies for the safe and appropriate use of injections, starting with an assessment. Second, manufacturers of safer injection technologies formed an association in 2001 so that they could participate actively in the formulation of international norms and standards for Auto-Disable (AD) syringes. Third, the international public health community is developing a more holistic approach to injection safety, with progressive engagement of those working in the prevention and care of HIV infection, in family planning and in essential drugs. Fourth, the board of the Global Alliance for Vaccines and Immunization (GAVI) endorsed a new injection safety policy in June 2001. Finally, active work is ongoing to advocate for the safe and appropriate use of injections throughout the SIGN network.

Proceedings of the meeting

Safer injection technologies were presented, including needle-free injection devices and AD syringes. Discussion regarding efficient health-care waste management strategies emphasized the need for policy frameworks to implement (1) streamlined strategies organized from waste production to waste disposal, (2) training at all levels and (3) the choice of options that include incineration and non-incineration alternatives. A number of countries reported injection safety plans that used across-the-board approaches to include preventive and curative health-care services. Mechanisms to ensure the quality and safety of injection equipment through international norms and standards enforced by national regulatory authorities were presented. Strategies to increase access to injection equipment were discussed, with a specific reference to the use of the essential drug system to bring safe syringes and needles into each health-care facility. Finally, the SIGN toolbox for safe and appropriate use of injections was launched.

Conclusion

The SIGN participants agreed on a list of action points and indicators to monitor progress in collaborative work. Overall, the network participants stated that the coalition made the total more than the sum of its parts and pledged to mobilize resources to achieve safe and appropriate use of injections worldwide.
TechNet-SIGN joint injection and waste management technology day

Prevent needle stick!

Always place the syringe and needle in a safety box immediately after use!

Avoid recapping the needle!

Burn safety boxes when full. Incineration is best.

Injection safety saves Lives

Wednesday 29 August 2001
Injection equipment from production to disposal

Life cycle of medical devices

Gerald Verollet
WHO, Geneva, Switzerland

Medical devices have a life of their own

Medical device safety requires risk management during the whole life cycle of the product. The goal is to maximize the benefits and minimize the risks associated with medical devices. The life of a medical device includes different phases from conception to disposal. The pre-market phase includes conception, design, manufacture, packaging and labelling. At this stage, norms and standards regulate the product. The market phase includes advertising and sales. At this stage, advertising control is important. The post-market phase includes use and disposal. At this stage, post-market surveillance of adverse events assesses the risks and the benefits associated with use.

A role for all to ensure the quality and safety of medical devices

All stakeholders that participate in the life cycle of a medical device have a role to play to ensure that medical devices are used safely and appropriately. These stakeholders include the manufacturer, governments, the public, users, importers and vendors. The manufacturer is the most important in the pre-market phase. His role is to ensure that the product meets or exceeds standards of safety and effectiveness. At the market stage, the vendor has an important role. In the post-market phase, the user should receive proper training so that he uses the product correctly. Over half of the adverse events associated with use of medical devices are the result of user errors. A public who understands that all devices carry some risk can put pressure on the vendor. Finally, governments have the responsibility to oversee the activities of the manufacturer and of the vendor.

Soaking syringes to reuse them in South Asia
(Photo: Catherine Dentinger)
Waste minimization: Role of manufacturers of injection equipment

Richard Carr
WHO, Geneva, Switzerland

Addressing waste management as part of the life cycle of medical devices

Manufacturers of injection equipment can play a role to minimize the waste associated with used syringes and needles. New delivery systems at various stages of development can prevent pollution. These include aerosol sprays, jet injectors, oral or transcutaneous administration and genetically modified plants and animal products. Each product can be evaluated to examine the health and environmental aspects of the life cycle of the product, from creation to disposal.

How manufacturers can contribute to safe waste management

Approaches to reducing pollution associated with health-care waste include 1) recovery and recycling through partnerships with local industries to formally recycle and safely reuse material, 2) use of biodegradable materials (e.g., starch or plastic needles), 3) reducing use of toxic materials throughout the product life cycle (e.g., removal of PVC and mercury), 4) reducing packaging, 5) funding disposal research efforts, 6) developing educational or outreach materials to be included with the products and 7) supporting workshops or training for country staff on safe injection practices, including waste management. Overall, the manufacturer needs to take responsibility for safe waste disposal according to the “Polluter Pays” principle. When there is waste, it should be biodegradable.

Key discussion points:

• An important part of waste reduction is reducing unnecessary injections. However, this approach may not benefit from support from manufacturers.

• It is overly simplistic to suggest that manufacturers are responsible for the pollution and that they should pay. If the manufacturer were to pay, they would have to pass on the cost to the end-user. Everyone involved in the process has a responsibility including manufacturer and the end-user.

• While waste should be minimized, the packaging of the syringe is also one of the ways that the public is empowered to know if the syringe is safe or new.

• End-users including nurses and health-care workers need to be involved in the design phase of manufacture.

• Work is ongoing on biodegradable syringes and plastic needles.

Small-scale incineration in Cote d'Ivoire (Photo WHO)
Technologies in support of immunization programmes

Michael Free
PATH, Seattle, WA, USA

An initiative from the GAVI research and development task force

The GAVI research and development task force has been asked to select three technologies or categories of technology (not including new vaccines) that could have a major impact on immunization programmes in the short (less than 5 years) or longer term (less than 10 years). Input from TechNet and SIGN members is requested in the selection of these technologies. Three teams are being organized. One will address hardware solutions to safety (coordinated by Michael Free). One will address access, management and operations (coordinator to be named). One will address vaccine formulation and process solutions (coordinated by Gordon Dougan).

Short-term and longer-term issues

In the short term, the team will be looking for improved management and tracking systems in the field, temperature stability technologies, combination vaccines, fixed cold chain, Monodose/ Self-Contained Unit Dose Administration Systems (SCUDAS) and sharps waste management. In the longer term, they will be looking for non-invasive routes of administration, more temperature stability and more combination vaccines. Research and development in the upcoming 5–10 years will include alternative thermostability technologies, auto-reconstitution, non-invasive SCUDAS and multivalent vaccines. Applications in development in the next 1–7 years include glassification drying, injection SCUDAS, Auto-Disable (AD) syringes for reconstitution and adapted sharps disposal options. Technologies that need field validation in the next 1–3 years include high-efficiency refrigerators using evacuated panels that can run on a single solar cell, ice-free cooling, outsourced logistics, out of the cold chain protocols and multidose jet injectors. Technologies for roll out in the next 0–3 years include monodose vials, injection SCUDAS for hepatitis B vaccine and tetanus toxoid, bundled AD syringes for routine immunization, waste management solutions, multivalent vaccines and outsourced logistics.

Key discussion points:

- There are marked delays in bringing new technology into public health practice. Delays in bringing new technologies to the market is caused by several factors. First, enough people need to be convinced of the advantage of spending more to move to a new technology. Second, the public sector immunization market is different from a traditional market. Demand cannot be aggregated. Manufacturers cannot develop a product for populations who are unable to pay without a firm commitment that goods will be purchased.

- When asked about AD syringe introduction, decision-makers in countries ask three questions: How do you introduce them? How do you pay for them in a sustainable way? How do you get rid of them? We need to be able to convince countries that they can switch to AD syringes and be able to manage waste. A plan needs to be developed and costed. There may be a role for the industry to make it easy for countries to make this decision.

- The industry would be willing to fund cost-benefit analysis studies conducted by independent parties that would demonstrate the cost-benefit of using AD syringes.
State of current safe injection technologies

Needle-free technologies

Mike Matthews
Association of Needle Free Injection Manufacturers (ANFIM), Lexena, KS, USA

Who are the people who constitute ANFIM?

The mission of ANFIM is to promote and protect public health through the advancement of needle-free injection technologies. ANFIM engages in advocacy and provision of information. ANFIM includes four manufacturers, four developers, two related industries and representatives from the Centers for Disease Control and Prevention (CDC), the Program for Applied Technology in Health (PATH) and the Food and Drug Administration (FDA).

Jet injection: Injecting without a needle

The basic approach of jet injection is that medication is driven at high speed through a tiny orifice (50% of the size of a 30 gauge needle) to create a fine stream that rapidly penetrates the tissue. The main advantage is that needle-free technology avoids (1) needlestick hazards, (2) sharps waste management hazards and (3) concerns over reuse of injection equipment in the absence of sterilization. Needle-free injections also reduce the pain associated with injections (in most cases), speed up the injection cycle and improve the bioavailability of vaccines. It has been used since 1947 in the military, in 1975 for smallpox eradication and in 1990-96 in Brazil for the administration of measles vaccine. The process must be safe and should produce minimum disposable biohazard. Earlier equipment transmitted hepatitis B virus (HBV). Cost needs to be comparable to or less than traditional needles and syringes. Several specific technologies are available while more are under development.

Key discussion points:

- Needle-free devices should not require ongoing user maintenance.
- Jet injector manufacturers have not worked closely with vaccine manufacturers though many products, including measles vaccine and Measles Mumps Rubella vaccine (MMR), mention on their label that they can be used with a jet injector.
- CDC formulated an informal specification for needle-free devices: Contamination is defined by the presence of more than 10 picoliters of contaminant per 0.5 ml of fluid in a second downstream injection.
- One company in California has suggested that skin patches could be used for multivalent vaccines. This technology would prevent mixing of vaccines. However, the company has not joined ANFIM.

Hand piece of a jet injector
(Photo: Felton International)
**Auto-Disable (AD) injection technologies**

Lillian Salerno
International Association of Safe Injection Technology (IASIT), Geneva, Switzerland

Who are the people who constitute IASIT?

The International Association of Safe Injection Technology (IASIT) is a recently-formed non-profit Swiss association based in Geneva. IASIT regroups 18 founding members who represent 70% of syringe production globally. An additional 15 – 20 new members are about to join. The goal of ANFIM is to act as an industry partner of the broader injection safety public health community.

What does IASIT do?

Tasks for the next year will include reviewing current technologies to avoid changing AD syringe specifications, coordinating technology transfer to ensure that it does not put people at risk, supporting efficient evaluation of AD technologies, being a partner for decision-making in the procurement of AD technologies and organizing task forces to assist with waste disposal.

Organizing a real public-private partnership

To assist the broader public health community, IASIT needs more information. The current situation is one of a market that has not been well defined. A number of questions need answers. How many AD syringes are needed? What price can the public health community pay for AD syringes? When are AD syringes needed?

The perspective of the makers of AD syringes

There are two types of participants in IASIT. The first type is a maker of standard disposable syringes that addresses a need for AD syringes. Engaging in the production of AD syringes requires an investment that needs to lead to profit. However, not all producers who engaged in the technology were rewarded by a contract. The second type is a player from outside of the syringe industry who created a technology and who requires moving to production. Making 50 million units requires an immense investment. To move forward, investors would need to know what the market is and what the profit margin will be. From the industry point of view, this has not been a commercially viable enterprise. While the public health community asks for technology changes, the willingness to pay is unclear. The industry needs to know what the needs are and how it can engage successfully in the enterprise.

Key discussion points:

- The prices of AD syringes are already close to the costs. However, time, volume and expansion of the market in the curative sector may further decrease prices.

- Whoever organizes injections needs to take care of the waste. If immunizations are to be delivered free of charge then EPI must cover these costs. We should ideally have cheap syringes, but we should also have responsible budgeting.

- The WHO specification for AD syringes allows fixed and removable needles. Removable needles allow “defanging”, and can lower prices. However, they may expose health-care workers to needlesicks and splashing because they require more needle manipulation. In addition, some have more dead space or can make drawing up vaccines more difficult and less efficient.
Waste management

Introducing technologies within a larger framework of health-care waste management

Richard Carr
WHO, Geneva, Switzerland

Health-care waste management is a public health issue

Poor management of health-care waste exposes health-care workers, waste handlers and the community to infections, toxic effects and injuries. Safety managing health-care waste requires a comprehensive system.

Assessing waste management needs

To develop an effective health-care waste management system, an assessment of the situation in the country should be conducted on a representative sample of health-care facilities. Information obtained from the assessment can then be used to develop a national plan for health-care waste management.

National health-care waste management plans

An effective national plan for health-care waste management requires:

- Development of a regulatory framework and designation of a responsible authority;
- Development of a comprehensive system, which includes assignment of responsibilities to personnel, allocation of resources and development of safe procedures;
- Awareness and training, including incorporation into school curricula, national training programmes and development of community outreach materials;
- Selection of sustainable, safe and environmentally friendly waste treatment options.

Balancing the risks between the environmental consequences of health-care waste management and the consequences of inaction

The greatest risk to human health from poor health-care waste management comes from the reuse of contaminated syringes and needles. In addition, improper disposal also may affect the health of health-care workers and the community. Proper management and the use of appropriate treatment technologies can reduce these risks, even if this leads to other, less harmful consequences, including air pollution. As always, risks and benefits should be balanced for good public health decisions.

What technological options are available to manage health-care waste?

There is no perfect health-care waste treatment technology that is adapted to every situation. Technology has to be coupled with good management practices to ensure safety. A number of treatment options are available for many different situations including, incinerators, needle cutters/destroyers, steam sterilizers, concrete burial pits and others. An on-line database is available at www.healthcarewaste.org to choose the one that suits the needs of your country or of your setting.
Contest for low-cost technologies to manage sharps waste

Susan Wilburn and Jorge Emmanuel
Health Care Without Harm, Washington, DC, USA

Who are the people who constitute Health Care Without Harm?

Health Care Without Harm (www.noharm.org) is an organization that includes 300 members in 33 countries. Its mission is to transform the health-care industry so that it is no longer a source of environmental harm. A key issue is to eliminate the pollution that is sometimes the consequence of health-care practices without compromising safety or care. The goals of Health Care Without Harm include:

- Promoting comprehensive pollution prevention practices;
- Supporting the development and use of environmentally safe materials, technology and products;
- Educating and informing health-care institutions, providers, workers, consumers and all affected constituencies about the public health impact of health-care waste.

The contest initiated by Health Care Without Harm

Health Care Without Harm is organizing a contest to look for simple, low-cost alternative waste treatment technologies that are appropriate for low-income rural areas. The contest wishes to involve academia, students and others interested persons. Final rules will be developed by the end of 2001 and posted on the Internet site of the association (www.noharm.org). The design criteria include (1) treatment capacity ideal for a rural clinic, (2) efficacy to treat microbial contamination, (3) ease of manufacture using simple skills and materials, (4) low cost, (5) low maintenance, (6) safe operation, (7) minimal air and water pollution, (8) non-hazardous waste residues, (9) low utility requirements, (10) reduction of waste volume and (11) community acceptance. The competition will require (a) sending a letter of intent, (b) describing the conceptual design and (c) describing how the design meets the proposed criteria. Monetary awards and recognition will be given to the contestants with the best designs. Assistance will be provided to selected contestants to construct prototypes and conduct performance tests. Intellectual property rights would be waived and successful designs will be made available in the public domain. Completion of the contest is expected by 2002.

Key discussion points:

- IV sets are a large generator of dioxins. The SIGN network should advocate for their removal. Manufacturers of sharps boxes should carefully avoid PVC plastics.

- Provision of sharps boxes in developing countries is often limited to the needs of EPI. When this is the case, sharps boxes cannot be used universally. Often, they will not even be used for EPI. Options should be examined to ensure provision of boxes for all needs. This may include use of locally-developed sharps boxes, even if they do not meet international specifications.
Overview of health-care waste management technologies

Jorge Emmanuel
Health Care Without Harm, Rodeo, CA, USA

Incineration: A waste treatment method that has limitations

Incinerators produce trace metals, dioxins and furans from chlorinated plastics, acid gases, carbon monoxide, particulate matter and other air pollutants. Bottom ash is also toxic. Epidemiological studies show high body burdens of various heavy metals and organic compounds. Incinerator emissions may lead to lung and laryngeal cancers, specific reproductive outcomes and urinary mutagens in populations exposed.

A framework for health-care waste management

A framework for health-care waste management should include waste segregation, waste minimization, protecting the environment, safeguarding public health and worker safety. Most of the waste produced by health-care facilities (about 85%) is non-infectious and non-hazardous and should be segregated from infectious waste and minimized through recycling, composting and other techniques. Incineration does not provide an incentive for segregation and minimization.

Alternative waste treatment technologies

Alternative waste treatment technologies include thermal, chemical, irradiation and biological processes. Low-heat thermal technologies (non-burn, <300 degrees Centigrade) include autoclaves, advanced autoclaves, microwaves and dry heat. Autoclaves are the simplest and cheapest. A pre-vacuum autoclave removes and decontaminates the air, then introduces steam, usually at 120 degrees Centigrade for 30 minutes. This time-temperature combination is typically sufficient to achieve high levels of disinfection as verified by spore tests. Advanced autoclaves include other features such as internal mixing, shredding, compaction and drying. Microwave units use microwave energy to generate heat and form steam that leads to disinfection. Dry heat systems achieve high levels of disinfection by combining shredding, air circulation and hot air treatment at 170 degrees Centigrade.

Alkaline hydrolysis is an example of a non-chlorine chemical treatment system wherein infectious waste is mixed with alkali such as sodium hydroxide and heated to about 120 degrees Centigrade for four to eight hours. Other technologies include medium and high heat thermal systems (which may produce pollutants if poorly designed) and chlorine-based chemical systems (which may discharge chlorine by-products in the waste water). Irradiative technologies use ionizing radiation and are, in general, expensive.

Factors to consider when evaluating a waste treatment option include its ability to destroy pathogens, environmental emissions, throughput capacity, safety, types of waste treated, space requirement, ease of use, reliability and cost. Over 50 alternatives are reviewed in Health Care Without Harm’s report Non-Incineration Medical Waste Treatment Technologies. However, Health Care Without Harm does not endorse any technology or company.
High-tech centralized facilities in developing countries: Are they realistic?

Ravi Agaarwal
Srishti, New Delhi, India

The role of centralized waste management option

On-site facilities for the treatment of health-care waste may be located in residential areas. Thus, there is demand for centralized waste management from private and medium/small facilities. It minimizes individual facility capital expenditure, eliminates the need for trained personnel and eliminates the need for extra construction space. In addition, it facilitates compliance, makes it easier to predict cash flow and eliminates the problem of idle capacity. Factors that encourage operators to use shared facilities include guaranteed waste quantity for sizing, accessible site to minimize transport, availability of a final disposal site, secure and safe transport, regulatory authorizations and the possibility of having Memoranda of Understanding with multiple civic agencies.

Centralized waste management in India

In Delhi 25,000 hospital beds are distributed over 1,500 facilities, most of which having fewer than 30 beds. A small proportion (1.5%) of all waste in the city comes from health-care activities. However, this small proportion reaches 60 tons per day. Of these, 15 tons are infectious. Two operators run a central facility. The cost is 10 US cents per day per hospital bed. These costs cover dedicated collection vehicles, waste bag collection, treatment and final disposal. In Hyderabad 413 health-care facilities are using two centralized facilities that handle 1.3 tons per day for a cost of seven US cents per bed per day.

Choosing between on-site and off-site waste management

When hospitals have more than 1,000 beds, on-site facilities may become more cost-effective. However, such health-care facilities need a high-level commitment to the issue of waste management so that the hospital engages in all necessary activities, including segregation, training, transport, storage, occupational safety, sharps management and monitoring. In contrast, the use of off-site facilities allows hospital managers to concentrate on critical in-house issues and to avoid regulatory problems. The question of liability remains however unresolved as the quality of the service may not be documented and the economic viability of the operator is unproven. In conclusion, high-tech centralized facilities can help provide essential services. Size and appropriate technology are critical choices. It should be viewed as only one component of a complete system.

Key discussion points:

- Electric needle destroyers can generate toxins. The legacy to future generations needs to be considered.
- In the case of South Africa, there are only eight hospital facilities that exceed 1,000 beds and transport costs can be overwhelming.
- Needle “de-fanging” has the advantage of segregating the waste and reducing the volume. This may help with safety and recycling. However, the risks associated with splatter and sterilization must be considered.
Case study of Hydroclave implementation in India

Rashid Tamboowalla and Rohini Kelkar
TATA Memorial Hospital and Hydroclave India Ltd, Mumbai, India

Background: health-care waste management issues

The heart of the problem of unsafe health-care waste management is dumping hazardous waste into municipal garbage. Thus, the key is to segregate the hazardous from the non-hazardous waste. A waste audit should estimate how much waste there is in each category to evaluate whether on-site treatment is appropriate or not. Older incinerators produced dangerous emissions and had harmful health consequences. Newer requirements for incinerators are more rigid to ensure safer burning.

The Hydroclave: A solution successfully tested in India

The TATA Memorial Hospital waste management system includes (1) segregation at source using locally-made bags that cost two Indian Rupees per bag, (2) standard waste bins that are colour-coded, (3) educational posters that clarify how to segregate waste, (4) a colour-coded collection network and (5) a Hydroclave. The Hydroclave is an advanced autoclave that has a double wall and uses steam as an indirect heat source. It sterilizes infectious wastes to a high degree Log 6-8 and reduces the weight and volume by an average 75%. Temperature, pressure and time are monitored with each cycle. The system treats 110 kg of waste per hour after manual loading. After sterilization, the material is shredded so that it can go to landfills. Current price for the Hydroclave is US$ 39 000, which does not include an additional US$ 6 000 for the installation. The operating cost is four US cents per kilogram of waste treated.

An advanced autoclave system that sterilizes and shreds health-care waste
(Photo: Hydroclave India Ltd.)
Principles used for the procurement of AD syringes by UNICEF

Public procurement requires integrity, client service, competition, equal treatment and consistency with the objectives of the organization. The objectives of AD syringe procurement include ensuring an affordable quality product and providing adequate service levels from financially sound contracts. Key tender requirements include minimum financial requirements, meeting minimum WHO performance specifications, proven production quality in a field user test, sufficient capacity, appropriate price and responsive account management.

What does UNICEF buy and at what price

UNICEF AD syringe purchases increased from 50 million in 1998 to 200 million in 2000. Projections suggest that 550 million should be bought in 2003. The price per AD syringe unit was 10 – 11 cents in 1998, seven to nine cents in 2000 and we expect five to seven cents in 2002. The quantity offered in 2001 has exceeded our demand, a reflection of an increased market. Prices have fallen as demand has risen. Currently, UNICEF is in the middle of a tender. UNICEF received clarifications. Recommended awards are currently being reviewed by the UNICEF contract approval body. Contract awards will be posted on the UNICEF Internet site.

An increasingly organized evolving market

AD syringes are a new and changing market. Preferences for selected designs at user levels and among manufacturers are changing. There is a steep and increasing demand curve, especially with donor-funded campaigns. To support the change, UNICEF tracks which AD syringe designs go to which countries. This helps to obtain feedback so that UNICEF can be responsive.

Upcoming issues

Upcoming issues include reviewing the physical bundling of AD syringes with safety boxes so that everything arrives at one time in a country. Currently they are fiscally bundled but not physically bundled. UNICEF is also examining the issue of AD reconstitution syringes. Finally, there is an ongoing field user trial of BCG AD syringes in India and Cambodia.

Key discussion points:

• Price has come down, but only for companies that receive large multi-year contracts. It disenfranchises the smaller, newer manufacturers. Manufacturers would appreciate a clearer understanding of the criteria that allow a company to bid.

• Some manufacturers offered only 5% of the UNICEF demand. If a manufacturer proposes an offer that is too small, UNICEF may not have the capacity to fully assess it.
Evaluating the quality of AD syringes in the field: Proposed WHO Tool

Bernadette Gergonne
Epicentre, Paris, France

Background of the proposed assessment tool

At the SIGN 2000 meeting in Cairo, SIGN participants agreed to encourage rigorous evaluation of safer injection equipment. Epicentre was then asked by WHO to design a tool to assess AD syringes in the field.

Terms of reference of the proposed assessment tool

The tool should be a practical tool to evaluate practices in different settings. It must address different disposable devices used for different types of practice in many different settings. Domains to explore include protection and sterility of the device, preparation, injection, recipient perception and destruction.

The proposed data collection instrument

The proposed data collection instrument should be filled after one day of observation by one person for one type of use on one type of equipment. It measures subjective appreciation and ease of use. Items on the current draft instrument need to be validated so that the tool can be feasible, reliable. Comments and suggestions will be welcome during the proposed one-year time period that will be used to develop and field test the tool.

AD syringes use will increase in immunization services over the coming years
(Source: UNICEF)
WHO specifications for immunization AD syringes

Gordon Larsen
WHO, Geneva, Switzerland

The WHO specifications for immunization AD syringes

WHO writes specifications that are used as a purchase requirement for UNICEF to procure immunization AD syringes. The specifications were last updated in 1999. Today, WHO considers potential changes in the specifications for 0.5 and 0.05 ml AD syringes and actively seeks suggestions.

Proposed changes to disposability for both 0.5 and 0.05 ml syringes

The materials used for fabricating all parts of the syringe barrel, piston, caps, seals and any other components should be combustible without production of toxic emissions of any kind. In particular, use of PVC or chlorine-containing plastics, butyl rubber or similar natural rubber-based substances are not acceptable for any part of a syringe or its components.

Proposed change to needle fixing

Fixed, standard or non standard luer-cone with a capped, 0.6 mm x 25 mm needle. For all fixing methods, needles, once attached, should not be removable. Needles and/or needle hubs should withstand an axial pulling force of 34 N without separating from the syringe.

Proposed change to ensure accurate dosing, reduction of errors and ease of use

Colour contrast between piston and barrel of the syringe to be a minimum of colour shades. Transparent or near transparent piston tips should no longer be acceptable.

Proposed change to ensure good standards for syringe manufacture

All manufacturers of ADs should possess current certification to ISO 9001/9002 which extends for at least the period covered by any UNICEF contract.

Future perspectives

WHO is developing new specifications for AD syringes for reconstitution syringes for sizes appropriate for two doses, 10 doses and 20 doses of 0.5 ml vaccine. The specifications will describe a non pre-filled, disposable, AD syringe for two-dose, 10-dose or 20-dose vial that uses a non skin-penetrating spike or transfer device that would easily penetrate vial septa or rubber caps. The penetrating system should allow septa or caps to re-seal following removal and smooth entry of the septa without contamination.

Key discussion points:

• The industry is delighted to improve products based on feedback from customers. However it is important that customer feedback is evaluated carefully. Valid technical data are needed. Complaints need to be heard early and documented. Customer needs should be well understood before any change of the specifications. The industry is less concerned with these specifications than in understanding the process for getting feedback into specification.
Towards ISO standards for AD syringes: An update from WHO

Gerald Verollet
WHO, Geneva, Switzerland

What is a good AD syringe?

A good AD syringe is manufactured according to international standards, used once and easy to dispose of. The immunization market for AD syringes is limited and well defined. It is based upon existing specifications and a WHO-UNICEF policy for use. The curative market has multiple user profiles, no norms and standards and an absence of evidence regarding the effectiveness of AD syringes in preventing reuse in the absence of sterilization in the field.

Towards international standards for AD syringes

The last SIGN meeting recommended that the International Standard Organization (ISO) develop international standards for AD syringes. There are specific ISO standards for medical devices and specific standards for sterile hypodermic syringes for single use. However, there is no specific ISO standard for AD syringes.

Practical steps towards an ISO standard for AD syringes

To develop an ISO standard, a proposal needs to be presented to the ISO Technical Committee 84 as a “new work item proposal”. To develop ISO standards for AD syringes, at least nine out of 16 countries participating in the committee need to accept the “New work item” proposal and at least five need to express interest in working on the issue. If the “New work item” proposal is accepted, then it moves to a preparatory stage where a draft is prepared by experts. The draft then goes to a committee. If accepted, it becomes a draft international standard that will follow a procedure that includes enquiry, approval and publication. The whole process is expected to take one year to 18 months.

Current status of the proposed ISO standard for AD syringes

WHO made contacts with ISO and forwarded a proposal. An AD syringe standard will take time, but in the interim, reference will be made to the existing WHO specifications. Initiatives from the industry to support the project of ISO standards will be welcome.

Current WHO specifications for AD syringes
SIGN meeting

Are you sure it's SAFE?

Thursday 30 August 2001
Friday 31 August 2001
Policy and plans for the safe and appropriate use of injections

The new injection safety policy of the Global Alliance for Vaccines and Immunization (GAVI)

Steve Landry
USAID, Washington, DC, USA

What is the GAVI alliance?

GAVI is an alliance that includes industry as a full fledged partner, as well as UNICEF, WHO, the World Bank and the Bill and Melinda Gates Foundation. GAVI raised one thousand million US dollars for the Vaccine Fund, 98% of which will be going to countries. So far, 37 countries have received awards from the Vaccine Fund.

GAVI and injection safety

GAVI places a high priority on injection safety. First, an injection safety component needs to be included in country plans. Also, GAVI is bundling each dose of new vaccine supplied by the Vaccine Fund with an AD syringe and adapted quantities of sharps boxes. Unmet injection safety needs identified by GAVI included the limited support available to assist countries in their transition to the use of AD syringes for all vaccines, the absence of ownership of the problem by local parties, the limited government support to develop and implement long-term plans and the lack of guidance and support to manage health-care waste resulting from immunization efforts. To address these unmet needs, the GAVI board endorsed in June 2001 the “bundling” policy at their fifth meeting in London. A commitment was made to apply the WHO/UNICEF/UNFPA Joint Statement to “bundle” AD syringes and safety boxes to new vaccines funded by the Vaccine Fund. To facilitate transition to AD syringes, the GAVI board took the “bundling” policy further and decided to provide AD syringes and safety boxes for all other traditional routine immunization injections for three years in all countries that received approval for application by the Vaccine Fund. GAVI also committed to follow the “Aide Mémoire” on health-care waste management. Each country must include a plan to develop a national policy for safe immunizations. This new GAVI policy will address the issue raised by the introduction of new vaccines with bundled AD syringes in countries where most immunization were given with sterilizable injection equipment.

The responsibility that we share to ensure safe injection practices

(WHO poster)
Towards a national policy for the safe and appropriate use of injections in Vietnam

Khong Chien
Ministry of Health, Hanoi, Vietnam

A pilot evaluation to direct prevention efforts

To provide guidance to an injection safety policy in Vietnam, a pilot evaluation was conducted in six hospitals and one health centre in Hanoi. Among 3,443 injections observed, 50% were intravenous and 49% were intramuscular or subcutaneous. Of these, 99.97% used a disposable syringe and 17.7% were followed by appropriate discarding in a sharps box.

A cross-sectional working group to address injection safety

The study led to a number of recommendations. The Ministry of Health should develop a steering committee to formulate an injection safety strategic plan. Hospitals should evaluate the safety of injections and medical schools should improve training. A working group on safe injection practices consisting of members from the Ministry of Health and of members from the National Institute of Hygiene and Epidemiology has been formed. The Ministry of Health has coordinated a communication campaign to use sterilized syringes and needles and to reduce the overuse of injections. It also promulgated a regulation on the safe management of solid health-care waste and developed a policy to protect health-care workers.

A souvenir given as a present by the Vietnam delegation to the 2001 SIGN meeting
Toward a national policy for the safe and appropriate use of injections in Nepal

Bal Krishna Suvedi  
Ministry of Health, Kathmandu, Nepal

The EPI injection safety policy in Nepal

Nepal’s immunization injection safety policy since 1989 was one syringe, one needle, one shot. For the implementation of this policy, the use of sterilizable syringes and steam sterilization was adopted. However, since 1999, AD syringes are now used for mass campaigns and subsequently burned and buried with the help of safety boxes.

A qualitative assessment in 2000

A qualitative assessment of injection practices conducted by an NGO in May 2000 reported that steam sterilizers were universally used but that there was a short supply of needles in some places. Reports specified that sometimes one syringe was used with multiple needles and that children played with discarded contaminated equipment. While health-care workers were generally aware of injection safety, they were uncertain of how to achieve it.*

A national injection safety assessment in 2001

The Ministry of Health of Nepal conducted an injection safety assessment using the WHO SIGN standardized tool in 30 districts covering 90 sessions through three weeks of field work. Preliminary results are available. Use of pressure sterilization is universal but gaskets are leaking and no timers were observed. The one syringe, one needle, one shot policy was observed, but other safety procedures were not always implemented. There was a short supply of needles and syringes in a few districts. Safety concepts were not clear among vaccinators and sharps disposal practices were unsafe.

Future perspectives

Current plans include (1) completing the assessment report by September 2001, (2) drafting and gaining approval for a national policy by December 2001 and (3) conducting training by March 2002.

Key discussion points:

- In Nepal, the combined use of AD syringes for campaigns and sterilizable equipment for routine activities might cause confusion among health-care workers. Health-care workers need to carry vaccine from the regional depot, sometimes travelling for three days. Carrying syringes and sharps boxes to these remote outposts may not be practical.

* This report was presented at the SIGN meeting 2000 in Cairo.
Data for decision making

Global burden of disease attributable to contaminated healthcare injections

Gregory Armstrong
CDC, Atlanta, GA, USA

Background

Unsafe injections given in health-care settings have been associated with hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) infection. However, the global burden of these infections attributable to unsafe injections is unknown.

Methods

To estimate the fraction of incident HBV, HCV and HIV infections attributable to contaminated injections in the health-care setting, we developed a mathematical model. The model was based on the annual ratio of injections per person, the proportion of injections that were reused in the absence of sterilization, the transmission rate after percutaneous exposure and the age- and region-specific prevalence, proportion immune and incidence of HBV, HCV and HIV infections. Data sources included published reports and unpublished WHO documents such as evaluations of national immunization programmes and reports to the SIGN Secretariat. Fourteen regions were defined by the Global Burden of Disease project based on mortality patterns and geography. The analysis excluded four regions (predominantly affluent, developed nations) where reuse of injection equipment in the absence of sterilization was negligible.

Results

In the 10 regions analyzed, the average annual ratio of injections per person was 3.7, with a range of 1.1 to 5.2. The proportion of injections administered with equipment reused in the absence of sterilization was 40.6%, ranging from 1.5% to 74.2%. Reuse was highest in regions SEAR D (seven countries including India and Bangladesh), EMR D (nine countries including Egypt and Pakistan) and WPR B (22 countries including China, Vietnam and the Philippines) which together accounted for 92% of the 7.5 billion injections given annually with equipment reused in the absence of sterilization in the world. Overall, contaminated injections accounted for 34% of HBV infections, 42% of HCV infections and 2% of HIV infections in the regions where reuse of injection equipment occurs in the absence of sterilization.

Conclusions

Injection overuse and unsafe practices are common worldwide and account for a high burden of infections with bloodborne pathogens. In many countries there is an urgent need to achieve safe and appropriate use of injections.

Key discussion points:

- Concerns were expressed about the adequacy of extrapolation from limited data points and the presentation of maps showing different countries having different rates when country-specific data were not available. The presenters acknowledged the need for more country-specific data but argued that these were the best available estimates and that such estimates are important for planning purposes.
Cost-effectiveness of safe injection policies: Study rationale and proposed methodology

Ulla Kou
WHO, Geneva, Switzerland

The need for cost-effectiveness estimates

The SIGN secretariat has received funding from the US National Vaccine Programme Office (NVPO) through the United States Agency for International Development to develop a model for estimating the cost-effectiveness of implementing safe and appropriate use of injection policies. While the overall methodology for this work has been developed, the SIGN secretariat welcomes suggestions and participation from SIGN participants.

The objectives of the planned project

The cost-effectiveness analysis will estimate the net costs of preventing infection and/or saving a life from implementing safe injection policies. Furthermore, the cost-effectiveness of safe and appropriate use of injection policies will be compared to other health interventions. Cost-effectiveness analyses are increasingly needed to advocate on the basis of evidence with Ministries of Health, Ministries of Finance, donors and the international community.

Proposed methods to estimate the cost-effectiveness of safe and appropriate use of injection policies

The overall method will be based on adding cost data to the burden of disease model that has already been developed by WHO (See Global burden of disease attributable to contaminated health-care injections). An incremental cost-effectiveness ratio will be calculated by comparing the "do nothing" scenario with a scenario where a safe and appropriate use of injection policy is implemented to various degrees. The outcome measures will be the cost per HBV, HBC and HIV infection prevented, the costs per death prevented and the costs per DALY gained.

The work ahead

An economist will be employed at WHO headquarters for 11 months to construct the model, identify data gaps and coordinate data collection in selected countries. The terms of reference for this position will be advertised on the SIGN Internet site by the end of September 2001. When the work is finalized the model will be published on the SIGN Internet site for easy use in different settings.

Years of life lost because of unsafe injections: A child with cirrhosis in Asia

(Photo WHO)
The rationale for assessing injection safety

Injection safety assessments identify local problems, provide a baseline, open the door to dialogue among stakeholders and support local ownership of the problem.

Objectives of injection safety assessment

The specific objectives of these assessments were (1) to determine if the country meets necessary requirements for staff competence, equipment, supplies and waste disposal, (2) to assess if the injections are administered according to recommended best practices, and (3) to estimate the proportion of health-care facilities where injection practices are safe.

Standardized methods of assessing injection safety

All assessments were based upon a standardized representative sample. A two-stage cluster sampling of 80 facilities in eight districts provides representative figures for the country. A cross-sectional observation of supplies available and injection procedures was conducted together with interviews of health-care workers.

A number of countries have conducted their assessment, more are planning it

Assessments have been conducted in 14 countries and additional assessments are planned in the coming months. Results from the first nine countries are available: Three countries were not using sterilizable injection equipment any more, six are using at least some sterilizable equipment and one is using AD syringes. Two countries bundle vaccine, injection equipment and safety boxes.

Difficulties to ensure safety with sterilizable equipment

100% of health-care facilities used sterile equipment for all observed injections in only one country where standard disposable syringes were used. In the six countries using sterilizable equipment, sterilization was not regularly documented with TST spot and only 55 – 88% used sterile equipment for each injections. Countries using AD syringes had them available in only 50–85% of facilities.

Challenges in waste collection and management

Safety boxes were found in 60% of facilities. Syringes were recapped dangerously using a two-handed technique in 54% of facilities. No contaminated sharps were found in the surrounding area in 50% of facilities. Only 5% of facilities had a health-care waste management policy.

Key discussion points:

- These assessments are limited to public sector health-care facilities. Thus, the results cannot be extrapolated to private sector health-care settings or to informal providers. Countries may need assistance in translating these assessments into action plans. Local costs for one assessment are estimated to be US$10 000 (To which about four weeks of consultant fees needs to be added).
**Advocating for the safe and appropriate use of injections**

**Global advocacy strategy for SIGN**

Susan Mackay  
WHO, Geneva, Switzerland

Defining what advocacy is

We are all part of the advocacy strategy of the SIGN network. Advocacy is a continuous process of gathering, organizing and formulating information into arguments to be communicated through various interpersonal and media channels with a view to raising resources and gaining political or social leadership acceptance and commitment, thereby preparing a society for its acceptance.

What should the injection safety advocate do?

An advocate will research the issue, believe in the issue, look for real examples, plan for small changes, be passionate, persuasive and focused. Advocacy efforts will be more effective if they set objectives, define a plan, secure resources and evaluate outcomes.

Contribution from the SIGN secretariat

The SIGN secretariat can provide global research. We created “document X”, an advocacy tool that we will publish to encapsulate key arguments to use for advocacy. In addition, a document called “How do I become an advocate for injection safety” was developed and is available on the SIGN Internet site at www.injectionsafety.org/toolbox.

Key discussion points:

- A picture can be worth 1,000 words. This is important because many times we do not have the time for 1,000 words. Professional associations were also identified as particularly important groups for advocacy.

**A briefing document for senior decision-makers**

(WHO document)
The injection safety working group of the GAVI advocacy task force

Heidi Larson and Rebecca Fields
GAVI Advocacy task force, c/o UNICEF, New York, NY, USA

Mission statement for the GAVI Advocacy task force

The mission of GAVI’s Advocacy and Communication Task Force is to raise global awareness of the key role that immunization plays in building healthy societies and to respond to growing inequities in access to vaccines with an increased public commitment to immunization. The messaging/branding subgroup will develop and disseminate core messages on GAVI, highlighting the value of vaccines and supporting the introduction of new vaccines. The special events subgroup will look at opportunities to place immunization in special events and conferences, particularly in those related to broader development issues and health events. The country support subgroup will support the strengthening of communication and social mobilization at country level to increase access to safe immunization. The injection safety subgroup will use advocacy, communications and behaviour change to focus on improving injection safety for immunizations.

Objectives for injection safety advocacy

The GAVI advocacy task force wants donors to build injection safety into their agendas, policies, plans and budgets. The task force also wants countries to develop, adopt and implement policies and plans allocating sufficient resources to do so. Finally, the task force wants health-care workers to improve their practices to minimize risks.

Proposed strategy

The task force wants to promote strategic exchange of experience, guidelines and policies by providing the right information to the right people at the right time. The task force wishes to learn from SIGN participants regarding perceived major unmet needs for advocacy and communication to support injection safety.

Driving progress in injection safety through the documentation of practices
(Source: WHO V&B)

Injection Safety Assessments
June 2000-August 2001

Assessments planned (14 countries)
Assessments done (14 countries)
Systematic documentation of success stories

Arshad Altaf
Aga Khan University, Karachi, Pakistan

Background

New information systems, technologies and interventions promise benefits, but require better use. SIGN’s advocacy strategy involves stressing interrelationships and promotion of the “first do not harm” principle.

The need for success stories

Injection safety is still under-recognized in settings where it is a problem. Many feel that nothing can be done. Thus, there is a need to document systematically all success stories. The objective is to publish updated positive impact to inspire and teach.

An electronic newsletter on the SIGN homepage

Success stories are placed on the homepage of the SIGN Internet site at www.injectionsafety.org. Recently Albania’s successful immunization campaign with its focus on safety was highlighted. The next story will be on Burkina Faso and its recent improvement of injection safety through increased access to injection equipment.

Safe injection practices during a vaccination campaign in Albania
(Photo: UNICEF)
SIGN: The network at work

Activity report for the SIGN secretariat

Yvan Hutin
WHO, Geneva, Switzerland

Differentiating the network and its secretariat

The WHO SIGN secretariat is often perceived as “SIGN”. However, SIGN refers to the whole Safe Injection Global Network while the secretariat is just the WHO component that facilitates the work of the alliance. The WHO department of Blood Safety and Clinical Technology (BCT) coordinates safe and appropriate use of injection activities. BCT handles (1) SIGN secretariat activities and (2) other activities to promote the safe and appropriate use of injections.

BCT activities to host the SIGN secretariat

The SIGN secretariat activities include (1) the annual SIGN meeting (1999 in Geneva, 2000 in Cairo and 2001 in New Delhi), (2) an electronic mail list server (SIGNpost) and (3) an Internet site at www.injectionsafety.org. Use of electronic media provide an inexpensive way to make documents widely available. While the network is still young, basic tools are in place. Every year we can feel more comfortable saying “We are SIGN”.

BCT activities for the safe and appropriate use of injections worldwide

The WHO BCT department has four objectives for the safe and appropriate use of injections worldwide. These are:

(1) Policy
   To strengthen the capacity of countries to formulate, implement, monitor and update safe and appropriate use of injection policies. Products under this objective include template policies and data for decision making.

(2) Quality and safety
   To ensure the quality and safety of injection devices. Products under this objective include norms and standards and strengthening national regulatory authorities.

(3) Access
   To ensure equitable access to injection device. Products under this objective include bundling of injection equipment and purchasing guidelines.

(4) Use
   To promote appropriate, rational and cost-effective use of injection equipment. Products under this objective include best practices reference guidance and a toolbox for behaviour change.
Use of the Internet is key to diffuse messages to selected innovators who can disseminate innovation further. The Internet also allows 24-hour access in a large variety of settings, including in developing countries. People who have to access the SIGN Internet site through slow phone lines can get documents mailed to them on a CD-ROM. The SIGN Internet site now features a new toolbox that can be accessed from the homepage with an animated logo. The toolbox allows searching for tools, including the newer tools recently developed to promote behaviour change.
SIGNpost: The SIGN electronic mail forum

Alan Bass
Australian Centre for Tropical and International Health and Nutrition, Herston, Australia

What is SIGNpost?
SIGNpost is a moderated discussion that provides a venue for collaborative work, presentation of work and discussion of new ideas. It can be used to disseminate tools, announce resources (e.g., policy documents, papers, abstracts, technical developments, strategies to prevent unsafe injections and news from industry) and advertise for jobs.

How does SIGNpost work?
SIGNpost is a weekly electronic mail that comes in text format. A convenient table of contents allows the user to quickly browse the post for issues of potential interest. Backissues are archived and made available for download via a web browser or ftp at: ftp://acithn.uq.edu.au/signfiles/SIGNpostArchives.

Who subscribes to SIGNpost?
The number of subscribers to SIGNpost rose from 20 in October 1999 to 701 in August 2001. Subscribers include health-care workers, government workers, international agencies, bilateral agencies, communicable disease specialists, health-care programme managers, other ListServ moderators, journalists, researchers, managers, engineers, anthropologists, behavioural scientists, economists, educators, trainers, manufacturers, industrial designers and victims of unsafe injections. Participants are from Asia, Africa, the Americas, Europe and Pacific Islands. Individuals can subscribe via the SIGN Internet site at www.injectionsafety.org or by email at sign@who.int.

Who contributes to SIGNpost?
The content of SIGNpost comes from all SIGN participants. Everyone is encouraged to send material. To contribute, click “reply” when you get the SIGNpost message or send your note to sign@acithn.uq.edu.au.

Key discussion points:
- Government workers cannot always contribute to SIGNpost because of clearance issues. However, they appreciate it every week.

What a bank of information I am having now!!
(All received from SIGNpost)

Dr Patrick Isingoma
EPI Uganda
SIGNPost 094 – 14 November 2001
Quality of injection equipment

Injection equipment recycling in Pakistan

Arshad Altaf
Aga Khan University, Karachi, Pakistan

Objectives of the study

To evaluate the risks of infection with bloodborne pathogens associated with breaks in universal precaution and how health-care waste produced by clinical laboratories in Karachi, Pakistan is managed.

Design

Interviews with a convenient sample of persons and observations of clinical laboratory procedures and disposal of health-care waste. Settings for the study included clinical laboratories, community waste sites and a particular area of the city where used goods are sold.

Participants

Pathologists and technicians working in clinical laboratories, dealers of health-care waste and used syringes, sweepers and scavenger boys.

Results

Out of 50 laboratories identified, 44 could be investigated. Only 4% of the 44 laboratories used gloves, the most important barrier protection. Protective gowns were observed in 27%. While needle cutters were available in 28 laboratories (64%), they were used in only eight sites (18%). Uncut needles were disposed of at community waste sites 80% of the time. An incinerator was available and reportedly used at 7 laboratories (16%). A total of 17 sweepers and 25 scavenger boys were interviewed in the study. All said that used syringes are sold to dealers in a particular part of the city. Ten dealers of medical waste and eight dealers of used syringes confirmed buying syringes along with other plastic wares like drips and blood bags from scavenger boys and the sweepers of medical facilities at US$ 0.06-0.19 per kg and they are reportedly sold to plasticware industry for remoulding.

Conclusion

Education of health-care workers about universal precautions and proper disposal of waste is urgently needed in Pakistan. A monitoring system should be developed to ensure safe infection control practices.

Key discussion points:

- The disease burden associated with these unsafe practices, particularly among persons handling waste, should be estimated. Dr Altaf mentioned that he would be in the position of conducting such a study if funding was made available.

- The government of Pakistan recently drafted an ordinance on medical waste. However, the impact that this will have in the future is not yet clear.
Disposable syringes and needles: Construction of an evaluation tool for field assessments

Bernadette Gergonne
Epicentre, Paris, France

The proposed tool was presented again by Bernadette Gergonne (See Evaluating the quality of AD syringes in the field: Proposed WHO Tool, Page 15).

Key discussion points:

- The primary goal of the tool is to determine the relative advantages that different designs of syringes may bring to health-care workers in the field. A secondary goal is to feedback this information to the manufacturer. Syringe manufacturers considered this to be a useful tool to get feedback, to identify deficiencies and to learn what needed to be improved, especially in the case of AD syringes. Such a tool will represent an important step to develop functional standards and norms.

- While such an assessment could have been broadened to include sterilizable syringes, the focus was intentionally restricted to disposable injection equipment. Ultimately it is hoped that this exercise will contribute to evidence-based standards for injection equipment.

- It would be helpful if this tool were adaptable to the private sector where the majority of health-care is dispensed.

- Other suggestions regarding the tool included: (1) assessment of intent versus functionality (e.g., do AD syringes really disable?), (2) collecting information on the injection provider, (3) addressing occupational safety, (4) estimating the proportion of syringes wasted and (5) examining packaging.
Feedback from the injection technologies day

Gerald Verollet and Lillian Salerno
WHO and IASIT, Geneva, Switzerland

Proposed roles for IASIT within the SIGN network

IASIT will support with both financial and human resources meetings or forums where an immediate need is recognized. With respect to standards, the association has a committee that will participate in the review of proposed specification changes and contribute to the proposed ISO standards. For transfer of technology, IASIT has a working group to participate in the preparation of recommendations. IASIT also want to review and participate in the development of the WHO end-user evaluation tool. IASIT is concerned about health-care waste management, will collaborate fully with all stakeholders and will provide feedback regarding this issue at upcoming SIGN meeting. Finally, IASIT is willing and ready to consider proposals for relevant studies.

Key discussion points:

- We now have a forum to collect input from both industry and other partners to address the issue of waste management that is key to acceptance of AD syringes. Suggestions for improving waste management included making wrappers for syringes from chlorine free plastic and using materials with a view towards environmentally sound waste treatment and recycling.

- If the syringe manufacturing industry organizes itself too much there is a risk of collusion. Thus, IASIT has sought and is guided by legal counsel.

- IASIT requests to be copied on tenders and specifications and to be notified by UNICEF on bids so that they are able to disseminate information.

Used syringes shredded for recycling in the plasticware industry
(Photo: SIGN Pakistan)
Increasing access to safe injection equipment

Increased access to injection equipment in Burkina Faso: When essential drug programmes improve injection safety

Sophie Logez
Pharmaciens Sans Frontières (PSF), Clermont-Ferrand, France

Objectives and methods of the study

The objective was to evaluate the impact of a National Drug Policy on injection safety between 1992 and 2001. The methodology was a two-stage cluster sample of health-care facilities.

Dramatic improvement of injection safety in Burkina Faso between 1995 and 2000

Compared to widespread reuse of injection equipment that exceeded 50% of health-care facilities in 1995, reuse of equipment was observed in 4% of health-care facilities in June 2000. Sharps were found in open containers in 83% of settings and found around 57% of health-care centres.

The national drug policy: A key to understanding the change

The national drug policy provided a framework for improved availability of essential drugs and injection equipment in Burkina Faso. Inclusion of disposable injection equipment in the national essential drug list allowed tax exemptions. At district level, wholesalers and supervisory teams were set up. Community pharmacies provided supplies at the health-care facility level using a cost recovery scheme that made drugs and injection equipment available at low cost to the population.

Accessibility and affordability of injection equipment in Burkina Faso

The proportion of health-care facilities that had access to a community pharmacy increased from 5% in 1992 to 95% in 2000 in Burkina Faso. The number of 5 ml syringes sold in the country increased from 884,000 in 1996 to 1,840,000 in 2000. The price of new 5 ml syringe is 10 cents and remained stable. Injection equipment is judged affordable by 88% of pharmacists and 55% of buyers. Thus, availability and affordability of injection equipment may have contributed to improved injection practices in Burkina Faso between 1995 and 2000. However, the most dramatic change observed was an improved geographical access since the price of injection equipment remained stable.

Additional progress to make for the safe and appropriate use of injection in Burkina Faso

Recommendations of the assessment included that access could be improved by monitoring prices and profit margins. Improved access to sharps boxes could occur through cost recovery and inclusion in essential drug lists since this mechanism was successful in the case of syringes and needles.

Key discussion points:

- The situation in Burkina Faso illustrates the synergies that can be created between the immunization and curative sectors. Rational drug use enhances attention to injection safety. The pharmacists understand the implications of safety. Cost recovery shows that patients have a willingness to pay for the commodities that they need.

- This example highlights the role of private pharmacists. This is a group for which we as SIGN should have an outreach strategy.
Bundling for family planning injections

Tabitha Keener
USAID, Washington, DC, USA

Why bundle AD injection equipment and boxes to injectable contraceptives?

As part of USAID's commitment to ensuring quality in service delivery programmes, USAID decided to supply AD syringes and sharps containers with shipments of medroxyprogesterone (Depo-Provera®, referred to as DMPA). Injections provided through family planning services are a small part of the 12 thousand million injections estimated to be provided each year and generally believed to be among the safest. The availability of new technologies (AD syringes) provides an opportunity to further highlight to service providers the importance of safe injection and disposal practices. USAID believes in the replacement of disposable syringes with AD syringes and in the provision of sharps containers. These decisions represent another indication of USAID's commitment to supporting the provision of the highest quality family planning services.

How will USAID work to implement bundling?

USAID is planning to launch the provision of AD syringes and sharps containers in October of 2001. Currently, USAID's shipments of DMPA are physically bundled with standard disposable syringes to help ensure that injections are given safely. The new shipments will also be bundled with one AD syringe for every vial of DMPA and one sharps container for every 100 vials. In preparation, USAID has undertaken several small field trials, the most recent being a pilot launch in Uganda. The major findings of this pilot assessment include:

- Providers in clinical settings in Uganda found the use of AD syringes to be easy.
- The experience in Uganda suggests that somewhere between 0 – 5 syringes (and smaller amounts of DMPA itself) per provider will be “wasted” per site during the short introductory period, due to practice or to "locking" before providers become comfortable with the technique. This small wastage rate should not require adjustments to forecasts or procurement decisions regarding DMPA during the introductory period.
- Safe waste disposal is a major issue to be addressed, but the disposal of AD syringes is no more problematic than for standard syringes.

Improvement of access to injection equipment parallels improvement of injection safety in Burkina Faso in the 1990s (Source: PSF)

[Graph showing improvement of access to injection equipment and proportion of reuse of injection equipment without sterilization]

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Appropriate, rational and cost-effective use of injections

Best infection control practices ID, SC and IM injections

Mary Catlin
University of Arizona, Tucson, AZ, USA

What best practices are

This group focused the practices of the injection provider that could spread bloodborne pathogens. Best practices were defined as those that minimize the risk of bloodborne pathogen transmission based on current evidence. These are not minimum standards, but “best practices” that countries can modify based upon the risks associated with current practices and cost of adopting practices in their programmes.

We divided evidence available for specific practices into three categories:

- Strongly recommended and supported by research with appropriate study design and analysis.
- Strongly recommended on the basis of strong theoretical rationale and suggestive evidence.
- Evidence does not exist, but there is expert consensus.

Four scientifically supported practice areas

These include (1) the use of sterile injection equipment, (2) preventing contamination of equipment and medication, (3) preventing needlestick injuries and (4) preventing contact or access to used needles.

Other practice issues

These included (1) use of engineered technology, (2) hand hygiene, (3) use of gloves for providing injections, (4) swabbing vials for ampoules and (5) skin preparation prior to injections.

A simple pamphlet was developed to communicate best practices to health-care workers. Pictogrammes were also developed to illustrate each of the points. These can be downloaded from the SIGN Internet site at www.injectionssafety.org/toolbox.

Key discussion points:

- Wearing gloves can result in latex allergy, asthma and anaphylaxis. Five deaths were reported among nurses in the USA.
- Stronger evidence than quoted in the document may be available on engineered technologies to prevent needlestick injuries. This should be re-examined.
- Pictures do not always cross cultures easily. Because compromises were made between exactness and easy understandability, all material should be pre-tested before use.
A WHO-sponsored working group for waste management

WHO formed a health-care waste management working group with external and internal resources. WHO is a normative agency that also tries to provide technical support. Comments are always welcome and the working group is interested in identifying case studies and new technologies adapted to specific situations. The WHO-sponsored working group on health-care waste management has an Internet site at www.healthcarewaste.org.

Products

WHO drafted national action plans, decision-making guides, a database of technical options for waste treatment, “Aide Mémoires” on safe management of wastes from health-care activities, teachers’ guides to the management of waste, decision-making guides for primary health-care and a rapid assessment tool. Additional tools are planned, including a waste management selection guide and guidelines for developing health-care waste management plans. An on-line database of waste management options is still under development. It currently lists 27 waste management options. WHO would like to add five to 10 per month, after peer review. Options should be relatively safe and environmentally friendly.

Managing sharps waste in a safe, affordable and environment-friendly way

(WHO pictogramme)
Behaviour change for injection safety

Susan Mackay
WHO, Geneva, Switzerland

Four problems - four solutions

There are four major problems contributing to unsafe injections: (1) injection overuse, (2) reuse of injection equipment in the absence of sterilization, (3) unsafe sharps collection, and (4) unsafe waste management. There are four solutions to these four problems: (1) rational use of injections, (2) use of sterile injection equipment, (3) safe sharps waste collection and (4) safe sharps management. Behaviour change is the glue that holds these solutions together.

Six behaviours needed to reach the four solutions

Six behaviours are needed to reach the four solutions. First, prescribers must prescribe oral medications whenever possible, second, patients should request oral medications, third, injection providers must use a sterile needle and syringe for every injection, fourth, patients must demand safe syringes, fifth, injection providers must collect sharps immediately in a sharps box (without recapping) and sixth, injection providers must manage sharps waste safely.

The circle of change

One needs to:

- Hear the message (appropriate channels, mass media at appropriate times);
- Understand the message (appropriate language, dialect, tone, style and level);
- Remember the message (ensure repetition, simplicity and stickiness);
- Discuss the message with friends and family (make it talk-provoking to reach secondary audience);
- Feel the relevance to your needs and life (testimonies and behaviour modelling);
- Like the message (popular formats, personalities, emotions and humour);
- Act on the message (be irresistible, motivating and offering something tangible, feasible, accessible and affordable);
- Talk about it to other people (if it’s a success they’ll want to tell others).

Fear appeals work if they are combined with a feasible, affordable and attractive solution to the problem.

Key discussion points:

- There are some people not readily reached by mass media, for which other solutions for communication need to be sought. Storytelling and posters with a calendar have been popular in some settings.
- Although mass media is expensive, when people are brought on board a broadcaster can become a partner. A popular soap opera, for example, might be willing to integrate a behaviour change message.
Action points

The SIGN participants agree that poor injection practices, including injection overuse and unsafe practices, transmit pathogens on a large scale, waste precious health-care resources and can be eliminated. To implement policy and plans for the safe and appropriate use of injections, the SIGN participants recommend holistic approaches that include (1) behaviour change among patients and health-care workers, (2) provision of safe injection equipment and supplies and (3) sharps waste management. More specifically, during the 2001 annual meeting, the SIGN participants pledged to engage in the following practical actions in the coming year:

**General**

The SIGN participants will engage in joint resource mobilization efforts with the assistance of the SIGN secretariat, which may include the recruitment of a specific short-term staff member.

**Indicator:** Resources mobilized by the network

**Safe and appropriate use of injection policies**

The SIGN participants will assist in the formation of national SIGN coalitions as described in the injection safety “Aide Mémoire”.

**Indicator:** Number of national SIGN coalitions

The SIGN secretariat will take input from the SIGN participants to develop a practical “Injection safety programme planning aid”.

**Indicator:** Availability of a draft document ready for field testing

The SIGN participants who have a specific interest in the issue will create a SIGN working group to engage health-care workers in all aspects of injection safety, including health-care worker protection.

**Indicator:** Identification of key steps and availability of key materials, including an “Aide Mémoire” for health-care worker protection

The SIGN participants will advocate for the adoption and dissemination of policy statements by professional associations of health-care workers calling for safe and appropriate use of injections.

**Indicator:** Adoption of policy statements by professional associations

The SIGN secretariat will take input from the SIGN participants to develop a SIGN advocacy kit, identify audiences and proposed distribution channels.

**Indicator:** Availability of a draft document ready for field testing

The SIGN participants located in regional WHO offices will create SIGN working groups.

**Indicator:** Number of regional WHO offices reporting on the formation of a SIGN working group
Quality and safety of injection equipment

The SIGN network will support an improved, peer-reviewed mechanism to formulate WHO specifications for AD syringes so that the process can progressively evolve towards ISO standards.

**Indicator:** Availability of ISO standards for immunization AD syringes

The SIGN network will generate more evidence regarding requirements for and the use of AD syringes in curative services.

**Indicator:** Initiation of one pilot project for introduction of AD syringes in curative settings.

The SIGN network will generate more evidence on the public health importance of reprocessing and repackaging of used disposable injection equipment.

**Indicator:** Availability of estimates of the proportion of injections given with recycled / repackaged syringes in selected regions where this practice is suspected of being a problem (e.g., South Asia).

The SIGN secretariat will take input from the SIGN participants to develop practical guidelines to strengthen National Regulatory Authorities.

**Indicator:** Availability of a draft document ready for field testing

Access to injection equipment

The SIGN network will advocate for the inclusion of matching quantities of injection equipment and sharps collection boxes to all orders and deliveries of injectable medications.

**Indicator:** Inclusion of recommendations to increase access to injection equipment in WHO model essential drug list

The SIGN participants who want to purchase AD syringes will communicate to the International Association of Safe Injection Technologies (IASIT) their needs and expectations.

**Indicator:** Availability of a database of AD syringes purchasers

WHO will provide technical guidance to facilitate the introduction of AD syringes in countries.

**Indicator:** Availability of a draft document ready for field testing

Safe, appropriate, rational and cost-effective use of injections

The SIGN network will identify key activities to be conducted with other initiatives, including Essential Drugs (EDM) and Integrated Management of Childhood Illnesses.
(IMCI) to (1) reduce injection overuse and (2) prevent reuse of injection equipment in the curative sector.

Indicator: Identification of a set of activities to be conducted with EDM and IMCI

The SIGN participants will increase the efficiency and usefulness of the WHO database on health-care waste management options through systematic network efforts to include and peer review all options relevant to developing countries.

Indicator: Number of options added to the database

The WHO-coordinated health-care waste management working group will formulate a short paper describing urgent needs in the area of technology development to improve health-care waste management in developing countries.

Indicator: Availability of a consensus paper

The SIGN participants will encourage local production of puncture and liquid-proof boxes for the collection of contaminated sharps.

Indicator: Availability of new sharps collection boxes

The SIGN participants will advocate for the use of environment-friendly material for injection equipment, their packaging and collection boxes.

Indicator: Availability of a list of compounds that should not be used for the manufacture of injection equipment and waste collection boxes

The SIGN participants will generate evidence regarding the feasibility of safe plastic recycling options, which could include the use of international plastic recycling symbols.

Indicator: Availability of new plastic recycling options

The SIGN participants will involve stakeholders in environmental issues in the activities of SIGN.

Indicator: Engagement of UNEP in the work of SIGN

The SIGN participants will explore possibilities to develop systems to collect and manage sharps waste centrally in selected settings.

Indicator: Identification of settings where centralized waste management systems may be effective and cost-effective
Appendices

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Appendix 1: List of participants

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Appendix 2: Programme of work

Wednesday, 29 August 2001: Injection and waste management technologies day

8:15 - 8:30 Election of chairperson and rapporteur

Opening session: Injection equipment from production to disposal

8:30 - 8:45 Life cycle of medical devices Gerald Verollet
8:45 - 9:00 Waste minimization: Role of manufacturers Richard Carr
9:00 - 9:15 GAVI research and development task force Michael Free
9:15 - 9:45 Working together for safer technologies Group discussion

Morning session: State of current safe injection technologies

9:45 - 10:15 Part 1. Needle-free technologies Mike Mathews
10:15 - 10:30 Panel question and answer session Group discussion
10:30 - 11:00 Coffee break
11:00 - 11:40 Part 2. Auto-Disable (SD) injection technologies Lillian Salerno
11:40 - 12:00 Panel question and answer session Group discussion
12:00 - 13:30 Lunch

Afternoon session: Waste management

13:30 - 14:00 Introducing technologies Richard Carr
14:00 - 14:15 Contest for low-cost technology solutions Susan Wilburn and Jorge Emmanuel
14:15 - 14:55 High-tech centralized facilities in developing countries: Are they realistic? Jorge Emmanuel and Ravi Aggarwal
15:55 - 16:30 Case study of Hydroclave implementation in India Rashid Tamboowalla and Rohini Kelkar
15:30 - 16:00 Action points for injection equipment and sharps waste disposal Group discussion
16:00 - 16:30 Coffee break

Meeting with AD syringe manufacturers

16:30 - 16:45 Procurement and tender issues Shanelle Hall
16:45 - 17:15 Evaluating the quality of AD syringes in the field: Proposed WHO tool Bernadette Gergonne
17:15 - 17:30 WHO specifications for immunization AD syringes Gordon Larsen
17:30 - 17:45 Towards ISO standards for AD syringes Gerald Verollet
17:45 - 18:00 Round table: Action points Group discussion

Evening: Poster session followed by the Joint SIGN / TechNet Gala Dinner
Thursday, 30 August 2001: SIGN Meeting, Day 1

Morning: Policies

8:45 – 9:00 Election of chairperson and rapporteur
   Formulating policies and plans for the safe and appropriate use of injections

9:00 – 9:20 The new GAVI injection safety policy Steve Landry
9:20 – 9:40 Towards a national policy in Viet Nam Khong Chien
9:40 – 10:00 Towards a national policy in Nepal Bal Krishna Suvedi
10:00 – 10:30 Coffee break
   Documenting the global burden of disease associated with unsafe injection practices

10:30 – 10:50 Global Burden of Disease Gregory Armstrong
10:50 – 11:10 Cost-effectiveness estimates Ulla Kou
11:10 – 11:30 The WHO injection safety assessment tool Charles Antoine Hofmann

Advocacy for policy and plans for safe and appropriate use of injections

11:30 – 11:50 Global advocacy strategy for SIGN Susan Mackay
11:50 – 12:10 Injection safety working group within the GAVI advocacy task force Heidi Larson and Rebecca Fields
12:10 – 12:30 Systematic documentation of success stories Arshad Altaf
12:30 – 14:00 Lunch

Afternoon: SIGN: The network at work

14:00 – 15:00 Round table: How to initiate national policy and plans for the safe and appropriate use of injections Group discussion
   Reports on the activities of the SIGN secretariat

15:00 – 15:20 The www.injectionsafety.org site Susan Mackay
15:20 – 15:40 SIGNpost: The SIGN electronic mail forum Allan Bass
15:40 – 16:00 Activity report for the SIGN secretariat Yvan Hutin
16:00 – 16:30 Coffee break
16:30 – 17:30 Round table: How to improve the network approach Group discussion
17:30 – 18:00 Action points for the day
Friday, 31 August 2001: SIGN Meeting, Day 2

First part of the morning: Quality of injection equipment

Ensuring the quality of injection equipment in countries

8:30 – 8:50 Injection equipment recycling in Pakistan
Arshad Altaf
8:50 – 9:10 A new tool to assess injection equipment in the field
Bernadette Gergonne
9:10 – 9:50 Feedback from the injection technologies day
Gerald Verollet and IASIT
9:50 – 10:20 Round table: What tools are needed to increase the quality and safety of injection equipment?
Group discussion
10:20 – 10:50 Coffee break

Second part of the morning: Increasing access to injection equipment

Increasing access to safe injection equipment

10:50 – 11:10 Increased access to injection equipment in Burkina
Sophie Logez
11:10 – 11:30 Bundling for family planning injections
Tabitha Keener
11:30 – 12:00 Round table: Strategies for improved access
Group discussion
12:00 – 12:15 Action points in access and quality
12:15 – 14:15 Lunch

Afternoon: Appropriate, rational, and cost-effective use of injections

Injection safety best practices

14:15 – 14:35 Best practices: Update on the project
Mary Catlin
14:35 – 15:00 Waste management
Richard Carr
15:00 – 15:30 Coffee break

Toolbox for behaviour change

15:30 – 16:10 Behaviour change for injection safety
Susan Mackay
16:10 – 16:40 Round table: Ensuring rational and safe use
Group discussion
16:40 – 17:10 Action points in appropriate use
17:10 – 18:00 Summary of action points for the meeting
18:00 Adjourn
The Safe Injection Global Network (SIGN) met for the third time on 29-31 August 2001 in New Delhi, India, to review progress and identify how the network participants could best facilitate safe and appropriate use of injections worldwide.

The Ministry of Health of India and the Director of the WHO regional office for South East Asia jointly opened the meeting. Three days of work allowed 120 participants to share their experiences. The WHO South East Asia region was particularly well represented as unsafe injections spread bloodborne pathogens on a large scale in this area of the world. The first day was specially dedicated to injection and waste management technologies. The remaining two days were dedicated to broader public health issues, including national policy and plans for the safe and appropriate use of injections, quality and safety of injection equipment, access to injection equipment and safe, cost-effective, rational and appropriate use of injections.

Progress made since the SIGN meeting 2000 was reviewed. First, a number of countries reported having taken steps to formulate national policies for the safe and appropriate use of injections, starting with an assessment. Second, manufacturers of safer injection technologies formed an association in 2001 so that they could participate actively in the formulation of international norms and standards for Auto-Disable (AD) syringes. Third, the international public health community is developing a more holistic approach to injection safety, with progressive engagement of those working in the prevention and care of HIV infection, in family planning and in essential drugs. Fourth, the board of the Global Alliance for Vaccines and Immunization (GAVI) endorsed a new injection safety policy in June 2001. Finally, active work is ongoing to advocate for the safe and appropriate use of injections throughout the SIGN network.

Safer injection technologies were presented, including needle-free injection devices and AD syringes. Discussion regarding efficient health-care waste management strategies emphasized the need for policy frameworks to implement (1) streamlined strategies organized from waste production to waste disposal, (2) training at all levels and (3) the choice of options that include incineration and non-incineration alternatives. A number of countries reported injection safety plans that used across-the-board approaches to include preventive and curative health-care services. Mechanisms to ensure the quality and safety of injection equipment through international norms and standards enforced by national regulatory authorities were presented. Strategies to increase access to injection equipment were discussed, with a specific reference to the use of the essential drug system to bring safe syringes and needles into each health-care facility. Finally, the SIGN toolbox for safe and appropriate use of injections was launched.

The SIGN participants agreed on a list of action points and indicators to monitor progress in collaborative work. Overall, the network participants stated that the coalition made the total more than the sum of its parts and pledged to mobilize resources to achieve safe and appropriate use of injections worldwide.