WORLD HEALTH ORGANIZATION

PILOT-TESTING THE WHO TOOLS TO ASSESS AND EVALUATE INJECTION PRACTICES

A Summary of 10 Assessments Coordinated by WHO in Seven Countries (2000-2001)

TABLE OF CONTENTS

ACKNOWLEDGEMENTS

Edited by
David Gisselquist
Yvan J. F. Hutin

I N T R O D U C T I O N

OPENING AND SHUTTING THE DOOR TO IATROGENIC INFECTIONS

The invention of the syringe in 1848 opened a new channel for pathogens to pass from one person to another.[1] Over time, doctors found more medications to inject and more conditions to treat. The awareness regarding bloodborne pathogens and hygiene only came later. The first recorded outbreak of what was later identified as hepatitis B may have occurred in a Swedish factory in 1883, following smallpox vaccinations.[2] Although it was widely recognized that jaundice followed injections to treat syphilis in the early decades of the 20th century, doctors blamed injected arsenic rather than a contaminating pathogen. In 1943, Bigger[3] and MacCallum[4] showed that non-sterile injections transmitted a pathogen that caused jaundice. Hence, the first safe injection initiative began almost 100 years after the first injection.

Over the last 50 years, scientists have discovered new bloodborne pathogens. In 1967, the Australian antigen – currently known as HBV surface antigen (HBsAg) was first linked to viral hepatitis. In 1983, human immunodeficiency virus (HIV) was found in blood. In 1989, the hepatitis C virus (HCV) and antibodies were identified.

The response in industrialized countries has been effective, if belated. After mid-century warnings about hepatitis from injections, doctors progressively shifted to a sterile syringe and needle for each injection. At the end of the 20th century, most injections are now given with new, single use injection equipment and episodes of transmission of bloodborne pathogens through injections are usually linked to the unsafe use of multi-dose vials or preparation of medications in areas potentially contaminated with blood or body fluids.[5] However, in developing countries, the last half of the 20th century saw enormous increases in numbers of injections with insufficient care for sterile conditions. People in developing and transition countries received an estimated 16 thousand million injections in 2000, of which 6.6 thousand million were given with equipment reused in the absence of sterilization.[6]

Unsafe injections have contributed to high hepatitis B virus (HBV), HCV and HIV prevalence for decades. In parts of Africa and Asia, for example, 80%-90% of the population has been exposed to HBV and 5%-15% have active infections. HCV prevalence is estimated at 3.9%-5.3% in the Near East, African and Western Pacific regions, with much higher rates in some countries (e.g., 18% in Egypt, 13% in Cameroon, 11% in Mongolia).[7] In too many countries, the door to iatrogenic infections through unsafe injections has been opened but not yet shut.

THE NEED FOR ASSESSMENT TOOLS

From the 1980s, spurred in part by concerns about HIV, public health experts expressed mounting concern about unsafe injections in developing countries. Early influential papers relied heavily on anecdotal information.[8] During the early 1990s, WHO's Action Programme on Essential Drugs sponsored well-designed and parallel studies of injection practices in Senegal, Uganda[9] and Indonesia. In 1999, the Bulletin of WHO published global estimates of annual unsafe injections and related HBV, HCV, and HIV infections.[10,11]

In 1999, representatives from WHO, the United States Agency for International Development (USAID), the Program for Appropriate Technology in Health (PATH) and other international and national public and private organizations came together to create the Safe Injection Global Network

(SIGN). SIGN is a coalition of participants with a small secretariat in the WHO Department of Blood Safety and Clinical Technology (BCT).

To facilitate the development of national programmes for the safe and the appropriate use of injections, WHO sponsored the development of tools to assess and evaluate injection practices. During 1999-2000, experts prepared drafts of protocols that were reviewed during a meeting of consultants. [12] In October 2000, this process led to the publication of five linked draft tools for pilot testing. The ten assessments in this volume come out of this process: each follows one of the draft protocols to examine injection practices in one of seven African and Asian countries. Each of these assessments has been carried out by, with or for a national organization or committee as part of a process to develop national policies for the safe and appropriate use of injections.

THE WHO TOOLS TO ASSESS AND EVALUATE INJECTION PRACTICES

The initial tools to assess and evaluate injection practices organized the investigations into four issues (Figure 1 and Table 1):

 (a) The determinants of injection practices, including knowledge, attitudes and institutions;

 (b) The frequency of injections;

 (c) The safety of injections;

 (d) The association between injections and adverse outcomes.

Figure 1: Injection-associated adverse events are caused by poor injection practices that are a consequence of behavioural and system determinants
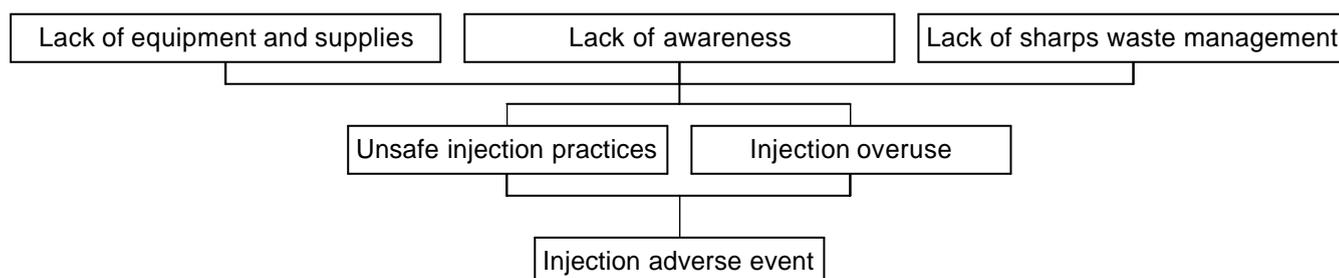
The objective of interventions for the safe and appropriate use of injections is to prevent adverse outcomes so that people do not contract bloodborne viruses or otherwise suffer from injections or needle-stick injuries. This depends on injection practices, which depend in turn on knowledge and other factors that influence behaviours.

ASSESSING DETERMINANTS OF INJECTION PRACTICES

Qualitative determinants of poor and good injection practices may be identified through focus group discussions and in-depth interviews. Results of such assessment provide guidance to assess quantitatively the knowledge and attitudes regarding injection practices. [13] Section 2 in this book presents two assessments of the determinants of injection practices.

ASSESSING PRACTICES

Risks with injections depend on how many injections each person receives, how safely injections are administered and how used syringes are disposed of. In developing countries, both trained and untrained providers, including neighbours and family members give many injections in the informal sector. Hence, it is useful to begin with the general public to find out how many injections they receive and from whom; designs for such surveys are presented in the tool to estimate the frequency of injections and identify injection providers. [14] Two surveys in Section 3 look at frequency and source of injections. Once one knows who is providing injections, an assessment of injection practices in a sample of providers can tell how safe those injections might be. The design for such assessments is presented in WHO's Tool for the assessment of injection safety.[15] Section 4 presents two assessments of injection practices in health care facilities.

ASSESSING OUTCOMES

The motivation for attention to unsafe injections is concern about adverse outcomes – that people are contracting bloodborne pathogens, getting abscesses and suffering otherwise from unsafe injections. The studies that are required to identify these outcomes can be conceptually split into three: ongoing routine monitoring of injection-associated adverse events as they occur; epidemiological studies of risk factors for infections with bloodborne viruses; and investigations into known or suspected iatrogenic outbreaks to determine numbers infected and the clinics and procedures responsible. The tool to assess the association between injections and infections [16] deals with the first two – monitoring adverse events and epidemiological studies of risk factors. Section 5 presents one evaluation of the risk factors for acute HBV infections.

TOWARDS A WHO "RAPID ASSESSMENT AND RESPONSE GUIDE"

On the basis of field testing, all of the four draft WHO tools were merged into one, the WHO: Injection practices: Rapid assessment and response guide.[17] The guide shows how to cover all four issues in an assessment that could be as short as three weeks. It has been field tested in the three assessments presented in Section 1 of this book. The final rapid assessment and response guide is presented at the end of this volume.

Table 1: Conceptual framework for the five tools

Outcomes of unsafe injection practices	Issue: Injection adverse events Tool: *Tool to assess the association between injections and infections*	
Injection practices	Issue: Injection overuse Tool: *Tool to estimate the frequency of injections and identify injection providers*	Issue: Unsafe injection practices Tool: *Tool for the assessment of injection safety*
Determinants of safe and unsafe injection practices	Issue: Public and provider knowledge, institutions, etc. Tool: *Tool to identify determinants of poor and good injection practices*	
All of the above	Issue: All of the above: Comprehensive tool: *Injection practices: Rapid assessment and response guide*	

ADDED VALUE FROM THESE ASSESSMENTS

These assessments served two purposes:

(a) Helping WHO and SIGN participants to develop protocols to assess injection practices;

(b) Promoting and guiding injection safety initiatives in each of the seven countries involved.

However, these papers have additional value. Taken together, they represent a large share of the work that has been done around the world over the last several years to describe unsafe injection practices in developing countries. Hence, the purpose of this volume is not only to introduce and demonstrate template protocols, but also to make the results of these assessments available to a wider international audience.

Section I: The rapid assessment and response guide

I.1. INJECTION PRACTICES IN ALBANIA: RAPID ASSESSMENT AND PROPOSED ACTION PLAN

June 2000

Yvan J. F. Hutin *

*Department of Blood Safety and Clinical Technology, WHO, Geneva, Switzerland.

INTRODUCTION

During plans for a mass measles/rubella vaccination campaign in November 2000, the Ministry of Health of Albania, fearing adverse events during the campaign in the absence of preventive measures, arranged with WHO a rapid assessment of injection practices. The objectives of the assessment were to: describe injection practices, propose a detailed, short-term injection safety plan for the immunization campaign and propose key elements of a longer-term initiative to achieve safe and appropriate use of injections in Albania.

More than ten years into the post-communist transition marked by social unrest in 1997 and the Kosovo crisis in 1999, Albania continues to pursue health system reforms. Key elements of this reform include:

1. Reforming regulation (e.g., changing the role of the Ministry of Health, defining new roles for professional organizations);

2. Reforming health financing and resource allocation;

3. Reforming health services production (e.g., improving quality of services, introducing family medicine).

There is little experience in the practice of infection control in Albania. The standard medical school curriculum does not include an infection control module. Although a unit was recently created in 1997 at the University Hospital of Tirana, it is comprised of one person without a budget or facilities to run a basic surveillance system. Thus, although an action plan was written, activities are limited to basic functions, including constitution of a functional infection control committee, provision of ad hoc advice and distribution of educational material to promote hand washing and other key infection control practices.

Initiatives for the rational use of medicines are recent in Albania. They include the National Drug Policy proposed in the health system reform that is currently being developed with the support of WHO's humanitarian office in Albania. [18]

METHODS

The assessment followed the methods described in WHO's Injection Practices: Rapid Assessment and Response Guide.[17] Interviews were conducted among key national and international informants from the Ministry of Health, the Institute of Public Health, UNICEF, WHO and selected nongovernmental organizations (NGOs) using standardized, open-ended interview forms. Selected documents (see references) were reviewed for relevant information.

We visited a small convenience sample of rural and urban health care facilities in Tirana and two rural districts to interview health care workers and to observe injection and health care waste management practices. Interviews were conducted with a convenience sample of physicians and nurses using standardized data collection instruments containing close-ended and open-ended questions.

In addition, a convenience sample of the general population, structured to include both genders and all age groups was interviewed in three field locations visited to estimate the frequency of injections and to identify injection providers, using a standardized, closed-ended questionnaire.

RESULTS

INJECTION PROVIDERS

Key informants, physicians and the population reported that nurses administer most injections in Albania. Physicians, midwives and dentists were also identified as occasional injection providers. A few key informants provided undocumented reports of administration of injections by unqualified providers (e.g., veterinarians) and pharmacists.

Of the 16 persons interviewed in the convenience sample of the population who could remember the provider for their last injection, 10 (63%) reported a nurse, three (19%) reported a physician and three (19%) reported a dentist. Nurses reported going often to patients' homes to administer injections. It was unclear whether nurses charged a fee for service when they administered an injection at home.

INJECTION FREQUENCY

Injection frequency was assessed through interviews of physicians, nurses and the population. The seven physicians interviewed in four health care facilities reported an average of 120 outpatient visits per week of which 37 (31%) would result in the prescription of an injection (the proportion of prescriptions with at least one injection is WHO's OT8 indicator), with an average of eight injections per prescription. The nine nurses interviewed reported administrating an average of 80 injections per week, of which seven (9%) were for immunization. Of 21 persons interviewed in a convenience sample of the general population (mean age 27 years; 53% female), five (24%) reported at least one injection in the last three months with a total of 11 injections (projected ratio of annual injections per capita: 2.1). The median time since the last injection was nine months (range 1-300).

UNNECESSARY INJECTIONS

Review of the injection registers in outpatient clinics indicated an overwhelming majority of unnecessary injections, including antibiotics (e.g., penicillin and gentamycin for acute upper respiratory tract infection) and anti-inflammatory drugs and vitamin B complex given for arthritis or neuralgia. Other selected examples include: use of penicillin and streptomycin to treat a six year-old child diagnosed with tonsillitis and bronchitis (although the nurse thought she was injecting penicillin and gentamycin) and use of intravenous dextamethazone in a four year-old child with urticaria.

A nurse who kept home supplies of injection equipment in case of emergencies among her patients presented a large cardboard box full of injectable medications. Reported usual use for these injectable medications suggested a predominance of unnecessary injections (Table 2).

Table 2: Usual uses for medical supplies with a rural Albanian nurse, June 2000

Medication	Usual use
40% dextrose	Diarrhoeal diseases (IV)
Prometazine	Allergies (IM)
Diazepam	Seizure (IM or intrarectal)
Furozemid	Acute hypertension (IM or IV)
Vitamin C	Diarrhoeal diseases (IV)
Luminal ®	Seizures (IM)
Papaverine	Abdominal pain (IM or intradermal)

RISK TO THE PATIENT

Key informants, physicians, nurses and patients all reported that new, single use injection equipment was almost universally used in Albania. Some of these reports were based upon frequent interactions and observations in multiple primary care facilities (e.g., the French Red Cross in the Skrapar District). During this assessment, we observed glass sterilizable syringes in use in one rural district hospital. Auto-disable syringes have not been introduced on a large scale. That reuse of syringes or needles in the absence of sterilization is rare in Albania is supported by a range of evidence, including:

- The observed availability of single use injection equipment in health care facilities and pharmacies;

- The low price of single use injection equipment (approximately 7-10 US cents for a 2 or 5 ml syringe with its needle wrapped individually in a sterile sealed package);

- Widespread knowledge among interviewed physicians and nurses of risks for transmission of HBV and HIV through reuse of injection equipment without sterilization (however, HCV was not reported as a potential injection-associated infection by any of the health care workers);

- Consumer demand for new, single use equipment in the population fuelled by the fear of HIV and reported by interviewed physicians and nurses;

- The absence of observation suggesting reuse of single use equipment in health care facilities visited (e.g., containers of tepid water with single use injection equipment).

Although reuse of injection equipment in the absence of sterilization is probably rare in Albania, other breaks in infection control practices were commonly observed that may expose patients to infections, including:

- The use of cotton balls that have been macerated in disinfectant vials contaminated by health care workers' fingers to wipe the skin before injections. In one instance, a nurse was observed cutting herself while opening a glass ampoule. To stop the bleeding, she dipped her finger in the glass container with cotton balls to grab one and did not evince concern over continuing to use cotton balls from the container to disinfect patients' skin;

- Practices allowing for cross-contamination of clean, sterile equipment by contaminated equipment or surfaces;

- Preparation of injections in areas potentially contaminated by blood or body fluids in hospitals;

- The use of 500 cc saline IV infusion bottles to dilute medications in one hospital;

- Preparation of injections with hands presenting bloody uncovered cuts following injuries caused by the opening of glass ampoules with bare hands.

RISK TO THE HEALTH CARE WORKER

Key informants and nurses reported that sharps waste was not collected in puncture- and liquid-proof sharps containers. This hypothesis was supported by the absence of observation of puncture- and liquid-proof sharps containers in health care facilities. In addition, observation of recapped used syringes in waste baskets suggests that recapping occurs. None of the nine nurses interviewed reported having received hepatitis B vaccine.

RISK TO THE COMMUNITY

Key informants and nurses reported that in most cases, in the absence of a functional health care waste management system, sharps waste was discarded using the regular waste disposal system, which exposes people who scavenge domestic waste to needle-stick injuries. However, none of the 21 persons in the convenience sample of the population reported ever having been stuck by a dirty needle left in the environment or in a garbage dump.

Nationally, 27% of hospitals separate health care waste.[19] Although some nurses reported disposing of sharps waste by supervised open burning in specific sites, these reports were inconsistently confirmed by the observation of incineration sites. Only 12 incinerators dedicated to health care waste are present in the country. The one in Tirana is in poor running condition. Most explain this situation by the absence of a national strategy, training, and equipment.

DETERMINANTS OF POOR INJECTION PRACTICES

Most physicians reported that patients – particularly older persons in rural areas – prefer injections for common medical conditions. As in many other cultures, injections are probably popular in the Albanian population, but not for everyone. A number of elements suggest that health care workers may also contribute to injection overuse. These include:

- The possible occurrence of under-the-table payment to nurses for the administration of injections at home,[18]

- The provision of rationalized, "scientific" explanations by physicians to justify their excessive prescriptions;

- The limited implementation of standardized, evidence-based treatment protocols for the treatment of common illnesses;

- The persistence of inappropriate policies (e.g., use of intramuscular vitamin D supplementation in children); and

- The reports of attitudes that may contribute to injection overuse among physicians of other former socialist economies of Eastern Europe.[20]

Although under-the-table payments of physicians are reported,[18] we did not hear of higher fees for service outpatient visits that led to the prescription of an injection. A lack of awareness on the part of health care workers of the risk of HBV transmission in health care settings even without reuse of non-

sterile equipment may explain a number of practices allowing for cross contamination that expose injection recipients to infections. In the Albanian setting where HBV infection has an intermediate endemicity profile and where injections are overused, the observed breaks in infection control practices may be sufficient to transmit HBV from patient to patient through injections. The absence of a culture to promote health care worker protection may explain the practices that expose injection providers to needle-stick injuries. Finally, a lack of concern for the management of health care waste associated with the absence of a waste treatment infrastructure may explain the practices that result in the presence of sharps waste in the environment.

No data are available regarding the association between injections and infections. Because surveillance for viral hepatitis is based upon reporting of acute hepatitis of unspecified etiology, and because no risk factor information is collected, routine surveillance data cannot be used to assess the association between injections and infections.

RECOMMENDATIONS

SHORT-TERM PLANS FOR THE MASS IMMUNIZATION CAMPAIGN

In a context where unsafe injection practices are reported, the mass immunization campaign and its planned one million injections will create an acute problem that requires pre-emptive action. Activities should be conducted to (1) promote safer practices and behaviour change, (2) provide sufficient quantities of auto-disable syringes and sharps containers and (3) manage sharps waste.

As the provision of matching quantities of auto-disable syringes, vaccines and sharps waste containers will be ensured through the WHO/UNICEF/IFRC[*] "bundling" policy, particular attention needs to be devoted to the promotion of safe injection practices and sharps waste management. Opportunities exist to broaden the Task Force alliance that was constituted to prepare the campaign to associate professional bodies (e.g., the newly formed Order of Physicians' Medical Council and the Direction of Nursing of the Ministry of Health). Because of the challenge represented by this campaign, its safety should be monitored by a combination of exhaustive routine reporting by all health care facilities and a validation survey conducted in a sample of health care facilities during the campaign. Finally, activities should be conducted so that results achieved and documented in the short term during the campaign will open possibilities of sustained prevention efforts.

Behaviour change

As provision of auto-disable syringes and sharps boxes will not be sufficient to ensure consistent use in a setting where they have not been routinely used, communication activities should be conducted among physicians, nurses and in the population with the following behavioural objectives: appropriate use of auto-disable syringes, appropriate sharps waste collection and appropriate sharps waste management.

Communication activities should be viewed in a perspective that goes beyond training and simple transfer of information. The goal is that participants want to play an active role, feel that they can make a difference, are able to identify the recommended behaviour and are rewarded for it. A framework for communication in the area of injection safety (to be integrated into other communication activities planned for the purpose of the campaign) is proposed in Table 3 to Table 5 for physicians, nurses and the general public, respectively. Of these three groups, nursing is of particular importance. Because of

---

[*] International Federation of Red Cross and Red Crescent Societies (IFRC)

the absence of a strong local partner in the area of nursing and infection control practices, a local nursing working group may benefit from temporary assistance from an international expert in nursing, infection control practices, and nursing education to plan communication activities and to prepare nurses' information, education, and communication (IEC) documents. All communication strategies should be pre-tested before implementation.

Sharps waste management

In the absence of a health care waste management system, disposal of sharps waste should be carefully planned. Potential waste treatment options in urban areas include burial pits, use of cement and rehabilitation of incinerators. Potential waste treatment options in rural areas include use of cement and incineration in open pits. Implementation will require training, supervision and monitoring.

Monitoring and evaluation

The safety of the injections that will be administered through the campaign should be monitored and evaluated through:

1. Preparation and analysis of routine reports by field staff in vaccination centres on vaccines, syringes and sharps containers received, doses administered and sharps containers filled and destroyed;

2. Validation by an injection safety assessment in a representative sample of health care facilities. For this purpose, the WHO tool to assess injection safety in health care facilities [15] may be adapted and used. A national evaluation team may take assistance from an international consultant.

LONG-TERMS PLANS FOR A NATIONAL STRATEGY

In view of the high level of injection use and the breaks in infection control practices, the Albanian Ministry of Health and its partners should consider a sustained national strategy for the safe and appropriate use of injections after the vaccination campaign. Efforts to reduce injection overuse and to achieve injection safety would fit in the objectives of the health system reform as they represent key issues and critical indicators in the upcoming National Drug Policy and in defining standards of care for the purpose of accreditation and total quality management. Many ongoing activities in the Ministry of Health and its partners could integrate components of an initiative for the safe and appropriate use of injections (Table 6).

Behaviour change activities should be conducted to reduce unnecessary injections, promote health care worker protection (including hepatitis B vaccination) and implement universal precautions in hospitals.

Provision of supplies entails: (1) supply and financing mechanisms to ensure universal and continuous availability of sharps containers in all health care facilities and (2) steps to ensure acceptable quality of single use injection equipment sold in Albania.

National policy and plans for health care waste should be implemented to ensure: (1) a comprehensive management system from waste production to waste disposal with (2) training at all levels and with (3) choice of affordable and environment-friendly options.

For long-term monitoring and evaluation, process indicators of injection frequency and safety should be combined with outcome indictors (i.e., the incidence of injection-associated infections).

Table 3: Proposed strategy of communication for behaviour change for physicians

Expected Behaviour	Knowledge area	Messages	Activity / Channel
Provide accurate reference information and appropriate advice to all injection providers to ensure injection safety during the campaign	Only auto-disable syringes should be used to administer vaccine during the campaign	Reuse of syringes and needles transmits HBV, HCV, and HIV	1. Letters/telegraph/fax from the Ministry of Health to all Albanian physicians 4 months before the campaign (co-signed by the President of the Order of Physicians) to explain that physicians will have overall responsibility for the campaign and its safety 2. Information session at the weekly physician meeting of the district public health department 3 months before the campaign to provide details about what physicians' role will be. Use of scientific background documents (e.g., WHO injection safety fact sheets) co-signed by Albanian opinion leaders (e.g., university professors) and task force agencies 1. Training sessions at the weekly meeting of the district public health department 1 month before the meeting to rehearse/model supervision situations
		HBV is of particular concern because: HBV is common in Albania; and it is easily transmitted through unsafe injections	
		Auto-disable syringes will ensure no equipment is reused	
		Auto-disable syringes are easy to use and will require limited adaptation on the part of injection providers	
	Health care worker protection should be ensured to prevent needle-stick injuries	Syringes and needles should never be recapped after injections as recapping increases the risk of accidental needle-stick injuries	
		Injection equipment should be discarded in sharps and liquid-proof containers immediately after use	
	Sharps waste should not expose the community to any risk	Disposal of injection equipment in regular garbage leads to needle-stick injuries among persons handling waste and waste scavengers	
		During the campaign, special arrangements will be made to collect and dispose sharps waste containers	
Take an active, leadership role in ensuring injection safety during the campaign	It is the physicians' responsibility to ensure injection safety; it is not only a "nurses' issue"	Physicians must ensure that sufficient stocks of auto-disable syringes are available and are exclusively used	
		Physicians must ensure that sufficient stocks of sharps containers are available and that sharps are deposited without recapping	
		Physicians should keep track of the expected number of sharps containers filled and sent for disposal	

Table 4: Proposed strategy of communication for behaviour change for nurses

Expected Behaviour	Knowledge area	Messages	Activity / Channel
Respecting three key rules while administering the vaccine: Use only auto-disable syringes; collect sharps immediately after the injection without recapping; centralize sharps boxes for appropriate disposal	No injection equipment should be reused in the absence of sterilization	Reuse of syringes and needles transmits HBV, HCV, and HIV	1. Constitution of a national nurses' working group 2. "Dear colleague" message from the Director of nursing, Ministry of Health, to all nurses 4 months before the campaign 3. Information session at the district level 3 months before the campaign to provide details about what the role of the nurses will be. Use of simple 1-page illustrated reference documents co-signed by the Director of nursing, Ministry of Health, and the task force agencies 4. Training sessions at the weekly meeting of the district public health department 1 month before the meeting to rehearse/model injection administration situations and flag good/bad practices 5. Poster to be placed above injection preparation tables summarizing the rationale for key infection control practices and presenting photos of good and bad practices 6. Card summarizing the same message for the nurses' personal use
		HBV is of particular concern because: HBV is common in Albania; and it is easily transmitted through unsafe injections	
		Auto-disable syringes will ensure that no equipment is reused	
		Auto-disable syringes are easy to use and will require limited adaptation from nurses.	
	Nurses should protect themselves to prevent needle-stick injuries	Syringes and needles should never be recapped after injections, as recapping increases the risk of accidental needle-stick injuries	
		Injection equipment should be discarded in a sharps- and liquid-proof container immediately after use	
	Sharps waste should not expose the community to any risk	Disposal of injection equipment in regular garbage leads to needle-stick injuries among persons handling waste and waste scavengers	
		During the campaign, special arrangements will be made to collect and dispose sharps waste containers	

Table 5: Proposed strategy of communication for behaviour change for the general population

Expected Behaviour	Knowledge area	Messages	Activities / Channel
Trust the mass immunization campaign because special care has been taken by the task force to ensure safety	Use of auto-disable syringes will guarantee that syringes and needles will not be reused	Auto-disable syringes will ensure that no injection equipment is reused because it inactivates itself by plunger blocking after a single use	1. Letters/telegraph/fax from the Ministry of Health to commune leaders 4 months before the campaign
		Auto-disable syringes can be easily recognized because they have a metal clip in them (this characteristic may vary according to the manufacturer)	2. Letters/telegraph/fax from the Ministry of Education to schools when children go back to school
		Auto-disable syringes will be provided free of charge in health care facilities during the campaign. There will be no need to bring syringes and needles	3. Kick-off press conference with detailed background material for the press
	Syringes and needles will not be strewn around vaccination clinics during the campaign	Special safety boxes will be used to collect sharps safely	4. Video modelling a nice interaction between health care workers and child showing the safe aspects of the campaign
			5. Pamphlets in all health care facilities and distributed by nurses at home 2 months before the campaign
	The campaign will be environment-friendly	Collection boxes will be collected for organized disposal	6. Messages in the mass media one month before the campaign
		The sharps waste produced by the campaign will not end up in rivers or in garbage dumps	7. Template scenarios for teachers to organize discussion sessions in classrooms 2 weeks before the campaign

Table 6: Activities and projects that could integrate components of an initiative for the safe and appropriate use of injections

Institution	Project	Description	Relevance to safe and appropriate use of injections
Ministry of Health/WHO liaison office	Health system reform	- Reforming regulation - Reforming financing and resources allocations - Reforming health services production	- Accreditation and quality control of health care facilities - Rights and duties of professional organizations - Establishment of a nursing association - Clarification of health care workers' remuneration - National essential medicine policy
WHO humanitarian mission	Rational use of medications	- Promotion of rational use of medicines - Establishment of a national formulary - Establishment of a drug therapy committee - Formulation of standardized treatment guidelines	Reduction of unnecessary injections
	Infectious disease surveillance	See Institute of public health	See Institute of public health
	Tuberculosis control programme	- Treatment guidelines - Directly observed therapy - Laboratory rehabilitation	Reduction of unnecessary use of IM streptomycin
National blood transfusion service	Laboratory services	Quality assurance and quality control in laboratory testing	- Prevention of transfusion-associated infections - Serological testing for surveillance for infections with bloodborne pathogens - Infection control practices in blood transfusion services
UNICEF	Health	- Acute respiratory infections case management - Control of diarrhoeal diseases - IMCI (starting in 2001)	Standardized case management, including reduction of inappropriate use of antibiotics and IV infusions

Table 6 (Continued): Activities and projects that could integrate components of an initiative for the safe and appropriate use of injections

Institution	Project	Description	Relevance to safe and appropriate use of injections
Institute of Public Health	Infectious disease surveillance	▪ Integrated surveillance for a selected short list of infectious diseases	▪ Surveillance for infections with bloodborne pathogens (e.g., viral hepatitis) ▪ Monitoring and evaluating the safety of the mass immunization campaign
	HIV/AIDS control programme	▪ Prevention of nosocomial infections	▪ Information, education, and communication among patients and health care workers to implement universal precautions ▪ Knowledge, attitudes, and practices survey regarding knowledge of modes of HIV transmission (completed)
Environmental Centre for Administration of Technology	Health care waste management	▪ Health care waste management	▪ Health care waste management
Medical council of Albania	Establishment of the code of deontology	▪ Increasing standards of training and practices ▪ Protection of the patient	▪ Establishing physicians' responsibility to prevent nosocomial infections ▪ Promotion of the rational prescription of injections ▪ Health care worker protection
American Red Cross	Support to Albanian Red Cross	▪ Community work	▪ Social mobilization
French Red Cross	Activities in the Skrapar District	▪ Training of nurses	▪ Promotion of appropriate infection control practices among nurses
Merlin	Rehabilitation of laboratory services	▪ Rehabilitation of laboratories	▪ Universal precautions in labs

I.2. INJECTION PRACTICES IN HEALTH CARE FACILITIES OF SHANGHAI, CHINA

2001

Cao Yang,* Chen Jie,* and Cao Jianwen*

*Medical Technology Assessment and Research Centre, Fudan University, People Republic of China.

INTRODUCTION

China has more than one-fifth of the world's population. Thousands of millions of injections are delivered every year in China, while reports suggest that unsafe practices occur often, transmitting bloodborne pathogens, including HBV, HCV and HIV. Thus, poor injection practice is one of the major public health problems in the country. The Government of China has paid attention to this problem and supported a number of initiatives. However, little information is available from systematic surveys to describe unsafe injection practices and there is little experience to integrate programmes linking the community with the health system to achieve the safe and appropriate use of injections.

The Medical Technology Assessment and Research Centre of Fudan University in Shanghai decided to cooperate with WHO to conduct a pilot assessment of injection practices in China. Shanghai was chosen for this assessment for two reasons. First, it has a dense population with a functional, integrated three-level health services network in urban and rural areas. Second, it is the home of Shanghai Medical University, one of China's most prestigious medical schools providing several teaching hospitals and active community outreach programmes.

The proposed objectives of this assessment included:

(1) To collect semi-quantitative and qualitative information on knowledge, attitude and practices regarding injections;

(2) To estimate the proportion of injections administered in a way that does not harm the patient, the provider or the community;

(3) To estimate the frequency of injections in the local population; and

(4) To determine how injections received by the population are distributed according to various injection providers.

METHODS AND SAMPLING

We followed WHO's proposed method for rapid assessment of injection practices.[17] We reviewed available documents, interviewed stakeholders, visited selected health care facilities, conducted focus group discussions and interviewed a general population sample to collect relevant information.

STAKEHOLDER INTERVIEWS

To obtain a preliminary description of injection practices, we interviewed 27 stakeholders, including two officials from the health administrative department, three educators from medical schools, six officials from hospital management, four heads of nursing, six physicians, four patients and two suppliers of medical equipment.

OBSERVATION AND INTERVIEWS AT SELECTED HEALTH CARE FACILITIES

The urban areas of Shanghai City include nine districts with a population of 6 930 400. The suburbs and rural areas include nine districts and one county (as of December 2002) with a population of 9 477 300. We selected urban areas and Jiading District of rural areas as survey fields. Within these areas, we selected six urban hospitals and eight rural health care facilities. The selection of the facilities was based on the economic level of the local area and geographic position (Figure 2 and Figure 3).

Figure 2: Location of studied health facilities and general population samples in Shanghai, urban area, injection practices assessment, Shanghai 2001

Figure 3: Location of studied health facilities and general population samples in rural Jiading District, injection practices assessment, Shanghai, 2001

From these facilities we selected a convenience sample of 100 injection prescribers (10 from each of six urban hospitals and five from each of eight rural facilities), 1 000 prescriptions (10 from each prescriber), and 100 injection providers (10 from each urban hospital and five from each rural facility). We used standardized rapid assessment instruments to collect information from prescribers, prescriptions and injection providers.[17]

A team of four investigators was trained to make structured observations of providers administering injections. Results of the interviews were triangulated with observational data, enabling to compare reported and observed injection hygiene behaviours.

FOCUS GROUP DISCUSSIONS

We assembled focus groups using a convenience sampling technique to identify determinants of poor and good injection practices. For each of five different categories of people involved with injections or injection equipment – injection prescribers, injection providers, auxiliary staff/workers handling health waste, patients and community – we organized three focus groups in urban areas and four in rural areas. In total we organized 35 focus group discussions around 14 health facilities. Each group consisted of 5-10 people, a moderator and a note-taker. The discussion process was conducted according to recommendations of the draft WHO tool to identify determinants of poor and good injection practices.[13]

INTERVIEWS WITH A GENERAL POPULATION SAMPLE

A convenience sample of the general population structured to include both genders and age groups was interviewed to estimate the frequency of injections and identify injection providers. We selected 800 people from the general population (400 from two urban communities and 400 from two rural townships and four villages). The proportion of genders and age groups of the sample (Table 7) were consistent with the latest census data.

Table 7: Age and sex structure of the general population sample, injection practices assessment, Shanghai, 2001

		Sex		Age			Total
		Male	**Female**	**0-14**	**15-64**	**>64**	
Urban	Community 1	66	65	16	100	15	131
Area	Community 2	140	132	33	208	31	272
Rural	Township 1	53	51	13	79	12	104
Area	Township 1	52	49	12	77	12	101
	Village 1	26	24	6	38	6	50
	Village 2	26	24	6	38	6	50
	Village 3	26	25	6	39	6	51
	Village 4	24	23	6	36	5	47
Total		413	393	98	615	93	806

Each person was visited and interviewed face-to-face with a standardized questionnaire combined with instrument 5 of reference 13 and instrument 1 of reference 14. When an interviewee could not understand a question or had difficulty answering, other family members helped. Confidentiality of all participants was assured.

<div align="center">

RESULTS

</div>

OVERVIEW OF STAKEHOLDER INTERVIEWS

Stakeholders reported that the popularity of injections remains high in China. HIV/AIDS prevention and care programmes communicated the risk of HIV infection associated with health care injections. National essential medicine policy proposed in the health system reform proposed to discourage injection overuse. Initiatives for the rational and safe use of medications, injections and blood products, including the health care waste management plan within the curative health system, were developed with the support of national and international organizations and relevant WHO departments.

Among 27 stakeholders, 66.7% stated that injection safety was a problem, 51.9% thought that injections were overused and 18.5% reported that syringes and needles were reused without sterilization in some areas in China. The main reasons offered for reusing contaminated equipment were that some health workers were driven by economic incentives and people could not afford single use injection equipment in some poor areas.

Most stakeholders (92.6%) stated that syringes and needles were immediately discarded in a sharps box and 88.9% thought that they were appropriately disposed of in China.

Less than half (40.7%) of the stakeholders were aware of specific information sources such as news media and health care department publications on injection practices and consequences and 63.0% had done some activities relevant to the area of safe and appropriate use of injections. But only 7.4% knew certain planned, ongoing or completed studies or surveys regarding injection practices in China.

Some informants mentioned that the subject was politically sensitive and that their statements were based only on their personal experience, suggesting that more reliable data be generated from large-scale and randomized population surveys.

INJECTION PROVIDERS

Key informants, physicians, nurses, patients and the population reported that nurses administer most injections in Shanghai. Physicians, private practitioners and traditional healers were also identified as occasional injection providers. Several people mentioned injections given by unqualified or illegal providers, including by patients themselves or by relatives in the home (e.g., patients with diabetes, illicit drug users).

Of persons from the general population sample who could remember the provider for their last injection, 60.2% reported receiving it from a nurse, 31.0% reported receiving it from a medical doctor, and 8.8% reported other providers (e.g., a dentist, self, friend or relative). There was a significant difference (Person $\chi^2=19.565$, P = 0.007) in the distribution of injection providers in urban versus rural areas. In rural primary health facilities, some general practitioners both prescribe and provide injections.

INJECTION FREQUENCY

Injection frequency was assessed through interviews of prescribers (physicians), injection providers (nurses) and the population.

Prescribers

One hundred prescribers were interviewed in 14 facilities (36 from outpatient departments, 15 from inpatient departments, 29 from emergency departments and 20 general practitioners, all from rural facilities). They reported an average of 87.9 patient visits per week of which 35.2% would result in the prescription of an injection (mean: 2.12 injections per prescription). The diseases and symptoms for which they prescribe injections included upper respiratory infection, heart and brain vascular diseases, pulmonary infection, urethra infection, fever, inflammation, heart failure, bleeding and pain (Table 8).

Table 8: Reported usual use of injectable medications, injection practices assessment, Shanghai, 2001

Medication	Reported usual use
Penicillin	Bronchitis, tonsillitis, pneumonia (IV or IM)
Cephalothin	Bronchitis, urethra infection (IV or IM)
Lincomycin	Bronchitis, Uri (IV or IM)
Analgin (Noramidopyrine)	Fever, headache (IV or IM)
Gentamycin	Pneumonia, Uri (IV or IM)
Radix salviae miltiorrhizae	Coronary heart disease, brain ischaemia (IV)
Furozemid	Acute hypertension, heart failure (IV or IM)
Virazole	Influenza (IV)
Metronidazolum	Toothache, pulmonary infection (IV)
Vitamin C	Diarrhoea (IV)
Anisodamine	Stomach ache (IM)
Vitamin B	Auxiliary medication (IV)
Reptilase	Alimentary tract bleeding (IV)
Etamsylatum	Bronchiectasis (IV)

IM: intramuscular. IV: intravenous.

We reviewed 935 valid prescriptions, of which 47.8% contained at least one prescription (WHO's OT8 indicator, Table 9.

Table 9: Indicators of injection frequency, injection practices assessment, Shanghai, 2001

Source	Indicator	Urban area	Rural area	Total
Prescriptions	Proportion of prescriptions containing at least one injection (%)	47.6	48.1	47.8
Interview of prescribers	Proportion of patients who received at least one injection during an average week (%)	33.4	38.1	35.2
	Mean number of injections by patients who received at least one injection	2.3	1.9	2.1
Interview of providers	Average number of injections administrating per week	84.3	101.0	90.9
	Ratio of therapeutic/immunization injections	5.4:1	12:1	7.3:1
	Therapeutic injections as a proportion of all injections (%)	84.3	92.5	87.9
Interview of the general population	Proportion of the persons who received injections in the last three months (%)	15.88	34.98	25.43
	Mean number of injections by persons who received injections in the last three months	3.1	4.9	4.3
	Ratio of therapeutic/immunization injections	5.5:1	10:1	8.7:1
	Average number of injections per capita per year	2.0	6.8	4.4
	Median time interval since the last injection (months)	4	2	3

Results from 50 prescribers of seven focus groups indicate that a physician treats 2-55 (3-55 urban and 2-50 rural) patients per day, averaging approximately 19 per day. Of these patients, 52.6% would be prescribed an injection.

Providers

The 100 nurses interviewed reported administrating an average of 90.9 injections per week, of which 12.1% are for immunization. The 50 injection providers in seven focus groups reported that a nurse dispenses medicines to 2-80 patients per day, averaging approximately 32 patients; 73.4% of these patients would receive an injection.

General population

Of 806 persons in the general population (mean age: 39, Table 7) 25.4% (15.9% urban and 35.0% rural) reported receiving an injection in the last three months for a total of 886 injections (Table 9). There was a significant difference in the frequency of injections in urban versus rural areas (Person $\chi 2$=37.79, P < 0.001). The average number of injections per capita and per year is 4.40. The median time interval since the last injection was three months (range 0-60 months).

INJECTION EQUIPMENT

Key informants, physicians, nurses, patients and members of the community all reported that new, single use injection equipment was almost universally used. All facilities studied had stocks of single use injection equipment (Figure 4). Auto-disable syringes were not used. Glass sterilizable syringes were observed being used in one village health centre (Table 10).

Figure 4: Stock of single use injection equipment in a village health centre, injection practices assessment, Shanghai, 2001

Table 10: Indicators about injection equipment, injection practices assessment, Shanghai, 2001

Indicator	Urban area	Rural area	Total
Proportion of injection providers reporting sufficient supplies of injection equipment (%)	98.33 (59/60)	97.50 (39/40)	98.00 (98/100)
Proportion of health care facilities using sterilizable injection equipment (observational data) (%)	0.00	12.50 (1/8)	7.14 (1/14)
Proportion of health care facilities using single use injection equipment (observational data) (%)	100.00	100.00	100.00
Proportion of health care facilities using auto-disable injection equipment (observational data) (%)	0.00	0.00	0.00
Proportion of health care facilities where injections are given with a sterile syringe and needle (observational data) (%)	100.00	100.00	100.00
Proportion of health care facilities with stocks of single use injection equipment (interview data) (%)	100.00	100.00	100.00

INJECTION SAFETY: RISK TO PATIENT

In our field observations, the injection procedure was tracked from the time that a provider decided to administer an injection until the time that she/he stored the used equipment away. Attention was paid to a variety of possible routes of contamination involving needle and syringe storage and cleaning, medicine drawing and injection giving.

In 96.4% of 140 observed injections (five intravenous and five intramuscular for each facility), equipment was taken from sealed packages and in 3.6% from a sterile pan. Only in 12 (8.6%) injections, we observed that providers cleaned their hands again before the next injection. In 91.5% (75/82) of injections from multi-dose vials, drawing needles were replaced by injecting needles before administration. In all 140 injections, providers disinfected the patient's skin twice with iodine and alcohol. In 95.6% of 135 injections, single use equipment was distorted and discarded right away in a sharps waste box. All 14 facilities had suitable work stations for preparing sterile injections; seven hospitals had specific regulations on injection safety displayed in the injection ward.

Discussions of seven patient focus groups suggested that there was no reuse of injection equipment without sterilization in studied facilities. Of 50 participants, 49 (98%) reported that they were satisfied with the injection procedure (Table 11). However, eight (16%) reported seeing used syringes and needles lying around the clinic and six (12%) thought that this could lead to needle-stick injuries.

Table 11: Indicators about injection safety, injection practices assessment, Shanghai, 2001

Indicator	Urban	Rural	Total
Proportion of providers who use reusable injection equipment (%)	0.00 (0/60)	2.50 (1/40)	1.00 (1/100)
Proportion of providers who collect sharps waste in a container (%)	100.00 (60/60)	100.00 (40/40)	100.00 (100/100)
Proportion of injection providers reporting sufficient supplies of sharps containers (%)	98.33 (59/60)	97.50 (39/40)	98.00 (98/100)
Proportion of injection providers reporting access to a sharps waste disposal facility (%)	88.33 (53/60)	90.00 (36/40)	89.00 (89/100)
Proportion of health care facilities where injections are given with sterile syringes and needles (observational data) (%)	100.00	100.00	100.00
Proportion of health facilities where used contaminated injection equipment can be observed in places where they expose health care workers to needle-stick injuries (observational data) (%)	33.33 (2/6)	25.00 (2/8)	28.57 (4/14)
Proportion of health care facilities where used injection equipment can be seen in the surrounding environment (observational data) (%)	33.33 (2/6)	37.50 (3/8)	35.71 (5/14)

Of 50 people in seven community focus groups, 15 (30%) had heard of local people receiving bad injections from unlicensed practitioners (13/15) and by self-injection (4/15). These injections were unsafe due to reuse of single use syringes and inadequate cleaning procedures.

INJECTION SAFETY: RISK TO HEALTH CARE WORKERS

Of the 100 nurses interviewed, 75% reported sharps injuries during the last 12 months (average annual number of injuries: 5.5, range 0-50). Only 39% of 100 nurses reported having ever received hepatitis B vaccine. Injuries mainly occur with the destruction of single use syringes and needles and opening of glass ampoules, despite the fact that there are tweezers and scissors to help nurses distort used needles. However, these simple tools did not prevent stick injuries. Eleven (22%) of 50 nurses and 12% (6/50) of physicians in focus group discussions thought the used injection equipment around their environment would lead to colleagues to suffer needle-stick injuries.

Of 31 auxiliary staff/workers handling medical waste in seven focus groups, 25.8% had ever been injured while handling waste and 35.5% reported needle-stick injuries occurring when people are handling waste. Though nobody thought the health care waste was being treated inadequately, 22.6% thought that there was risk of needle-stick injuries in their work environment.

INJECTION SAFETY: RISK TO THE COMMUNITY

Almost all key informants, nurses and workers handling health care waste reported that sharps waste was collected in puncture- and liquid-proof sharps containers. These reports were supported by the observation of puncture- and liquid-proof sharps containers in health care facilities (Figure 5). They also reported a functional health care waste management system, with sharps waste discarded separately from regular waste. However, among 806 people from the general population, six (0.74%) reported being stuck by an injection needle in the garbage or in the environment during the last year.

Figure 5: Plastic bucket for collecting used single use syringes and needles, injection practices assessment, Shanghai, 2001

In focus group discussions, 26% (13/50) of community people said that they had seen discarded syringes and needles in their environment and all 13 of them thought the discarded needles were risky. Six (12%) of 50 nurses and 12% (6/50) of physicians in discussions reported that there was a risk for needle-stick accidents in the community.

According to most key informants, physicians, nurses and medical waste handlers, used injection equipment is distorted, soaked and sterilized in disinfectant, then stored in a special room. The Centre of Medical Waste Disposal of Shanghai City periodically goes to every facility to collect the waste, then burns it in specific sites. But some interviewers mentioned that there were scavengers who collected used needles and syringes through illegal channels and sold them to vendors who repacked and sold them to certain health care facilities and practitioners at competitive rates.

DETERMINANTS OF POOR INJECTION PRACTICES

Injection overuse (Table 12):

Stakeholders mentioned several reasons to explain why people preferred injections to other forms of treatment. These included:

(a) Beliefs about their efficacy, strength and fast action;

(b) Dramatic demonstration effects experienced immediately at the site of the body;

(c) Affordability (sometimes injections are less expensive than oral medications),

(d) Promotion by practitioners as a means to reduce non-compliance, and

(e) Aggressive marketing of injectable medications by pharmaceutical companies.

Table 12: Indicators about injection overuse, injection practices assessment, Shanghai, 2001

Indicator	Urban	Rural	Total
Proportion of prescribers perceiving patients' preference of injections over oral medications (%)	45.00 (27/60)	42.50 (17/40)	44.00 (44/100)
Proportion of prescribers perceiving that he or she prescribes too many injections (%)	20.00 (12/60)	25.00 (10/40)	22.00 (22/100)
Proportion of providers perceiving injection overuse in local area (%)	56.67 (34/60)	25.00 (10/40)	44.00 (44/100)

Nearly half (44%) of 100 physicians reported that patients – particularly in rural areas – preferred injections for the treatment of common medical conditions. However, only 22% perceived that they had prescribed too many injections. In focus group discussions, 46% of 50 physicians reported that patients demanded injections in many cases. But from the population survey, only 14.3% of 806 persons preferred injections for treating a fever, 39.2% preferred oral medication and 44.4% reported no preference. In focus group discussions, 62% of 50 community members and 90% of patients reported that physicians initiated the injection in the therapeutic encounter. Twenty-two (44%) of 50 injection providers in focus group discussions thought injections were overused in their local area.

Unsafe injection practices

There was high awareness regarding the risk of disease transmission by injection among health workers (Table 13). This may explain why we did not witness any unsafe injection practices directly. But among members of the community, the perception of the association between injections and infections was insufficient. No more than 30% of 806 persons thought that HBV could be transmitted by a contaminated syringe and needle.

Table 13: Proportions of prescribers, providers, and general population perceiving possibility of HBV, HCV, and HIV associated with unsafe injections, injection practices assessment, Shanghai, 2001

Interviewer	Pathogen	Proportion (%)		
		Urban area	Rural area	Total
Prescribers	HBV	96.7	92.5	95.0
	HCV	85.0	82.5	84.0
	HIV	93.3	92.5	93.0
Providers	HBV	95.0	100.0	97.0
	HCV	76.7	75.0	76.0
	HIV	95.0	95.0	95.0
Sample of general population	HBV	66.5	66.2	66.4
	HCV	32.5	23.3	27.9
	HIV	69.7	64.8	68.6

In focus group discussions, five of the 50 nurses and 10 of the 50 doctors reported that unsafe injection practices had occurred in their local area. Reported practices included inadequate cleaning, reuse of single use equipment and illegal injections. Reported reasons included inadequate provider skills,

insufficient medical supplies, outmoded disinfecting devices, time constraints and absence of supervision.

DISCUSSION

As in many other cultures, injections are popular in China. This is more obvious in the rural area, where injection frequency is twice as high as in the urban area. In our survey, a number of elements suggested that health care workers may contribute to injection overuse. These include economic incentive, limitation of standardized and evidence-based treatment protocols for common illnesses and the persistence of inappropriate policies. An uncorrected feedback loop exists. Practitioners think patients want injections. This prompts them to administer more injections than they deem necessary to remain popular in a competitive health care market. As a result, patients think that far more injections are required than are actually needed.

Though qualified providers administer most injections in Shanghai, there still are some injections given by persons other than trained health care workers, including unlicensed practitioners, family members or friends. Such injections are likely to be less safe than those given in health care facilities.

Sharps injuries happened frequently among injection providers and medical waste handlers. There is no culture to promote self-protection. In addition, puncture-proof containers are lacking. The presence of sharps waste in the environment shows that Shanghai's waste treatment infrastructure needs to be strengthened.

Public education is an urgent need. Most people want health workers not only to provide more rationalized, scientific explanations with their prescriptions but also to come into the community often to provide health care knowledge and information. It may be better to focus on changing the traditional relationship between patient and practitioner than to push the negative image of the dangerous (deviant) under-qualified quack.

It could be argued that immediate steps need to be taken to reduce the harm of current injection hygiene practices. An obvious starting point is to advocate for the use of fewer injections and more oral medications. Weaning the public and practitioners off injections is desirable, but will take a long time. Harm reduction is another option: One might try to convince practitioners to use auto-disable syringes. For such a programme to be successful, creating consumer demand is essential along with educating practitioners. Consumers and practitioners among less educated and poorer sections of the population must be ready to shoulder the costs of using auto-disable syringes and see it as an investment in health.

Our assessment also finds a bright side. A functional system for injections – provision, management, supervision and waste handling – has been set up in Shanghai. All injection prescribers and providers interviewed in urban and rural areas are well trained and willing to protect the health of their patients. Single use syringes and needles have been completely accepted by practitioners and patients. According to statistics from the concerned department, single use equipment accounts for more than 99% of all injection equipment consumed. Over two-thirds of the general population are aware of the association between injections and infections.

There are limitations in our work. Notably, the site selected was Shanghai, a developed city with a high level of health care consciousness. Results cannot represent the condition of less developed areas in China. In addition, we were well aware that their presence might alter providers' injection practices. Efforts were taken to reduce this bias by collecting a range of data. Laboratory analysis of the transmission of infectious disease through contaminated injection equipment was not included in this work. More information about risk factors should be collected and combined with routine surveillance data to assess the association between injections and infections in the future.

RECOMMENDATIONS

In view of the high level of injection use and breaks in infection control practices, the China Ministry of Health and its partners should consider a long-term national strategy for the safe and appropriate use of injections. Efforts to reduce injection overuse and to achieve injection safety would fit in the objectives of the health system reform indicators within the National Drug Policy and the definition of standards of care for accreditation and total quality management. Proposed components of such a long-term, integrated strategy include:

BEHAVIOUR CHANGE

Behaviour change needs to be promoted through educating and supervising health care workers to reduce unnecessary injections and unsafe practices; through educating patients about the hazards of unsafe injections to reduce demand for injections; and through educating health care workers for self-protection (including use of hepatitis B vaccine).

PROVISION OF SUPPLIES

Provision of sufficient supplies needs to be addressed through both mechanisms to ensure universal and continuous availability of sharps containers in all health care facilities and taking steps to ensure the quality of single use injection equipment sold.

SHARPS WASTE MANAGEMENT

National policy and plans should be implemented to ensure a comprehensive management system from waste production to waste disposal; training at all levels and choice of appropriate, affordable and environment-friendly options.

MONITORING AND EVALUATION

Process indicators of injection frequency and of injection safety should be combined with outcome indicators (the incidence of injection-associated infections).

ACKNOWLEDGEMENTS

I. 3. RAPID ASSESSMENT OF INJECTION PRACTICES IN MONGOLIA, 2001

September 2001

Sophie Logez,[*] Gochoo Soyolgerel,[†] Rebecca Fields,[‡] Steve Luby,[§] and Yvan J. F. Hutin [*]

*Blood Safety and Clinical Technology, World Health Organization, Geneva, Switzerland. [†]Ministry of Health, Mongolia. ‡Project Officer, The Change Project, Washington, DC, United States of America. § Visiting Scientist, Centers for Disease Control and Prevention, Atlanta, GA, United States of America.

INTRODUCTION

As an initial step towards a policy for the safe and appropriate use of injections, the Ministry of Health of Mongolia conducted a rapid assessment of injection practices. Mongolia is a geographically large country with a population of 2 400 000 located between China and the Russian Federation. As in many former socialist countries, anecdotal reports suggested injection overuse in health care.[21] The prevalence of antibody to HCV (anti-HCV) in Mongolia reaches 16% to 24%, one of the highest rates in the world (unpublished WHO report, Dashdelger Alimaa, WHO collaborating centre, Mongolia, WPR/EMC/CDC 98.15). In countries with high HCV prevalence, unsafe injections often account for a high proportion of infections. [22,23]

METHODS

To guide assessment activities, we used the WHO rapid assessment and response guide.[17] Activities in the assessment included interviews of prescribers, interviews and observations of injection providers and interviews of persons from the general population. In addition, we interviewed key national and international stakeholders using open-ended questionnaires to ensure the usefulness of the recommendations and to identify projects and activities that could play a role in a future initiative for the safe and appropriate use of injections.

With advice from public health experts, we selected a sample of 20 health care facilities in four districts (referred to in Mongolia as "aimags") and the capital city for a three-week assessment by a team of two persons. The sample was purposefully selected to represent the national demographic and economic situation. From each facility, we selected one or more prescribers and one or more injection providers (the one administrating the largest number of injections). In facilities where injection providers from different backgrounds practised, we selected two injection providers. In addition, from the community served by each health care facility, we selected approximately three persons from the general population who were not seeking care that day. This sample was structured to ensure that all ages and genders were represented.

Using questionnaires and checklists, a Mongolian paediatrician with special training for the assessment conducted the interviews with prescribers, providers and the general population. Questionnaires were translated into Mongolian and translated back into English. In addition, we observed injection practices according to a standardized checklist.

We calculated proportions and means for each variable using the relevant sample size as denominator. In some cases, we compare results for variables estimating the same quantities (e.g., proportion of injections administered by various injection providers) but collected from different information sources (e.g., general population and prescribers).

RESULTS

CHARACTERISTICS OF THE SAMPLE

We selected 20 health care facilities in urban, semi-urban, and rural areas in four districts (Darhan, Tov, Dornogobi and Ovorkhangai) and in Ulan Bator, the capital city. In these facilities we selected a convenience sample of 28 injection providers and 21 prescribers. From the general population in surrounding communities we selected a convenience sample of 65 persons (37 females and 28 males), 21 from urban areas, 19 from semi-urban areas, and 25 from rural areas.

INJECTION PRACTICES

Thirty-one (48%) of 65 persons from the general population reported at least one injection in the last three months, for a total of 210 injections (i.e., some had received more than one injection), of which 15 were for immunization (Table 14). From this, the average number of injections per person per year is 13, and the ratio of therapeutic to immunization injections is 13 to 1.

Table 14: Findings from interviews with 65 persons from the general population, Mongolia, 2001

Issue	#/Total	Percent
Received at least one injection in the last 3 months	31/65	48
Remembered the last injection	62/65	95
Provider for the last injection:		
Nurse	51/62	82
Physician	2/62	3
First aid worker	4/62	6
Family member	4/62	6
Midwife	1/62	2
Setting for the last injection:		
Hospital	30/62	48
Clinic	9/62	15
Home and other venues	23/62	37
Prefers injections to treat fever	18/65	28
Administers injections to relatives or neighbours	21/65	32
Has been stuck with a needle in the environment	1/65	2

The 21 prescribers reported a total of 1 905 prescriptions per week on average, of which 265 (14%) included at least one injection. The most common conditions for which injections were prescribed included pneumonia, genitourinary infections, cardiovascular diseases and asthenia. Common injectable medications included antibiotics, vitamins and anti-hypertensive drugs. Prescribers estimated that an average treatment included 20 injections in the case of antibiotics and 10 for vitamins. The 28 providers reported administering a total of 2 098 injections each week, of which 1 638 (78%) were therapeutic and 460 (22%) were immunizations (Table 15).

Table 15: Findings from interviews and observation with 28 injection providers, Mongolia, 2001

Issue	#/total	Per cent
Average reported vaccinations among weekly injections	460/2 098	22
Average reported therapeutic injections among weekly injections	1 638/2 098	78
Observed use of new single use injection equipment	28/28	100
Reported occasional reuse of single use injection equipment on the same patient	8/28	29
Observed recapping with two hands after injection	19/28	68
Reported needle-stick injury in the last 12 months	16/28	57
Has received three doses of hepatitis B vaccine	0/28	0

Twenty (95%) of 21 prescribers reported that nurses administered some of the prescribed injections, 13 (62%) reported general practitioners did so, 14 (67%) reported family members and 4 (19%) reported first aid workers administered prescribed injections. Of the 62 persons from the general population who reported the provider for their last injection, 51 (82%) reported a nurse and others reported first aid workers, physicians, family members and midwives (Table 14). Twenty-one (32%) of 65 persons in the general population reported that they occasionally administered injections to relatives at home.

Of the 62 last injections recalled by the general population, nine (15%) were in clinics, 30 (48%) in hospitals and 23 (37%) in other venues, mainly at home (Table 14). People from the general population reported that the median price paid per syringe and needle set for a curative injection was seven US cents. No patient reported paying any fee for service to injection providers. None of the persons interviewed reported any charges for immunizations.

RISK TO THE PATIENT

During observation, injection providers consistently used new single use syringes and needles from sealed packages for all injections. All syringes and needles came from a national manufacturer. During interviews, the general population confirmed these observations. Of the 62 persons who could recall their last injection, 51 (82%) reported that a new single use syringe and needle set had been used, six (10%) could not remember and five (8%) reported use of sterilizable injection equipment before 1990. Eight providers (29%) reported occasional reuse of syringes with new needles to administer antibiotics to the same patient in hospital (one syringe per day per patient). This practice was also anecdotally reported for injections given in patients' homes when the poorest population could not afford the required number of syringes and needles.

Observations in hospitals identified additional breaks in infection control practices, including use of 500 ml intravenous infusion bottles as multi-dose diluent vials, use of intravenous infusion bottles for more than one patient, presence of needles left in the septum of multi-dose medication vials and use of needles alone to perform phlebotomies.

RISK TO THE PROVIDER

Of the 28 providers observed, 10 (36%) discarded sharps in puncture- and liquid-proof safety boxes. Other providers discarded used injection equipment in a pot or open cardboard box. Only nurses in

charge of immunization had access to safety boxes, which were centrally provided. However, these boxes were often emptied and reused so that the whole health facility could use them.

We observed 19 (68%) of the 28 injection providers recapping used needles with a two-handed technique. Commonly, the injection provider would recap, collect the recapped syringes and needles in a box and, at the end of a day, open the box to count by hand the used syringes before disposal. Sixteen (57%) of 28 providers reported needle-stick injuries in the last 12 months for an average rate of 2.6 needle-stick injuries per person and per year. No providers reported receiving hepatitis B vaccine.

RISK TO THE COMMUNITY

All health care facilities followed a national regulation to burn sharps waste at an open site or in a drum or stove. We found no dirty sharps around any of the 20 health care facilities. Nurses and first aid workers giving injections at home reported recapping and returning used syringes and needles in plastic bags to health care facilities. After self-injections at home, people put used injection equipment in the home garbage. One of 65 persons in the general population reported having ever been stuck by an injection needle left in the environment (Table 14).

DETERMINANTS OF INJECTION PRACTICES

Of 21 prescribers, 18 (86%) reported that they did not over-prescribe injections. Those who reported over-prescribing injections justified doing so on the basis of patients' demand. Fourteen (67%) reported that patients preferred injections for the treatment of conditions that could be treated with oral medications. However, only 18 (28%) of 65 persons from the general population reported preferring injection treatment for fever.

The general population was much less aware of risk of injections than were health care workers. Approximately half of the population was not aware that they could acquire HIV from injections, while most health care workers were aware of this risk. However, among prescribers only 5% were aware of the risk of HCV associated with unsafe injections (Figure 6).

Figure 6: Proportions of prescribers, injection providers and the general population spontaneously reporting risk of acquiring HIV, HBV and HCV through unsafe injections, Mongolia, 2001
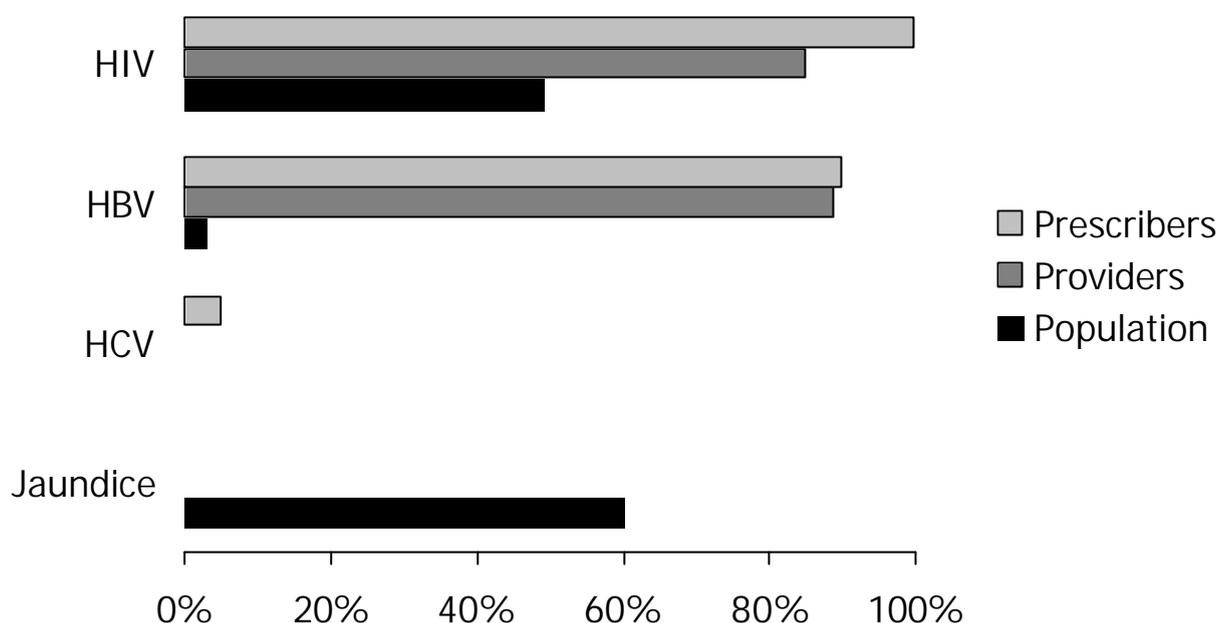
DISCUSSION

The situation that we observed during our assessment contrasts with anecdotal reports that most injections before 1990 were given with equipment reused without sterilization. In 2001, all the health care facilities visited used new, single use injection equipment. Two main factors may explain this improvement. First, there was good awareness regarding the risks of transmission of bloodborne viruses. Second, single use equipment is universally available at low cost. Local production of single use injection equipment began in 1995 and use of sterilizable syringes has been discontinued. We also found that each health care facility methodically destroyed sharps waste. However, despite these improvements, challenges remain, including injection overuse, breaks in infection control practices, poor health care worker protection and the absence of a sharps waste management infrastructure.

Evidence for injection overuse includes: reported injections per person per year higher than any regional estimate worldwide;[6] and reported prescriptions of injections for conditions that could have been treated without injections. Most prescribers did not perceive that they over-prescribed injections and many attributed high use of injections to patients' demand. However, only a minority of patients reported a preference for injections in the case of fever, suggesting that patients may be open to oral medications. As in many other countries, prescribers may overestimate patients' preference for injections.[24] Injection overuse wastes resources and contributes to current large hospital debts to suppliers.

While reuse of injection equipment was uncommon in Mongolia in 2001, other breaks in infection control practices persist that may lead to transmission of bloodborne pathogens.[25] In 1998-1999, the prevalence of HCV infection was 10.7% among children 0-15 years in Ulan Bator.[26] The report of reuse of injection equipment on the same patient in hospitals is all the more worrisome due to widespread use of 500 ml multi-dose diluent vials, which creates opportunities for spread of infection through contaminated multi-dose vials.[27] Experience from other countries where injections are overused

suggests that even if injection equipment is not reused, other breaks in infection control practices may lead to bloodborne pathogen transmission.[25] Reasons that may explain unsafe injection practices in Mongolia include an insufficient understanding of the spread of bloodborne pathogens in health care settings, shortages of injection equipment and the overuse of injections that creates shortages of available equipment.

Health care workers in Mongolia commonly recapped used needles using the two-handed technique and reported a high frequency of needle-stick injuries. Widely distributed educational posters illustrate the safe, one-handed scoop recapping technique and appropriate discarding practices. However, other factors lead injection providers to continue unsafe practices. First, sharps containers are provided for immunization only, which accounts for a minority of injections. Second, a policy recommendation designed to prevent equipment reuse instructs health care workers to clean and count used equipment before burning.[28] These system issues need to be addressed to protect health care workers.

We found no sharps waste around health care facilities. Instead, following Ministry of Health requirements to destroy used injection equipment, facilities burned contaminated sharps by any local means. However, open-air burning or drum-incineration can only be considered an interim solution since it can produce persistent organic pollutants.[29] More environment-friendly treatment options for health care waste disposal are urgently needed in Mongolia.

This assessment has three main limitations. First, we used a convenience sample instead of a random sample and the sample size was small. The decision to use a convenience sample was based on the absence of a sampling frame for Mongolia's nomadic population, the logistical constraints imposed by a large and sparsely-populated country and the limited resources available for the assessment. Use of a small convenience sample creates a substantial source of uncertainty around our estimates. Because this uncertainty cannot be measured, we do not report confidence intervals. On the other hand, for several key issues we were able to compare information from different sources and public health experts familiar with the country believed the sample to be representative and that results reflected the situation well. Second, our review of prescriptions and providers in outpatient facilities did not address injection use in hospitals or in homes, which represents a majority of injections in Mongolia. Thus, injection frequencies and the ratio of immunization to curative injections as reported by the general population may be more representative of the situation in the country. Third, we were not able to completely rule out the reuse of injection equipment in the absence of sterilization. The number of health care facilities visited was small, half of the general population was not aware of the risk of HIV infection associated with unsafe injections and shortages of injection equipment were reported in some situations. Thus, efforts conducted by the Ministry of Health to eliminate reuse of injection equipment in the absence of sterilization should be continued.

On the basis of the results of this assessment, the Ministry of Health is committed to implementing policies for the safe and appropriate use of injections in the country. To decrease injection overuse, approaches may include: interactional group discussions between patients and prescribers,[24] revision of recommended treatment protocols, promotion of new standards of care, restricted access to over-the-counter injectable medications and promotion of oral medications in the community. To improve injection safety, the proposed approach will include: disseminating information on risks to the general public and health care workers, providing safety boxes in sufficient quantities and repealing the requirement to count used injection equipment by hand. Finally, a procurement plan is being prepared to improve waste treatment options with financial provision for training, operation and maintenance.

ACKNOWLEDGEMENTS

SECTION II: THE TOOL TO IDENTIFY DETERMINANTS OF INJECTION PRACTICES

II. 1. FOCUS GROUP DISCUSSIONS WITH THE PUBLIC IN SINDH, PAKISTAN

January – February 2001

Arshad Altaf*

*Senior Instructor, Community Health Sciences, Stadium Road, The Aga Khan University, Karachi 74800, Pakistan.

BACKGROUND

Hospital admission data suggests that the number of persons hospitalized with end-stage chronic liver disease from hepatitis B and C virus (HBV and HCV) infection is increasing in Pakistan.[30] HBV and HCV infections are common and are primarily spread through the reuse of needles and syringes in health care without sterilization,[31,32] while many of these injections are unnecessary.[10]

Eighty per cent of health care in Pakistan is provided by the private sector. Private general practitioners establish small to medium sized clinics all over the country.[33] Some of these general practitioners never receive formal medical training; some are either working or have worked as a nurse, dispenser or an orderly in a hospital. Communities visit these general practitioners frequently because of convenience and cheap rates. Efforts to reduce the frequency of poor injections have produced modest improvements in different communities.[34,35,36] To obtain a broader impact, communication for behavioural change needs to be conducted more widely and should be based upon a deeper understanding of the reasons why people in Pakistan seek so many injections.

The overall objective was to identify the determinants of poor injection practices in communities of Sindh Province, Pakistan. Specific objectives were: to identify the determinants of patients' preference for injections; to describe community knowledge about the advantages and risks of injections; to provide a qualitative description of the frequency of injections in urban, peri-urban and rural communities; to estimate the cost of prescriptions with and without injections; to determine the community's perception regarding the quality of prescribed treatments; to explore community suggestions for the safe and appropriate use of injections and to obtain qualitative information on health care waste management.

METHODS

A qualitative approach (focus group discussions) was used to better understand the determinants of poor injection practices. We adapted WHO's standardized tool to identify determinants of poor injection practices.[13] The proposal was submitted to the Ethical Review Committee of Aga Khan University. Approval was granted on 6 December 2000.

SELECTION OF COMMUNITIES

The team held initial meetings with key community contacts to identify areas in urban, peri-urban and rural Sindh where focus group discussions could be conducted. Based on community contacts, access and other factors, we selected settings for 19 focus group discussions.

Eight focus group discussions (six male and two female) were carried out in Karachi, an urban setting. Karachi is the largest city of the country with an estimated population of more than 10 million and is also the economic hub of the country. While most of the population is Urdu speaking, residents come

from all four provinces. Urban slum areas comprise almost 40 per cent of the metropolis. We selected two typical urban slum areas, Liyari and Bilal Colony. Liyari's population is comprised of Balochi, Pushto, Punjabi and Urdu speaking people. Urdu, Sindhi and Punjabi are spoken in Bilal Colony.

Six focus group discussions (four male and two female) were carried out in the two peri-urban areas of Darsana Channa and Jumma Himayati Goth. Darsana Chana is in Malir District of Karachi and is about 25 kilometers away from the city. Sindhi is the main language. Jumma Himayati Goth is in District East of Karachi. Most of the population is Sindhi and works in the adjacent industrial area or in dairy farming.

We arranged five focus group discussions (two male and three female) in two rural communities. Khipro is in District Sanghar of Sindh and is about 350 kilometres Northeast of Karachi. Sindhi and Urdu are the main languages and farming is the main occupation. Garhi Yassen is in District Shikarpur about 700 kilometres north of Karachi. Farming is the main source of income and majority of the population are Sindhi.

FOCUS GROUP DISCUSSIONS

We developed discussion guides and pre-tested them at two different sites in urban Karachi. Appropriate changes were made after pre-testing the tools. Focus group discussion sessions were carried out during January and February 2001.

With the help of key community contacts, homogenous groups for age and sex and occupation were selected. The average number of participants in each of the 19 sessions was eight. The age range was 18-80 years (female) and 20-55 (male), except for one session among students of a government school in rural Sindh (age range 14-16 years). Venues for focus group discussions included houses, community halls and field (teashops, factory). The sites were selected according to the convenience of the participants and the community contact person. Focus group discussions with female participants were held in one of the houses of the community as culturally appropriate.

In each session there was a moderator and a note-taker. The moderator explained the objectives before each focus group discussion and participants were assured of the anonymity of their responses. Participants were offered tea and drinks by the host where the interviews were conducted. They were also informed that a doctor would provide health education at the end of the session. A verbal consent was taken to tape-record the sessions. In addition, the note-taker simultaneously took written notes and observed and recorded expressions of the participants.

The first section of the discussion addressed common conditions and health care-seeking behaviours. The second part addressed types of treatment prescribed and costs. Finally, the discussion probed injection practices, perceptions about injection safety and injection-associated infections, attitudes towards injections and suggestions to improve injection practices. The moderator based the discussion on the WHO tool but did not restrict it to these specific questions or probes. At the end of each session the moderator gave an informative talk about injection safety.

ANALYSIS

First, missing information was added after listening to the tapes of the discussion sessions. Second, data were transcribed into a word processor. Third, content analysis organized raw data into readable

narrative descriptions with major themes, categories, and illustrative examples. Finally, frequencies of responses were estimated from all focus group discussions.

<p align="center">**RESULTS**</p>

AWARENESS REGARDING QUALIFICATION OF DOCTOR

In rural communities people were not aware about doctors' qualifications. They were more concerned about cure of the ailment than the qualification. Men and women of peri-urban areas mentioned that they knew their health care provider personally. Urban participants reported looking for the Bachelor of Medicine, Bachelor of Surgery (MBBS) acronym on the signboard of clinics, while in rural areas participants reported that they perceived the presence of a board as a reassuring sign.

COMMON CONDITIONS, TREATMENT MODALITIES, AND INITIATION OF INJECTION PRESCRIPTION

Diarrhoea (referred to as abdominal pain), cold and influenza were the most common ailments mentioned by groups in all areas. Conditions for which communities did nothing or took self-medication included cough, cold and headache.

Pills, injections and syrups were the main mode of treatment in all areas. Peri-urban areas mentioned that injections are necessary in a prescription and they prefer what the doctor prescribes. Communities in rural areas said that young doctors (fresh graduates) prescribe fewer injections than older doctors. They also suggested that health care providers have a financial interest in prescribing injections. Fever, influenza, abdominal pain and headaches were the common conditions that led to an injection. Most participants reported that doctors took the initiative to prescribe an injection but there were some groups where it was revealed that patients asked for injections.

PERCEPTION OF GOOD TREATMENT

Communities believed that the doctor is the better judge of a good treatment. Communities related good treatment to receiving injections or any treatment that can give them cure. They were also concerned about the quality of essential medicines available in the market. A few groups suggested that injections are necessary in a good prescription. For example, an old woman from urban Karachi said, "Injection is a must and we get cured with it." Another middle-aged woman from urban Karachi replied, "Without injections there is no relief." Participants also suggested oral medication for children and injections for adults as the best treatment.

NUMBER AND COST OF INJECTIONS

Participants reported clinic visits usually lead to the prescription of 2-3 injections. In most cases, the dispenser, a health care aide hired by the doctor to dispense medications, gives the injections. The average cost of prescriptions with injections was Rupees 37 (US$ 0.60) versus Rupees 31 (US$ 0.51) for prescriptions that did not include injections. The average cost of intravenous infusions, prescribed in cases of weakness or diarrhoea, was Rupees 221 (US$ 3.60).

REUSE OF SYRINGES

People reported that injection equipment was supplied by the clinic. Most participants reported not paying attention and not being able to observe the opening of a new packet when they received an

injection. Some participants reported witnessing reuse of single use syringes in the absence of sterilization. From an urban area a male respondent said: "We do not know. They bring the syringe from behind the counter." People generally do not ask for a new packet, but those few who reported asking for a new syringe were not provided with one. In such instances, the participants reported that the dispenser assured them the syringe was clean. Communities did not recognize sterilization of syringes as an important issue. When probed further they replied that sterilization is necessary and hot water kills germs.

ADVANTAGES AND RISKS OF INJECTIONS

Quick, early relief from disease was reported as the main reason to prefer injections. People reported the main reason to visit a clinic is to get relief from illness and they believe that an injection serves this purpose well. Allergic reactions and abscesses were reported as the most common side effects of injections. AIDS was the main risk of poor injection practices mentioned by communities. However, people do not ask for a new syringe because they see the doctor as a saviour, and he could not spread AIDS. They also believe that AIDS is widespread in Pakistan.

Although jaundice was known among the participants, they did not associate it with poor injection practices. Few knew about chronic liver disease and about the specific causes of viral hepatitis, including HBV and HCV.

SOURCES OF HEALTH INFORMATION AND SUGGESTIONS TO IMPROVE INJECTION PRACTICES

Television and doctors were reported as the most credible sources of information. Television was suggested to be the best media to convey messages about the safe and appropriate use of injections. Although most of the participants preferred injections, some said that they would be open to use of oral medicines if they could be convinced that oral medications work as fast as injected medications.

HEALTH CARE WASTE MANAGEMENT

People in all groups had seen syringes and drips lying around, not only at community waste sites but elsewhere as well. Some had seen children playing with syringes.

DISCUSSION

Injections are overused in Sindh Province as patients prefer them, believing that they provide quick relief and perceive them as a social norm. However, prescription of injections usually results from an initiative from the doctor. The communities consider injections in a prescription as a standard practice. Patients are not aware of the risks associated with reuse of injection equipment. Doctors and television are considered as the most credible source of providing health care information.

Injection overuse has become a social norm among Pakistan's general practitioners. A majority of injections are administered under unsafe conditions, exposing the patient to infectious diseases, including abscesses, AIDS and hepatitis B and C. Because patients strongly trust doctors, concerted efforts should be made to engage and educate these practitioners, so that they improve their practices. At the same time, the public must be educated so that patients can express a preference for oral medications for conditions such as fever, diarrhoea and body aches. Oral medications are widely available for almost all conditions in which injections are prescribed.

"Quickness" in relief is an important concept and has two perspectives. First, health care providers want to prove to patients their ability to provide rapid cures. Second, there is an economic perspective for patients, who want quick relief to be fit for work. For quick relief, providers and patients go for injections. This situation can be addressed with interactional group discussions engaging health care providers and the public to curb injection overuse.[24]

People seldom notice what kind of syringe is used. To improve poor injection practices, the public should take the initiative to ask injectors to take syringes out of sealed packages in front of them. Consumer demand for safe injection equipment can only occur if patients are aware of risks with unsafe injections. The additional cost for prescriptions including an injection is six Rupees (US$ 0.10), whereas new syringes and needles from pharmacies cost Rupees 3-6 and Rupees 1-2, respectively.

Our focus group discussions were limited to selected urban, peri-urban, and rural communities and included mostly low and middle income persons. However, we were able to select different ethnic and gender groups from these areas. Urban slum areas of Karachi include populations of different ethnic groups from all over Pakistan. Urban slum areas account for almost 40% of the population of Karachi, and if peri-urban areas are included it becomes 50%.

To achieve the safe and appropriate use of injections in Sindh Province, the general population should understand that injections do not work faster than oral medications and that injections can be dangerous unless administered with new single use equipment. Doctors should be engaged in these interventions because they are trusted by patients and they often take the initiative of prescribing injections. Additional public education should empower the community to question health care providers about the need for injections and the type of syringe used. These campaigns should be conducted using the mass media, including the television that is a trusted source of information in the area of health. Further research should be conducted to understand the perspective of health care providers regarding the overuse of injections and unsafe injections. Finally, economic analysis should be conducted to understand how financial incentives to prescribe injections could be addressed and how new single use injection equipment could be made available at low cost to the public and to health care providers.

II.2. IN-DEPTH INTERVIEWS REGARDING INJECTION PRACTICES IN SINDH, PAKISTAN

July 2001

Arshad Altaf,[*] Ajmal Agha,[*] and Mubina Agboatwalla[†]

[*]Department of Community Health Sciences, the Aga Khan University, Pakistan. [†]Health Oriented Preventive Education (HOPE).

BACKGROUND

Patients in Pakistan do not have access to safe therapeutic injections. Poor injection practices, particularly reuse of syringes and needles without sterilization, are common. Ninety-four per cent of injections administered by primary care practitioners at one peri-urban site in Karachi were with a needle used on a previous patient and reused without sterilization.[37] Epidemiological studies demonstrate that the primary risk factor for HCV infection in Pakistan is receiving injections.[22,38] The incidence of hospitalization for end-stage liver disease is high and growing in Pakistan. At the Aga Khan University Hospital in Karachi, the proportion of patients with end-stage liver disease due to HCV has steadily increased, surpassing HBV in 1994 as the primary cause. [30]

Seventy per cent of health care in Pakistan is in the private sector.[39] Medical doctors with Bachelor of Medicine, Bachelor of Surgery (MBBS) degrees establish small to large clinics all over the country. They are commonly known as general practitioners. Besides the formally trained doctors there are also a few who do not have an MBBS degree but have worked in a hospital or clinical setting. These also establish their clinics and start working as general practitioners. They become an important part of the health care system and are called "quacks" or informal providers. While fees at public hospitals and dispensaries are low, getting there requires transportation and there are often long waits. People from low to middle income areas visit general practitioners routinely because of easier access, less wait and better attitude of the staff.[40] According to the Pakistan Medical Association, there are 50 000 general practitioners in the country who provide primary care to a majority of the population all over the country. At each clinic there is a dispenser – a hired aide to the general practitioners – whose job is to dispense medicines, administer injections and intravenous fluids and collect fees.

From 2000, the Safe Injection Working Group of Pakistan, a group of health professionals from government hospitals and health centres, nongovernmental organizations (NGO) and academic institutions, has been investigating determinants of therapeutic injections in Sindh Province. As part of this assessment, the Group arranged focus group discussions of male and female adults from the general population in Karachi and rural Sindh Province in 2001 (see II. 1. focus group discussions with the public in Sindh, Pakistan, Page 42). For further information on determinants of therapeutic injection practices, the Group arranged this assessment to gather additional qualitative information from in-depth interviews of health care providers, patients and infant caregivers in Sindh Province.

METHODOLOGY

To gather qualitative information regarding injection practices, the team proposed in-depth interviews (unstructured but guided by a list of questions) of health care providers and patients. The design followed WHO's Tool to identify determinants of poor and good injection practices, [13] with advice from Ann Reeler, a WHO consultant. The proposal was submitted to the Ethical Review Committee of the Aga Khan University, who reviewed it on 24 November 2000 and granted approval on 6 December 2000.

We tested questionnaires at a squatter settlement and at tertiary and secondary care hospitals in Karachi. In July 2001, we interviewed private sector formal and informal general practitioners, dispensers, vaccinators at the Expanded Programme on Immunization Vaccination Centres, patients at general practitioners' clinics and infant caregivers in immunization clinics (Table 16).

Table 16: Health care providers, patients and infant caregivers interviewed, in-depth assessment of the determinants of injection practices, Pakistan, 2001

Area	GPs*	Dispensers	Vaccinators	Patients	Care-givers
Civil Hosp Karachi (urban)	0	0	0	0	5
Liyari (urban)	5	7	2	5	2
Bilal Colony (urban)	5	5	1	2	2
Memon Goth (peri-urban)	4	4	2	2	1
Juma Himayati Goth (peri-urban)	5	5	2	2	3
Garhi Yasin (rural)	8	6	2		2
Khipro (rural)	5	7	2	2	2
Nousehero (rural)	0	0	4	0	0
Total interviewed	32	34	15	13	17

* GPs: General practitioners.

GENERAL PRACTITIONERS

A total of 32 (10 urban, nine peri-urban and 13 rural) private general practitioners were interviewed, including five informal ones.

DISPENSERS

We interviewed a total of 34 dispensers (12 urban, nine peri-urban, 13 rural). Efforts were made to contact the dispensers of the same clinics where general practitioners were previously interviewed to validate the responses in addition to assessing their own practices. However, five dispensers could not be interviewed because they were busy, unavailable or the general practitioners who owned the clinic did not allow it. To overcome this loss we interviewed five dispensers from other clinics.

VACCINATORS

We interviewed 15 vaccinators at immunization centres (public facilities), including three urban, four peri-urban and eight rural.

PATIENTS

Patients at general practitioners' clinics waiting to receive an injection or medicines or after the health care provider had seen them were requested to participate. We interviewed 13 (seven urban, four peri-urban, two rural), eight at private and five at public clinics, including eight females and five males.

INFANT CAREGIVERS

We interviewed 17 mothers and other caregivers with infants at immunization centres regarding the vaccination of their child (nine urban, four peri-urban and four rural).

INTERVIEWS AND ANALYSIS

All participants were interviewed in a semi-structured manner with some interview guidelines and a list of questions. Two persons conducted each interview, a facilitator and a note-taker. Verbal consent was requested from each participant and those who agreed were included in the assessment. The note-taker was also asked to observe injection practices of different participants such as general practitioners, dispensers and vaccinators and to look for evidence of poor injection practices.

We assembled data from questionnaires. Contents were analyzed and organized into a readable narrative description with major themes, categories, and illustrative examples.

RESULTS

GENERAL PRACTITIONERS

Common presenting complaints include acute respiratory infections, gastro-enteritis, other infections, pain and fever. Most general practitioners reported treating 30-40 patients on an average day. Injections were prescribed to most patients except children. Common conditions for which an injection was prescribed include pain, fever, infections and abdominal colic. Routinely injected medicines included antibiotics, painkillers, multivitamins, anti-malarials and antihistamines.

Average reported cost of treatment was Rupees 30-35 (US$ 0.57), which included consultation fee, the charges for an injection and the medicines provided from the clinics. The difference in amount paid by patients without injections was Rupees 5 (US $ 0.08). Intravenous fluids were provided to 4-5 patients in a day, mostly in the summer season, for Rupees 200-400 (US$ 6.50) per IV infusion. Common reasons for intravenous fluids included diarrhoea and weakness.

Most general practitioners suggested that there is a vast difference between government and private health care facilities. They informed that in government settings low quality medicines and care are provided. However, the note-taker observed that some of the medicines at private clinics we visited were also manufactured by shady or unknown pharmaceutical companies.

General practitioners reported that the main advantages of injections are early relief and satisfaction for most patients. Hypersensitivity and allergic reactions were the major reported risks for injections. Most of the general practitioners suggested that they routinely see patients with HBV and HCV infections but could not order any laboratory investigations because patients could not bear the costs of such tests. They also suggested supportive measures or referral to a specialist as management strategies for HBV and HCV cases and vaccination to prevent hepatitis B.

Most general practitioners suggested that use of single use syringes is the only way to make injections safe. On further probing, almost all general practitioners reported that they only use single use syringes, though an electric boiler was found in almost all clinics. Almost all general practitioners suggested use of single use syringes, strict laws regarding quackery and mass educational campaigns to improve poor injection practices. Not many talked about fewer injection prescriptions.

From observation, general practitioners spent approximately two minutes with each patient and during this time there was very little interaction and knowledge transfer. Patients were rarely informed about their disease and condition and the communication appeared only one-way. A complete physical examination was uncommon.

DISPENSERS

The work experience of dispensers ranged from 2-16 years. Only two persons reported receiving formal training from a government facility, but even that was not a structured programme. They also reported learning to administer medications and injections while on the job, practising on different patients without supervision.

To validate information from general practitioners, we asked dispensers questions about costs. Dispensers also reported average cost of Rupees 30-35 (US$ 0.57) per treatment. According to dispensers 90%-100% of patients attending the clinic receive an injection. Common reported conditions for which an injection was prescribed include fever, pain and diarrhoea. When questioned about the type of syringes used and cleaning of equipment, dispensers reported that they always use single use syringes. However, there were some contradictions regarding the use of single use syringes between the statements of general practitioners and dispensers in the same clinics. Several dispensers reported that they clean syringes in boiling water or change the needle for every patient, while the general practitioner had earlier reported that the clinic uses only single use syringes. A majority of dispensers reported that they clean the injection site with spirit swab. Most had heard about HBV or HCV, but only a few knew how they are spread.

Many dispensers reported overuse of injections according to patients' demands, but quite a few of them considered their employer (the general practitioner) responsible for excessive prescription of injections. Most dispensers suggested that it is not possible to improve poor injection practices. However, there were a few who suggested that patients' education might change that.

The clinics' waste was reportedly collected by the sweeper and thrown at community waste sites. However, from observations by note-takers, syringes on the floor were rarely observed. There were numerous open plastic syringes lying on the counter of the dispenser and at some places syringes were seen in the electric boiler.

VACCINATORS

All vaccinators at public sector immunization clinics reported receiving formal training from the National Immunization Programme. Most had been working for more than five years at the same facility. Vaccinators reported an average of 40-45 children vaccinated per day in urban areas, 15-20 in peri-urban areas and 5-10 in rural areas.

In urban areas mothers brought their child to immunization clinics for vaccination, whereas in peri-urban and rural areas vaccinators provided outreach services as well.

Vaccinators reported use of single use syringes for administration of all kinds of injectable vaccines. A majority of vaccinators reported that the supply of injection equipment was sufficient, but few also reported shortages in the past six months. They further suggested that in case of shortage, syringes were arranged from donations; in two areas parents were asked to bring their own syringe because the syringes were not available at the immunization clinic. Every vaccinator was observed opening and using a new single use syringe.

Most vaccinators informed that they burn or bury the used syringes. Some reported that they also cut their needles with a needle cutter before burying or burning.

PATIENTS ATTENDING GENERAL PRACTITIONERS' CLINICS

Patients were 25-50 years old. All females were housewives and males were labourers, watchmen or drivers. Many patients informed that they were unaware of the qualification of general practitioners. Fever, influenza, headache and diarrhoea were the common reported conditions that led to a visit. Every patient indicated receiving pills, syrups and an injection. Injections were suggested by the general practitioner. The average reported cost of treatment was Rupees 30-35 (US$ 0.57) with or without an injection. Common reasons given for visiting a particular facility include near to home, cheaper or no one else around.

Every participant reported that the dispenser of the clinic administered the injection and the syringe was provided from the clinic. They further reported that they were not sure whether the syringe was new or old. Patients indicated that the dispenser cleaned the injection site on their body with a wet swab and then injected the medicines. Patients also suggested that as long as they get well they are satisfied with the injection procedure and treatment. Regarding cleaning of injection equipment, a majority of patients agreed while few suggested that boiling water was the best way to clean the injection equipment.

According to patients, intravenous fluids were helpful in case of weakness and diarrhoea and blood transfusion should be given for weakness and anaemia. Most patients opined that doctors knew better about hazards of intravenous fluids and blood transfusion including risk of hepatitis.

Doctors, television and family elders were the most credible reported sources for health care information. Most patients associated injection use with good treatment and injection safety with single use syringe.

MOTHERS AND OTHER INFANT CAREGIVERS

Infant caregivers reported that children had received, from birth, 3-5 vaccinations depending on the age of the child. Caregivers reported that syringes were provided by the immunization clinic except on the few occasions when parents had to buy and bring their own syringes. Caregivers seldom noticed what kind of syringe was used to administer vaccine.

DISCUSSION

Patients visiting general practitioners in Sindh Province receive unnecessary injections. There is a communication gap between the general practitioners and patients. General practitioners routinely prescribe injections for conditions which can be treated with oral medicines. General practitioners related injection overuse to patients' demand, whereas patients suggested that doctors are betters judges to prescribe injections. However, patients also reported that injections are essential for good treatment. Most general practitioners knew the consequences of poor injection practices, while a majority of patients did not. Dispensers who work for clinics cannot make any decision and have to do as they are told.

The difference in cost of a treatment with or without an injection was Rupees 5 (US$ 0.08). The doctor was not making a lot of money from injections since the cost of syringes and needles was Rupees 3-6 and Rupees 1-2, respectively, depending on the quality (personal communication from pharmacies). However, it was the number of patients that made a practice successful and if general practitioners prescribed injections, they expected more patients to visit the clinic. Patients can easily buy medicines from any pharmacy just by stating the condition and symptoms but often cannot get an injection there. Provision of an injection at a doctor's clinic gives patients the satisfaction of getting complete and quality treatment.

Vaccinators informed that they only use single use syringes and in case of shortage they do not vaccinate the child. They also reported that in the last six months there has been shortage of supply of syringes at least once.

Our assessment is limited to selected areas. Fortunately, in urban settings, we were able to capture different socio-economic groups. We interviewed participants from lower to middle income groups, which represent most people in the country. Our questions regarding cost of treatment did not examine differences across regions, though we have examined differences in overall costs with and without injections. Findings are similar to findings from focus group discussions among the public that we arranged earlier in the same communities.

General practitioners and patients are the two important groups that should be addressed to minimize poor injection practices. Patients suggested doctors and television as credible sources to disseminate information about safe injection practices. Interactional group discussions, community meetings and television are the recommended methods to disseminate information regarding safe injections. In Indonesia, researchers brought patients and providers together in moderated interactional group discussions to expose what providers think patients want and what patients think providers believe, and to work together towards a safer synthesis.[24] However, television should be used as mass media so that the information about safe injections can reach to far-flung areas as well. Mass education is required on risks associated with poor injection practices to encourage patients to question general practitioners about the need for injections and the type of syringe used.

SECTION III: THE TOOL TO ESTIMATE THE FREQUENCY OF INJECTIONS AND IDENTIFY INJECTION PROVIDERS

III.1. INJECTION USE IN MBARARA DISTRICT, UGANDA: A POPULATION SURVEY

February 2001

Gerardo Priotto,[*] Ana Ruiz[*] and Catherine Kyobutungi [†]

[*] Epicentre, Paris, France. [†] Mbarara University of Science and Technology, Mbarara, Uganda.

INTRODUCTION

An increasing body of evidence links the unsafe and inappropriate use of injections to the spread of bloodborne pathogens. An assessment of injection practices provides the basic evidence needed to design and direct injection safety initiatives. This survey pursued the double objective of providing a baseline measurement of injection frequency and injection providers and testing WHO's proposed standardized methodology to do so.[14]

The survey was conducted in Mbarara District in south-western Uganda, 300 kilometres from Kampala (Figure 7). The population of 1 038 409 is 94% rural (versus 86% of 22.7 million people for Uganda). Mbarara city with 53 764 inhabitants is the main urban area in the district; two other centres are considered urban, Ibanda and Ntungamo, with 3 900 and 3 400 inhabitants, respectively. The demographic density in the district is 98.1 persons per square kilometre (versus 94.2 for Uganda). The district is divided into eight counties, 47 sub-counties, 204 parishes and 2 257 villages.

Figure 7: Area of the assessment, Uganda, 2001
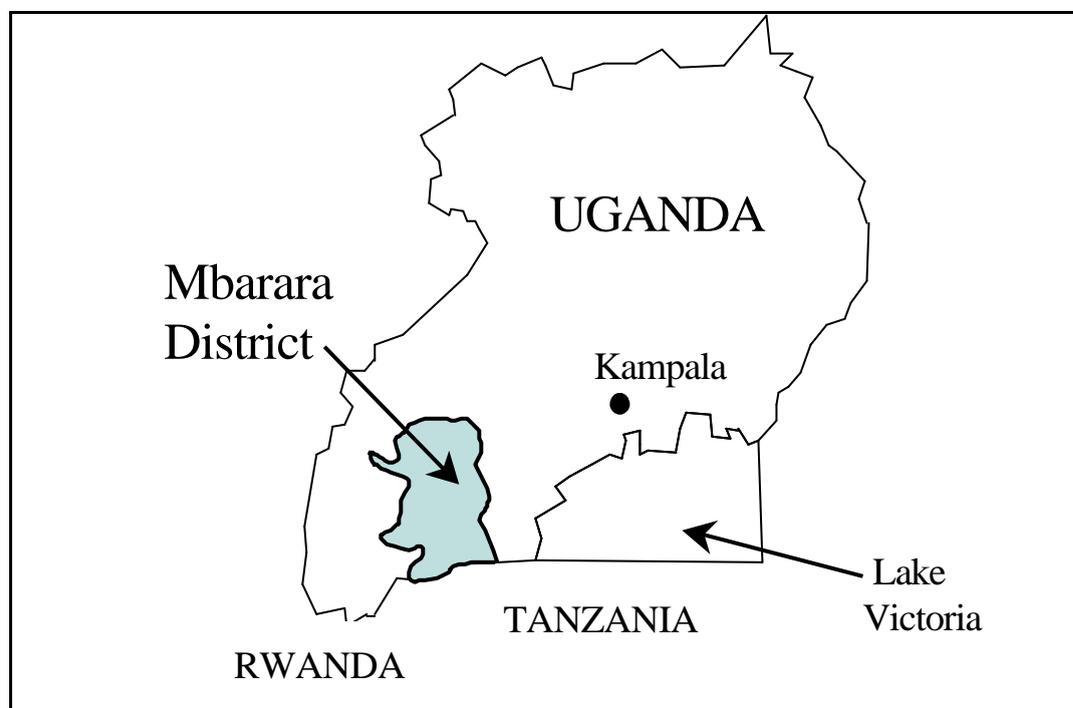
Research on injection practices had already been conducted in Uganda, including a one year ethnographic study and a WHO-funded Injection Practices Research Project during 1992-93.[941] From these studies, 30% of households in the Ankole region (Mbarara and Bushenyi Districts) had received one or more injections in a 2-week period (measured among families with pre-school children only). Fifty-nine per cent of prescriptions from health care providers in Ankole included injections, far above

the desired national level of 15%. Private medical practices were very popular and informal providers and family members gave many injections. This reflected the trend of informalization in Uganda, where public facilities were often distrusted and held responsible for the spread of AIDS. The assessment also showed inadequate hygiene for medical injections. The recommendations that followed included interventions at four levels: regulatory, managerial, education of health providers and public education.

The health infrastructure in the district is composed of 76 units, including: hospitals run by the Ministry of Health at Mbarara and Itojo; hospitals run by nongovernmental organizations (NGOs) at Ibanda and Rushere; 6 Health Centres level IV (out and inpatient services, maternity, surgery); 28 Health Centres level III (out and inpatient services, maternity); and 38 Health Centres level II (outpatients and maternal services). Mbarara Regional Hospital is a teaching hospital for the Medical School of Mbarara University of Science and Technology and is the referral hospital for the western region of Uganda.

METHODS

The survey followed methods described in the WHO Tool to estimate the frequency of injections and identify injection providers, a document available at draft stage during the investigation.[14] We adapted these methods to the specific context of our survey and the findings of our pilot phase.

SAMPLE SELECTION

The design was a cross-sectional, general population survey. The sampling frame was the general population of Mbarara District. We used two-stage cluster sampling, similar to what is used in vaccination and nutrition surveys.[42] Using an updated, complete list of parishes with their population, 30 parishes were selected with probability proportional to size and a village (cluster) was selected at random from each parish. Within each cluster, the listing unit was the household (people sharing the same roof and meals for at least three months) and the elementary unit was the individual respondent. The size of each cluster was fixed at 25 individuals.

In the field, respondents were selected with the following procedure: The geographical boundaries of the village were identified and the team moved to the geographic centre. A direction axis was selected by a random procedure. All contiguous households following that axis were selected and all members present or possible to be summoned were interviewed until completing 25 individuals.

All information collected referred to individuals, a unit that allows comparisons across settings and countries. During the design stage the possibility of dividing the sample into urban and rural strata was considered and discarded, because in the past survey done in Mbarara District, no significant differences were shown between urban and rural populations in the parameters measured.

SAMPLE SIZE

For an expected proportion of 40% of the population having received an injection, a precision of ± 5%, a risk alpha of 5%, a power of 80%, and a design effect of two (cluster technique), a sample size of at least 738 respondents was needed.

TEAMS, TRAINING AND PILOT TESTING

Each of two survey teams included an experienced health care worker and a driver, who assisted in the interviews. These teams – including the driver – had a one-day training consisting of a theoretical part and a field situation simulation with group feedback. To ensure that the type of injection was correctly

classified, the team received refreshment training on vaccination schedules, body sites for each vaccine and contraceptives available in Uganda. A pilot test was carried out, choosing a village not included in the sample; each team completed a cluster. On the same day a meeting was held to review the questionnaire and field methodology. At this point, we introduced several modifications in the questionnaire.

DATA COLLECTION AND SUPERVISION

At each survey site, teams sought collaboration from a member of the local community to act as interface. One of the co-investigators joined one of the two teams alternately every day, while the principal investigator and other co-investigator often joined the other team.

The first step was to identify a person in the house capable of providing information about the whole household, usually the head of household or an adult who takes charge of sick members. A demographic reconstruction of the households was carried out, listing all members by age and gender. Arrangements were made to call rapidly those members that were out of the house but within a reasonable distance (e.g., sending a child). In the meantime, the members present were being interviewed.

Due to the scattered distribution of the population in an eminently rural setting, it was judged not practicable to come back a second or third time to attempt to interview members missing during our visit. The majority of houses were surrounded by matooke (banana) trees and isolated. Distances between clusters were considerable.

Individual information was collected by means of face-to-face interviews conducted with all household members present or possible to summon within a short time. All persons above 14 years of age were interviewed directly, while a selected adult responded for all household children that were 14 years old or younger.

To facilitate recall, when asking for the providers of injections, the potential providers were mentioned to the respondent ("prompt" technique). We collected the following information: demographic characteristics of all household members; number of injections or intravenous infusions each person received in the last three months; distinction between curative, vaccination and contraceptive injections; provider and setting for each injection; safety circumstances; price paid; injections given by household members and needle-stick injuries from sharps waste.

The investigators systematically checked questionnaires either directly in the field or immediately upon return to ensure that data were complete and consistent, no invalid or illegible answers, etc. Whenever important information was found to be missing, the team went back to the household to complete it. Data were then entered in an electronic database and analyzed using Epi-Info software (Centers for Disease Control and Prevention, Atlanta, GA, USA). After data entry, the database was checked against the source documents. Analysis and reporting was done by Epicentre.

ETHICAL ISSUES

The Uganda National Council for Science and Technology, an ethics committee, approved the protocol. Copies of the written approval were remitted to all partners involved. During the survey, the investigators were committed to inform the ethics committee of any emergent problems or protocol amendments (none were made). We obtained clearance from the Mbarara District Director of Health

Services. Interviewees were systematically explained the purpose of the work and oral consent was requested.

RESULTS

Description of the sample

During 6-14 February 2001, a total of 752 persons were interviewed in 176 houses (Table 17). This sample was composed of 22 clusters of 25 persons, three of 24, and five of 26 persons. For the main indicator studied (frequency of injections), the global variance was 0.000291, the cluster variance 0.000653, and the design effect 2.24. The overall sex ratio (M/F) was 0.79 (331/425), with a marked decrease in the age category ≥15 years old. The median age was 12 years (range: 0-90 years).

Table 17: Demographic characteristics of the sample, injection frequency assessment, Uganda, 2001

Age in years	Numbers interviewed			Sex ratio M/F	Proportion of sample (%)
	Female	Male	Total		
0-4	65	77	142	1.18	18.9
5-14	163	139	302	0.85	40.2
³15	193	115	308	0.60	41.0
Total	421	331	752	0.79	100.0

The number of houses selected was 176 for a total population of 1 000 persons (Table 18). Therefore, we interviewed 75.2% of the household members. The group that was the most missed was males ≥15 years of whom only 50.7% were present or could be summoned during the visits.

Table 18: Complete demographic structure of the houses visited, injection frequency assessment, Uganda, 2001

Age in years	Numbers of family members			Sex ratio M/F	Proportion of family members (%)
	Female	Male	Total		
0-4	80	89	169	1.11	16.9
5-14	182	159	341	0.87	34.1
³15	263	227	490	0.86	49.0
Total	525	475	1000	0.90	100.0

Since there was an imbalance in the age and sex categories of household members not interviewed (an anticipated and unavoidable fact), we used the demographic structure of the households' population to weight the information from the sample according to age and sex categories. The weights (Table 19) correspond to the number of population members that each respondent represents, because of his or her age and gender.

Table 19: Weights to adjust for age and gender differences between survey respondents and household population, injection frequency assessment, Uganda, 2001

Age category	Female	Male
0-4	1.231	1.156
5-14	1.117	1.144
³15	1.363	1.974

Frequency and type of injections

The overall, crude frequency of injections was 5.5 per person per year (95% confidence interval [CI]: 4.26-6.70). The age and gender adjusted frequency was 5.3 per person per year (95% CI: 4.11-6.43). The proportion of the sample receiving at least one injection in the last three months was 32.3% (243/752), while the weighted proportion with at least one injection was 31.6 % (95% CI: 26.7%-36.6%, Table 20). The difference between children under five years and any of the other age groups was statistically significant for both indicators of injection frequency.

Table 20: Frequency[*] of injections by age and gender, injection frequency assessment, Uganda, 2001

	N	Injections/person/year [†]		Persons injected last 3 months	
		Mean (weighted)	95% CI	Proportion (weighted)	95% CI
Injections by age					
0-4 years	142	10.0	7.6-12.5	49.9	41.8-58.1
5-14 years	302	4.6	3.0-6.2	26.2	20.0-32.4
³15 years	308	4.1	3.0-5.3	29.1	23.6-34.6
Total	752	5.3	4.1-6.4	31.6	26.7–36.6
Injections by sex					
Female	421	5.2	3.8-6.5	32.5	26.5-38.5
Male	331	5.4	3.7-7.0	30.7	24.6-36.7
Total	752	5.3	4.1-6.4	31.6	26.7–36.6

N: Number of persons interviewed. CI: Confidence interval.

*Frequencies in the table are adjusted with age and gender weights from Table 19.

† Calculated as 4 x [(number of injections reported in the last 3 months)/(number of persons interviewed)]

Respondents reported a total of 1 031 injections in the last three months. One thousand and eight (97.8%) were for therapeutic purposes, while 12 (1.2%) and 11 (1.1%) were for vaccination and contraception, respectively. There was no vaccination campaign in the district during the three-month recall period (November 2000 to January 2001). The last campaign was in August-September 2000.

Injection providers, settings and safety

Two hundred and forty-one (99.2%) of 243 persons reporting an injection in the last three months could provide information about their last injection, of which 237 (98.3%) stated the provider (Table

21). Circumstances that prevented recall included a coma during the survey visit and unavailability of parents who had accompanied children for injections. Assuming that the categories "family members," "friends/neighbours," and "self" define informal providers, formal health providers administered 66.6% of the injections, while 33.4% were done by the informal sector. Among respondents of 15 years old and over, 9.8% (30/307) had given one or more injections to a family member in the last year.

Table 21: Distribution of injections by provider, classified by sector,
injection frequency assessment, Uganda, 2001

Provider	Sector	N	Proportion
Medical doctor	Formal	10	4.2
Nurse	Formal	143	60.3
Acting nurse	Formal	3	1.3
Dentist	Formal	2	0.8
Traditional healer	Informal	0	0.0
Family member	Informal	63	26.6
Self	Informal	0	0.0
Friend/neighbour	Informal	16	6.8
Total		237	100.0

N: Number of injections.

All 241 respondents remembered the setting of their last injection (Table 22). The majority received their injections at outpatient clinics, which are mostly small private clinics staffed by nurses and sometimes by clinical officers or doctors. More than one-third of the injections were administered at home.

Table 22: Distribution of injections by setting,
injection frequency assessment, Uganda, 2001

Setting	N	Proportion
Outpatient clinic	127	52.7
Hospital	24	10.0
Dental office	0	0.0
Home	86	35.7
Drug shop	2	0.8
School	2	0.8
Total	241	100.0

N: Number of injections.

Of the 241 respondents, 32 (13.3%) did not remember or did not know from where the injection equipment was taken before the injection. The descriptions given by the remaining 209, who had seen and remembered the source of the equipment, allowed for classification into five groups, where the most common was the blister package of sterile, single use equipment (Table 23). Only 0.3% of all respondents (2/752) reported a needle-stick within the past year.

*Table 23: Distribution of injections by source of equipment,
injection frequency assessment, Uganda, 2001*

Source of equipment	N	Proportion
Blister package	119	56.9
Fitted with two caps	1	0.5
Pan of boiled water	82	39.2
Sterilizer	6	2.9
Cold tepid water	1	0.5
Total	209	100.0

N: Number of injections.

Cost of injections

In most cases it was not possible to report the cost of the injection only, since the charge covered a package of services such as the outpatient visit fee, the medication injected (some or all, depending on the case) and the oral medication prescribed. We attempted to break down the costs by subtracting the costs of the consultation and oral medications and dividing the rest by the number of injections within a prescription. Of the 220 interviewees who provided information on cost, eight had received the injections for free. The remaining 212 paid a range of Uganda shillings (Ush) 50-4 500 (US$ 0.03-2.57). Excluding three outliers above Ush 2 500, the mean price paid was Ush 821 (95% CI: 742-901) or US$ 0.47, which includes the injected medication, the injection equipment (syringe, needle, etc.) and the fee for service. The cost did not vary substantially for the three age categories considered (Table 24). These calculations agree with information from 68 respondents, who reported the cost of their injections (equipment, medications and service) isolated from other costs such as consultation and oral medicines. The average of their reported costs is Ush 809 (95% CI: 714-904) or US$ 0.46.

Table 24: Cost of injections by age category, injection frequency assessment, Uganda, 2001

Age in years	N	Cost per injection (Uganda shillings*)		
		Mean	95% CI	Range
0-4	64	816	650-982	50-3000
5-14	66	741	624-857	130-2500
³15	82	890	776-1005	67-4500
All ages	212	821	742-901	50-4500

*Ush (Ugandan shilling) 100 ˜ US$ 0.06.

The cost of the injected medication alone was provided by 68 respondents, where the mean was Ush 496 (95% CI: 416-577) or US$ 0.28. For the cost of equipment alone, reported by 62 respondents, the mean was Ush 310 (95% CI: 272-347) or US$ 0.18. None of the respondents reported a service fee for the injection.

DISCUSSION

Findings from other countries on injection frequency, considering studies with comparable methodologies, range from 1.2 to 8.5 per person per year.[10] In Africa, findings range from 1.2 to 3 per person per year. Our survey indicated a higher frequency of 5.3 in this densely populated, mainly rural

district in south-western Uganda. Children under five years old receive more than twice as many injections as older children and adults, even without a vaccination campaign. On the other hand, the same frequency of injections was found in both genders. There is definitely a high frequency of injections in the district, which is probably similar in some other districts of Uganda. One can infer the occurrence of a steady rate of bloodborne infections being transmitted silently on a daily basis.

In our sample adult males were under-represented, due mainly to their absence from home during the hours when the visits were performed. We attempted to minimize this problem by including two Saturdays in the survey. The effect of this under-representation was the overestimation of the global injection frequency, which we corrected in the analysis with weighting by age and gender.

Our design effect, calculated *a posteriori*, of 2.24, was greater than the one used for the estimation of sample size, which was two, based on vaccination and nutrition surveys. For injection surveys the cluster sampling effect may be greater than two and therefore larger sample sizes may be needed. In our survey we were still able to achieve the desired precision of 5% around the point estimate thanks to injection frequency lower than expected (31.6% instead of 40%) and an increase in sample size by rounding up.

We determined that 97.8% of the injections received were for therapeutic purposes. An important proportion of these injections was for malaria, most commonly treated with chloroquine. Nurses administered the majority of injections in outpatient clinics or home visits. We did not distinguish between true nurses holding a diploma and informal injection providers that are called "nurses" in the community. On the other hand, we classified as "informal" all injections given by family members, though some may be formally trained. In any case, more than half of the injections are given within the formal sector. This information is important to consider when designing strategies aimed to reduce the number of unnecessary injections.

The findings about source of injection equipment are encouraging since the majority of injections used single use equipment. However, it must be kept in mind that common people in the rural area have a limited capacity to judge if the equipment was sterile, if the package was unopened, not expired, etc.

RECOMMENDATIONS

The high rate of injections needs a high-level response, including a clear and energetic strategy to educate the public and health providers about the wrongful indication of many injections, especially at the level of outpatient clinics. Additional research at the provider level would complement the knowledge acquired through this work, to describe the medications injected, the basis for the indications and safety of the procedures. This would allow interventions to be better focused.

ACKNOWLEDGEMENTS

III.2. INJECTION PRACTICES IN SINDH, PAKISTAN: A POPULATION SURVEY

July - September 2001

Naveed Zafar Janjua,[*] Saeed Akhtar[*] and Yvan J. F. Hutin [†]

* The Aga Khan University, Karachi, Pakistan and [†] Department of Blood Safety and Clinical Technology, WHO, Geneva, Switzerland.

INTRODUCTION

Injection administration in the developing world became popular when injectable antibiotics provided remarkable recovery from disfiguring infections of kala azar, yaws, malaria and sleeping sickness.[8] Injection use in developing countries is not only rampant and unnecessary but also unsafe. The advent of single use syringes was considered to overcome the problem of inadequate sterilization practices. However, these syringes and needles are often reused. [10] Reuse without sterilization can transmit HBV,[43] HCV,[44] HIV,[45] viral haemorrhagic fever,[46] and other bloodborne pathogens.[47]

Some reports suggest injection overuse in Pakistan.[48] However there have been no population-based studies to quantify injection overuse and to quantify the distribution among providers. Studies investigating prescribing practices suggested that injections are administered to most people who present for treatment.[49] Anecdotal reports suggest that in Pakistan a wide variety of providers give injections, including health care workers and traditional healers. Many people tend to visit traditional healers first before consulting a qualified doctor.[50] However, the distribution of injections received in the population according to various providers was unknown.

Studies to identify risk factors for HCV in a peri-urban community in Karachi and a town in Punjab Province suggest that most of the injections provided were unsafe and unnecessary.[22,37] As a consequence of injection overuse and poor practices, injections administered in health care settings have been identified as a major risk factor for HBV and HCV in Pakistan.[22,51,52]

To decrease the disease burden and cost associated with injections, overuse needs to be decreased. Interventions to decrease the number of injections may be better conducted if initial assessments are made to estimate the frequency of injections and to identify the health care providers who are administering them.

A standardized assessment method is essential to compare the situation across different countries and settings and at different points in time. WHO proposed a standardized design to estimate injection frequency and to identify providers.[14] The objectives of this work were dual. First, we aimed to field-test WHO's proposed methodology. Second, we aimed at estimating the frequency of injections and identifying injection providers in selected urban and rural communities in Sindh Province, Pakistan.

METHODS

TYPE OF SURVEY

We followed WHO's proposed methodology and adapted it to local conditions.[14] We gathered evidence from a population-based cross-sectional survey in two communities in Sindh Province: Lyari Town, an urban slum community in Karachi and Digri subdistrict of rural District Mirpur Khas. Lyari Town has an average household size of 6.5 persons and 32% of houses have a single room.[53] Health care is provided by public facilities, private general practitioners and unqualified dispensers. People in Digri

live in scattered small villages – clusters of houses on individual land holdings – separated by long distances, and agricultural labour is the primary source of income.[54] Qualified doctors are present only at few facilities in public Basic Health Units. Unqualified dispensers are common in Digri, while private general practitioners are found in three small towns. People have to travel long distances on mud roads to seek health care.

SAMPLE SIZE CALCULATION

The sample size was calculated to achieve a desired 3% bound on error of estimation with 95% confidence for the proportion of the population receiving an injection during the past three months. Sample size calculations assumed that 17% of the population received at least one injection in that period. The design effect was calculated taking into consideration the ethnic background, considering that ethnic groups may differ with regards to attitude towards injections. For design effect calculation, the estimate for intra-class correlation coefficient was not available and was assumed to be 0.02 as suggested by Bennett et al.[42] By this method, a design effect of 1.68 was obtained. After inflation for design effect and expected 10% refusals, the sample size of 1 149 was proposed.

SAMPLING

A two-stage clustering sampling was applied to select subjects. Clusters were defined population groups having specific administrative boundaries (sectors defined by the Lyari Community Development Project in Karachi and in Deh, an administrative division of Digri). These clusters were of unequal size. Households were defined as a group of people living together and sharing the same kitchen. The survey population was defined as those who had been residing for at least three months in the selected localities and who were at least three months of age. The sampling units were households and sampling elements were individuals selected randomly from within that household.

The sample of 1 149 was selected equally from urban and rural areas. Thirty-four clusters were selected, 17 each from rural and urban populations based on probability proportional to population size. From each cluster 35 households were selected through systematic sampling with random start by applying the right hand rule as used in WHO's Expanded Programme on Immunization cluster sampling.[55] From each household, one person was selected randomly by a lottery method among those present at the time of survey.

PREPARING THE QUESTIONNAIRE AND INTERVIEWERS

We adapted for use the questionnaire provided in the WHO template tool.[14] The questionnaire was translated into Urdu and the interviewers were conversant with one or two other local languages. The teams were constituted in such a way that both the interviewers should know Urdu and at least one other local language -- Sindhi or Punjabi in rural areas and Balochi, Sindhi or Punjabi in urban areas.

Two teams were selected for each region. Investigators were trained in-office for one day using participatory methods. On the same day the field workers practised interviews by interviewing their fellows. On the next day they conducted interviews under supervision in a cluster that was not selected for the survey and was far from the selected clusters. After this a meeting was held for reviewing the questionnaire and field methodology, so that some minor modifications and adaptations could be made to the questionnaire.

DATA COLLECTION AND MANAGEMENT

The survey was conducted from 25 July to 30 September 2001. Subjects 15 years of age or older answered for themselves, while adult caretakers provided information for children under the age of 15 years. We explained the purpose of the survey and asked for verbal informed consent. Recall of injections was facilitated by the "prompt technique," listing providers and asking about specific episodes of illness as specified in the questionnaire. At the end of an interview, health education regarding hazards of injections was provided and a pamphlet was distributed.

Information collected on the questionnaire was checked to ensure that information was complete, logically consistent, that there were no invalid characters and that the values were within the specified range. These checks were conducted twice, in the field by the supervisor and upon return from the field by the principal investigator. The participant's name was erased after field editing to maintain confidentiality. Final editing was done before data entry. Data was double entered in Epi Info software version 6.04 (CDC, Atlanta, GA, USA). The entered data was validated for consistency and correctness by using Compare Programme for Fox pro (Compare: A programme for comparing databases for Fox Pro. The Aga Khan University, Karachi, 1999).

STATISTICAL ANALYSIS

An analysis was performed to describe the characteristics of the survey population. Different indicators for injection use were calculated. The ratio of injections per person in the last three months was multiplied by four to obtain the annual ratio of injections per capita. The estimates for annual ratios of injections per capita and the proportion of participants who received at least one injection were adjusted for the age and sex distribution of the population in the area as obtained from the National Population Census, 1998.[53,54] The sampling design was taken into account during calculation of point estimates and confidence interval and hypothesis testing of injection use indicators. Quantitative variables were compared using t-test, ANOVA or equivalent non-parametric tests while categorical variables were compared using the Chi-square test.

HUMAN SUBJECTS

The Ethical Review Committee of the Aga Khan University, Pakistan, approved the protocol. Permission for the survey was also obtained from local health authorities and district administrations. We explained the purpose of the work to the participants and obtained a verbal informed consent approved by the Ethical Review Committee.

<div align="center">

RESULTS

</div>

DESCRIPTION OF THE SAMPLE

Of the 1 150 subjects included in the sample, an equal 575 were from urban and rural areas (Table 25). The mean age was 25 years (median: 27 years). The sample included 873 (75.9%) females and 277 (24.1%) males. The proportion of illiterate subjects was 56% and 75% in urban and rural areas, respectively. Because the age and sex distribution of the sample indicated imbalance, the frequency of injections was adjusted for the regional age and sex distribution from the 1998 census. The median family income was Rupees 4 000 (US$ 63) with a mean of Rupees 4 825 (US$ 74).

Table 25: Demographic characteristics of the participants, injection frequency assessment, Pakistan, 2001

Variables	Urban		Rural		Total	
	n	%	n	%	n	%
Gender						
Female	441	38.3	432	37.6	873	75.9
Male	134	11.7	143	12.4	277	24.1
Age categories (years)						
¼- 5	116	20.2	79	13.7	195	17.0
5- 14	65	11.3	34	5.9	99	8.6
15- 45	331	57.6	361	62.8	692	60.2
>45	63	11.0	101	17.6	164	14.3
Education (years)						
Illiterate	321	55.8	424	73.7	745	64.8
1- 5	119	20.7	64	11.1	183	15.9
6- 10	104	18.1	59	10.3	163	14.2
>10	31	5.4	28	4.9	59	5.1
Ethnicity						
Mohajir*	94	16.3	26	4.5	120	10.4
Sindhi	37	6.4	343	59.6	380	33.0
Punjabi	130	22.6	203	35.3	333	28.9
Pushto	55	9.5	2	0.3	57	4.9
Balochi	259	45.0	1	0.2	260	22.6
Occupation						
Housewife/not employed	338	58.9	304	53.1	642	56.0
Govt./military servant	7	1.2	17	3.0	24	2.4
Business	21	3.7	30	5.2	51	4.4
Employed in private firm	27	4.7	102	17.8	129	11.2
Student/NA	181	31.5	120	20.9	301	26.2

N: Number. NA: Not applicable.

*Includes Urdu, Kachi, Memon and Gujarati. All of these originated from parts of India not presently included in Pakistan.

FREQUENCY AND TYPE OF INJECTIONS

Among this population, the proportion who reported having received at least one injection in the last three months 68% (after adjustment for age and sex , 95% confidence interval [CI]: 66%-69%, Table 26). The proportion receiving injections was higher among under five year-olds in both rural and urban areas. The proportion of those receiving injections was higher in rural areas in all age groups (81% vs. 65%, P <0.001).

Table 26: Proportion* of subjects by age group who received at least one injection in the last three months, injection frequency assessment, Pakistan, 2001

Age in years	Urban		Rural		Total	
	%	95% CI	Mean	95% CI	Mean	95% CI
¼ - 5	74	74-75	100	100-100	79	79-80
5- 14	74	73-75	84	82-86	76	75-77
15- 45	57	56-58	77	77-78	60	59-60
>45	72	70-74	63	61-65	71	69-73
Total	65	64-66	81	80-82	68	66-69

CI: Confidence interval.
*Age and sex adjusted.

The crude frequency of injections was 14.7 per person per year (95% CI: 14.5-15.0). The age and sex standardized annual ratio of injections was 15 injections/person/year (95 % CI: 13.9–16.2; Table 27). The age group under five years received the highest number of injections in both rural and urban areas.

Table 27: Annual ratio of injections per capita by age*, injection frequency assessment, Pakistan, 2001

Age in years	Urban		Rural		Total	
	Mean	95% CI	Mean	95% CI	Mean	95% CI
¼ - 5	25.0	22.9-27.8	9.0	8.8-9.3	21.8	19.5-24.2
5- 14	22.2	20.0-24.4	6.7	6.4-7.1	19.5	17.6-21.4
15- 45	10.2	9.8-10.6	7.6	7.4-7.9	9.9	9.5-10.3
>45	20.5	19.1-22.0	9.9	9.0-10.7	19.2	17.8-20.5
Total	16.3	15.0-17.5	7.9	7.5-8.2	15.0	13.9-16.2

CI: Confidence interval.
* The estimates are standardized to the age/sex distribution of the population from which sample was taken.

Injection frequency was higher in the urban area even though the proportion of the population that received at least one injection in the last three months was higher in the rural area (Table 27). Also, the mean number of encounters in the last three months in the urban area was 2.2 and in the rural area 1.2 ($P < 0.001$, Mann-Whitney U test). This means that an encounter with a health care provider in rural areas is less likely, but when it occurs, it is more likely to result in an injection.

A total of 3 587 injections were administered in the last three months to participants, of which 96% were for therapeutic purposes. The proportion of injections administered for vaccination was higher in the rural area (7.5%) than in the urban area (2%, $P < 0.001$). The intra-class correlation coefficient estimated on the basis of the data collected for the proportion of those who received at least one injection during past three months was 0.0229; slightly exceeding the ICC we used to estimate sample size.

INJECTION PROVIDER AND SETTING

All those who provided information about the last injection were able to remember the provider. Most injections (75%) were administered by the dispensers (who administer injections and dispense medicine at clinics) or nurses on doctors' advice. We did not ask if these dispensers and nurses were formally qualified. Another group of dispensers and nurses (providers without MBBS degree) worked independently; they administered 6% and 11% of injections in urban and rural areas, respectively. Injections received in urban areas were more likely to have been administered by medical doctors than in rural areas (20% vs. 11%, P < 0.001). None of the injections was administered by a dentist or family member or self-injected (Table 28, Page 71). Most of the injections were administered at private general practitioners' clinics in urban and rural areas. However, a higher proportion of injections were given in the private sector in urban areas (83% versus 56%, P < 0.001, Table 29, Page 72). Most injections both in urban and rural areas were given to outpatients. Only 7% and 4% of injections in urban and rural areas, respectively, were provided to inpatients. Very few injections were administered at home (0% in urban and 1% rural area).

SAFETY CIRCUMSTANCES OF INJECTIONS

We considered a syringe taken from a new packet or brought by patients in a closed packet to be sterile. According to this definition, 51% of last injections used sterile equipment. The condition of the remaining 49% of injection equipment was uncertain. The syringe used for the last injection was reported to come from a new packet opened in front of the patient for 35% and 40% of respondents in urban and rural areas, respectively. The proportion of patients who brought their own syringe to the health care facility was higher in rural than in urban areas. In the rural area, 9 (1.2%) patients reported that they were injected with the same syringe, needle and left-over medication from the previous patient (Table 30, Page 73).

COST OF INJECTIONS

In most cases, the cost of an injection (medication, equipment and service) was included in the amount paid for consultation, medication and injection. Average out of pocket expenses for an encounter with a health care provider were Rupees 83 (95% CI: 80-86) or US$ 1.3 and the average amount paid for an injection was Rupees 66 (95% CI: 64-68) or US$ 1.1 (Table 31, Page 74).

Another way to impute the cost of injections was to compare the cost for visits to providers when injections were and were not administered. The mean (± standard deviation) price paid when injections were not administered was Rupees 44 (±81) or US$ 0.7, with a median of Rupees 20. When injections were administered, the price paid was Rupees 95 (±483) or US$ 1.5, with a median of Rupees 35. The difference of Rupees 51 or US$ 0.8 can be taken as the price for an injection. The cost of the visit was significantly different between those who received injections and those who did not (P < 0.001, Mann-Whitney U test) The cost of a visit varies significantly across age groups (P = 0.011, Kruskal Wallis test).

NEEDLE-STICK INJURIES

Only 2 (0.2%) respondents reported needle-stick injuries from inappropriately disposed of syringes. Both of these received one injury each.

DISCUSSION

Our results showed that a large proportion of subjects received at least one injection during the past three months and that the annual ratio of injections per capita was high (15 injections per person per year). Nurses and dispensers administered most of the injections in private settings for therapeutic purposes. The sterility of injection equipment was questionable in 49% of the injections received and on average, patients paid Rupees 66 (US$ 1.05) to receive an injection.

The injection frequency in our survey can be compared to findings from other parts of the world. A survey conducted in Uganda in 2001 with a similar methodology estimated 5.3 injections per capita per year (See III.1. Injection use in Mbarara District, Uganda: A population survey, Page 54). In an Indian village 2.5 injections were received per person per year in 1999, [56] and in Moldova and Romania, reported injection frequencies were 5.3 and 11 injections per person per year respectively.[21,57] In this regard, injection frequency in this area is among the highest ever reported. Moreover, 96% of injections were administered for curative purposes, most often for the treatment of minor ailments like fever, influenza, cough and body aches. These prescriptions bore no relation to types of complaint.

Children below five years of age received greater numbers of injections as compared to the other age groups, even after excluding vaccinations. This was also evident from the proportion of children receiving an injection: in the urban areas it was 74% and rural areas 100%. Similarly, higher injection frequency in this age group has been observed in Uganda (See III.1. Injection use in Mbarara District, Uganda: A population survey, Page 54).

Safety of injections cannot be accurately determined from the population survey. From information on source of equipment, we estimate that 49% of injections may have used non-sterile equipment. A more reliable method can be the direct observation of injection administration. However a similar estimate of unsafe injections was reported by observing the injection practices in a peri-urban community of Karachi.[37] As a consequence of this high frequency and poor safety, there is a high probability of exposure to infection with bloodborne pathogens.

The private sector was the major provider of health care (80%) and injections (85%). The National Health Survey of Pakistan 1991-94 also reported 80% of private health care utilization.[58] Similar utilization of private providers (80%) for health care has been reported from India.[59] Higher utilization of the private sector may have been due to easy accessibility and flexible timing of the private practitioners. In the private sector, dispensers were the major providers of injections at general practitioners' clinics. However, a small proportion of injections was prescribed and administered by unqualified practitioners, i.e., dispensers not formally qualified and working independently. In the survey it was not possible to obtain additional information about the formal qualifications of dispensers in clinics. Difficulty in ascertaining qualifications of private providers has also been reported by a study of health seeking behaviours in India.[59] By providing injections, private providers can earn more money,[60] and injection supply can easily be controlled as compared to oral medications. While prescribing oral medications there is risk of by-passing the physicians by purchasing prescription medicines for the same or similar future episodes without consultation.[61,41] In our sample, homeopaths, hakeems and other traditional healers did not administer injections. However, injection provision by traditional providers has been reported from other parts of the world. One obvious policy implication of injection provision by the private sector is that attempts to improve injection safety must give priority to the private sector, which provided 85% of the injections.

The mean number of injections received and visits to health care providers was higher in urban than in rural areas. One reason for the low mean number of injections in rural areas could be the low utilization of services for illness in rural areas.[58] It may be due to economic reasons or possibly due to non-

availability of health care services at a reasonable distance that have also been reported from India.[62] Similarly, there are other competing factors for non-utilization of health care services, including work in fields during harvesting season and care of children. Although general practitioners' clinics were the major providers of injections, public sector facilities and dispensers administered a greater proportion of injections in rural than in urban areas. The difference in accessibility and the relative costs of services may be the possible reasons for differences in utilization of providers. This trend of consulting and spending money on the private providers by urban women more than the rural women was seen in India as well,[62] and a higher proportion of visits to the public sector in rural than urban areas has been reported from Vietnam.[63]

Utilization of the private health care providers exposes the population to injections. Higher health care utilization by urban than rural residents puts them at higher risk of receiving unsafe injections. In developing countries harbouring most of the world population, such as India and Bangladesh, similar health care utilization patterns as in Pakistan prevail. In these countries with high prevalence of bloodborne pathogens, unsafe injections administered by the private providers may be one of the important risk factors for the spread of pathogens. Assessment of the injection practices and investigation of the relationship between injections and infections with bloodborne pathogens could be crucial in understanding the dynamics and control of global epidemics.

The out-of-pocket expenses for a visit were estimated to be Rupees 83 (US$ 1.40). The average amount spent on an injection was Rupees 65 (US$ 1.00). However, this needs to be interpreted with caution, as information was available for very few subjects who purchased the injection separate from consultation and oral medications. The cost of visits was higher in rural than in urban areas. A large proportion of subjects for whom costs were available visited private general practitioners in the rural areas, who charged more than general practitioners in the urban areas. This may have been due to easy accessibility and more frequent visits to urban general practitioners. In the urban areas, general practitioners are easily accessible, even at street corners and they dispense medicine for 1-2 days, asking patients to return for a refill. In contrast, in rural areas, such a follow-up pattern is not feasible, so that general practitioners might charge more during a first visit.

CONCLUSIONS AND RECOMMENDATIONS

In Sindh Province, Pakistan, health care injections are overused, with ratios of annual injections per capita among the highest ever reported. General practitioners in the private sector are the major contributors to this overuse and so are the efficient targets of interventions to reduce injection frequency. Common use of non-sterile injection equipment spreads bloodborne pathogens. Overuse of injections imposes costs for medication and equipment on poor patients that can be avoided by use of oral preparations.

The very high frequency of injections in the region needs attention of high-level decision-makers. A strategy is needed for decreasing the number of unnecessary injection. This can be accomplished through developing treatment guidelines and changing behaviour of the providers and patients towards injections. Future interventions should specifically target the private sector, which administers most injections. A mass media campaign on injection safety and the myth of injection efficacy should be started immediately.

Since injection frequency in the age group of less than five years is very high, implementation of integrated management of childhood illness (IMCI) and treatment guidelines should be considered to reduce injections. With more injections, the probability of infection increases and in this age group the probability of developing chronic liver disease due to HBV is high.

Further studies are needed to quantify the proportion of injections that are unnecessary, how much money is being wasted on unnecessary injections and the cost of treating and managing infections arising due to injections. These studies can contribute to plans to reduce the number of injections and establish more rational prescribing practices.

Table 28: Reported injection provider for the last injection received, injection frequency assessment, Pakistan, 2001

Provider	Urban			Rural			Total		
	N	%	95% CI	N	%	95% CI	N	%	95% CI
Doctor	84	20.1	11.0-29.0	36	11.0	5.4-17.6	120	17.0	10.8-23.8
Nurse/dispenser on doctor's prescription	289	73.9	65.9-81.8	355	77.6	72.6-82.6	644	75.1	69.3-80.7
Dispenser working independently	22	5.9	2.8-9.1	61	11.3	5.2-17.3	83	7.5	4.9-10.2
Hakeem*/homeopath	0	0	0	1	0.2	-0.2-0.4	1	0.1	-0.1-0.1
Dentist	0	0	0	0	0	0	0	0	0
Self	0	0	0	0	0	0	0	0	0

N: Number received injections by provider.
*Hakeem practising Eastern medicine.

Table 29: Distribution of setting for last injection received, Injection frequency assessment, Pakistan, 2001

Setting	Urban			Rural			Total		
	N	%	95% CI	N	%	95% CI	N	%	95% CI
Government hospital	19	4.7	2.7-6.7	5	1.2	0.2-2.2	24	3.6	2.2-5.0
Private hospital	8	2.1	0.9-3.3	10	2.7	0.6-4.8	18	2.3	1.2-3.3
Outpatient clinic	18	4.7	1.9-7.3	117	26.1	21.2-30.8	135	11.3	8.3-14.2
Private GP clinic	382	82.6	77.3-87.8	243	55.7	46.7-65.2	571	74.4	69.9-78.8
Dispenser's own clinic	2	5.9	2.8-9.1	58	10.6	4.6-16.7	80	7.4	4.7-10.1
Traditional healer's clinic	0	0	0-0	1	0.2	-0.2-0.5	1	0.1	-0.1-0.1
Home	0	0	0-0	19	1.0	0.4-6.1	19	1.0	0.2-1.8

N: Number of received injections by setting.

Table 30: Safety circumstances of last injection received, injection frequency assessment, Pakistan, 2001

Source of syringe	Urban			Rural			Total		
	N	%	95% CI	N	%	95% CI	N	%	95% CI
Newly opened from the packet*	141	34.8	26.2-43.5	193	39.9	26.2-53.7	334	36.4	29.1-43.7
Picked up from the table/tray	2	0.5	-0.2-1.2	10	2.8	0.9-4.7	12	1.2	0.4-2.0
Pot of water	3	0.9	-0.1-1.9	11	2.9	0.6-5.1	14	1.6	0.6-2.5
Sterilizer	110	29.4	18.6-40.2	0	0	0	110	20.3	11.8-28.8
Behind the counter	58	13.8	7.8-19.8	94	19.6	14.4-24.6	152	15.6	11.0-20.1
Patient brought with him/her*	50	12.4	8.7-16.1	70	15.5	8.3-31.7	120	14.7	9.9-19.5
Changed needle	3	0.9	-0.1-1.8	0	0	0	3	0.6	-0.1-1.2
Syringe used on previous patient	0	0	0	9	1.2	-0.2-2.7	9	0.4	-0.1-0.8
Don't know	28	7.3	4.3-10.2	66	13.5	9.4-17.7	94	9.2	6.9-11.6

*These syringes were considered sterile as they came from sealed packet opened in front of the patient.

Table 31: Cost of a visit to a health care provider and cost of injection received, injection frequency assessment, Pakistan, 2001

Cost category and age in years	Urban			Rural			Total		
	N	Mean cost (Rs)	95% CI	N	Mean cost (Rs)	95% CI	N	Mean cost (Rs)	95% CI
Cost to visit a provider									
¼ - 5	103	99.9	90.9-108.9	44	68.9	67.7-70.2	147	94.7	87.2-102.1
5- 14	55	44.9	43.5-46.4	19	45.2	43.7-46.7	74	45.0	43.7-46.3
15- 45	254	55.9	54.5-57.2	202	213.7	196.0-231.4	456	93.2	88.9-97.5
>45	49	33.8	32.9-34.7	68	75.4	70.7-80.1	117	49.0	47.2-50.9
Total	461	61.9	59.8-64.0	333	154.0	143.5-164.5	794	82.9	80.0-85.8
Cost of an injection									
¼ - 5	6	70.2	64.6-75.9	8	34.9	32.7-37.0	14	55.8	52.3-59.3
5- 14	4	126.0	118.9-133.0	0	-	-	4	126.0	118.9-133.0
15- 45	30	78.2	74.7-81.7	13	13.5	12.9-14.1	43	65.9	63.0-68.8
>45	1	20.0	20.0-20.0	6	13.3	12.9-13.8	7	15.8	15.3-16.2
Total	40	80.1	77.3-82.8	27	21.2	20.2-22.0	68	65.7	63.5-67.9

N: Number of reported visits or injections from which the mean is calculated. Rs: Pakistani Rupees; Rs. 100 ˜ US$ 1.55

.

Section IV: The tool to assess injection safety

VI.1. SURVEY OF INJECTION SAFETY IN BURKINA FASO

June 2000

Julia Fitzner,[*] Jean-François Aguilera,[†] and Andre Yameogo[‡]

[*]Robert Koch-Institut, Berlin, Federal Republic of Germany. [†]Communicable Diseases Surveillance Centre, London, United Kingdom. [‡] Vaccine Prevention, Directorate of Preventive Medicine, Ministry of Health, Ouagadougou, Burkina Faso.

INTRODUCTION

To evaluate injection safety in Burkina Faso in 2000, the Ministry of Health with WHO decided to collect data on injection practices. In 1989, observation of injections in four clinics in Burkina Faso found overuse of injections and use of non-sterile material.[64] In 1995 and 1996, WHO's Africa Region (AFRO) Logistics Project evaluated injection safety in Burkina Faso and 11 other African countries with cross-sectional surveys, observations, interviews and focus group discussions. Findings in Burkina Faso in 1995-96 indicated, inter alia, frequent use of non-sterile injection equipment, shortages of equipment and other problems (Table 32).[65]

Table 32: Injection safety indicators in Burkina Faso, 1995 [65]

	Proportion of health centres (%)		
	Provincial	**Urban**	**Rural**
Use sterile syringe and needle	60	80	11
Secondary abscesses found on centre's patients	NA	40	78
Sufficient injection materials available	52	80	67
Injections by unqualified staff	20	NA	55

NA: Not available.

As a result of (a) these studies, (b) the Bamako initiative and concern about the transmission of bloodborne pathogens through unsafe injections, the Government of Burkina Faso encouraged the sale of single use injection equipment to the public through community pharmacies located close to the health centres. To allow cost recovery and the broadest possible access to material, the price of a single use syringe and needle has been set at Central African franc (CFA) 75 (US$ 0.10 as of May 2001). This has made it possible to set up depots of community-managed supplies throughout the country.

The current assessment provides an opportunity to examine the impact of new policies. The aim of the survey was to estimate the frequency of unsafe injections and contributing factors, including:

(a) Determine whether the health centres providing injections satisfy the conditions for safe injections in terms of staff training, availability of equipment, supply of sterile equipment and disposal of infectious waste;

(b) Determine whether the different safe injection procedures are observed in accordance with good practices;

(c) Identify unsafe injection practices that might cause infection by bloodborne pathogens;

(d) Estimate the proportion of health centres in which safe injections were provided.

METHODS

We conducted a descriptive cross-sectional survey. The data were collected in June 2000 using standardized reporting forms for stocks of injection equipment and structured observation of injections and questionnaires for interviewing centre staff. Design followed methods proposed in WHO's Tool for the assessment of injection safety.[15]

We identified health centres with two-stage cluster sampling. For the first stage, we selected eight districts with a probability in proportion to their population (1996 census projected to 2000, National Institute of Statistics and Demography of Burkina Faso). For the second stage, we identified 10 health centres in each district by simple random sampling from the list of health centres in each district (Burkina Faso health map, Department of Studies and Planning, Ministry of Health, 1997). For sampling purposes, districts with less than 10 health centres were grouped with the districts closest to them. In each district, a number was assigned at random to each health centre to enable them to be ranked. The ten centres with the lowest numbers were selected. The next five centres were used for the list of replacement centres. Finally eight districts with ten centres each were selected.

Between 13 and 20 June 2000, four teams comprising a supervisor, an investigator and a driver collected data in the field under the supervision of two WHO consultants. Each team visited the health centres in two districts, i.e. 20 health centres. The data collection method was standardized before fieldwork began. The informed consent of the health workers in the centres, who were free to refuse to participate, was obtained.

To analyze data, we calculated the proportion of health centres presenting various characteristics, using as the denominator the number of centres in which at least one injection was observed or the total number of centres in which the observation in question was considered to have been made, as appropriate. Cluster effects were calculated using the CSAMPLE module of Epi-Info, version 6.04, which uses Taylor's linear deviation principle for calculations (CDC, Atlanta, GA, USA). The cluster effects thus obtained were entered into Epi-Info's EPITABLE module to calculate the confidence interval using Fleiss's quadratic formula. When no cluster effect could be calculated (when replies were 100% identical) we assumed a value of two to allow the confidence interval to be estimated.

RESULTS

Eighty health centres were included in the survey; 13 (16%) were taken from the replacement list because those chosen initially were inaccessible for logistical reasons. The majority of centres used new single use injection equipment, which was purchased by patients at a depot close to the centre, both for vaccinations and therapeutic purposes (Table 33). The staff of the 80 health centres said that depots were regularly supplied. Vaccines were supplied to the health centres without the corresponding quantities of injection equipment. Five centres (6%) used sterilizable equipment for BCG vaccinations. In three, UNICEF-donated needles, which were initially sterile but whose sterile packaging had been opened, were used without being sterilized (Table 33). Fifty-one per cent of the centres had a stock of safety boxes (Table 34).

Table 33: Injection equipment in health centres, Burkina Faso, 2000

Type of equipment	Centres with equipment	Centres observed	Observed centres with equipment (%)	95% CI	DE
Sterilizable injection equipment	5[*]	80	6	1-20	1.9
Sterilizable injection equipment other than for BCG	0	80	0	0-11	2[‡]
Disposable injection equipment not provided by patient	0	80	0	0-11	2[‡]
Centres that reported stock-outs of injection equipment	0	80	0	0-11	2[‡]
Centres receiving vaccines with adequate quantities of injection equipment	2	77[†]	3	1-9	0.9
Centres receiving vaccines with adequate quantities of safety boxes for sharps	1	77[†]	1	0.8	1.0

CI: Confidence interval. DE: Design effect.

* Three of these centres used sterilizable and single use needles for BCG.

† Three centres not providing vaccinations.

‡ The design effect could not be calculated, and was set at 2.

Table 34: Stocks of sharps safety boxes in health centres, Burkina-Faso, June 2000

Number of boxes	Number of centres	(%)	95% CI	DE
0	41	(51)	30-72	3.5
1-4	23	(29)	13-51	
5-9	6	(8)	1-28	
10-19	5	(6)	1-27	
>20	5	(6)	1-27	

CI: Confidence interval. DE: Design effect.

In all, we observed 116 injections in 52 (65%) centres. Of these, 40 (34%) were vaccinations. The centres' staff said that on average there were more vaccinations than therapeutic injections, with a weekly average of 47 vaccinations (range: 1-210) to 32 therapeutic injections (range: 1-210); data on vaccinations was originated out of 76 centres only.

RISK TO PATIENTS

Despite the predominant use of single use injection equipment, non-sterile injection equipment was still being used in a minority of the centres visited. In two centres (4%), the syringe had been reused without sterilization (Table 35), and in one centre (2%) the needle was new but taken from a non-sterile (opened) package donated by UNICEF for BCG vaccination. In 27 centres (52%), a special clean area was set aside for preparing injections. In 38 centres (73%), the skin was cleaned prior to the injection, in every case using a swab with alcohol. Skin was cleaned for all therapeutic injections and 35% of vaccinations (there is currently no Ministry of Health directive concerning skin cleaning before

vaccination). In 19 centres (95% of those in which at least one vaccination was observed) vaccines were stored at the correct temperature during the vaccination session.

Table 35: Frequency of injection practices affecting risk to patients or health care workers, Burkina Faso, June 2000

Practices	Centres observed	Number (%) centres observed with the practice	95% CI	DE
Practices affecting risk to patients				
Use of sterile syringe	52	50 (96)	85-99	1.13
Use of sterile needles	52	51 (98)	89-100	0.89
Use of clean area to prepare injections	52	27 (52)	32-71	2.00
Withdrawal of needle from flask between each injection	19	17 (89)	64-98	1.07
Vaccines stored at correct temperature during session	20*	19 (95)	70-100	1.17
Skin cleaned before injections	52	38 (73)	55-86	1.55
Practices affecting risk to health workers				
Two-handed recapping	52	29 (55)	36-74	2.0
Needles disposed in a safety box	52	3 (6)	1-23	1.8
Needles present in open boxes	80	66 (83)	55-96	5.1

DE: Design effect. CI: 95% Confidence interval.
*In two centres vaccination was halted because the vaccines were not kept at the correct temperature.

RISKS TO HEALTH CARE WORKERS

Practices at most of the centres exposed health care workers to needle-stick injuries. In 29 centres (55%), the staff recapped needles with two hands after an injection (Table 35). Only three centres (6%) disposed of needles in a safety box immediately after use. In 66 centres (83%), used sharps were found in open boxes or other unsafe containers in the centre. Some centres collected needles in used plastic bottles or home-made safety boxes.

Health care workers in 71 centres reported an average of 2.2 needle-stick injuries (range: 0-22) per health centre during the previous 12 months, i.e. 0.5 needle-stick injuries per health care worker over the twelve-month period. In nine centres, it was not possible to determine the number of needle-stick injuries. The average number of staff per centre in 71 centres was 4.7 (range: 3-22).

RISKS TO THE COMMUNITY

The practices of most of the health centres for dealing with sharps left much to be desired. We found used sharps in the vicinity of 46 (57%) centres or outside the centres' waste dumps. The main waste disposal techniques for used sharps were uncontrolled open burning (41 centres) and controlled open burning (32 centres, Table 36).

Table 36: Frequency of main methods to dispose of sharps, Burkina Faso, June 2000

Method of elimination	Number (%) of centres	95% CI	DE
Uncontrolled open burning	41 (51)	34-69	2.5
Controlled open burning	32 (40)	24-58	
Functioning incinerator	1 (1)	0-15	
Burial	0 (0)	0-13	
Disposed in latrines or other safe depository	4 (5)	1-20	
Disposed in unsafe places	2 (3)	0-17	
Taken away for disposal at another location	0 (0)	0-13	

DE: Design effect. CI: Confidence interval.

DISCUSSION

This assessment has made it possible to highlight an increase in the use of new single use injection equipment in Burkina Faso since the 1995 assessment.[65] This improvement may be attributed to a change in policy regarding supplies of injection devices. However, there are still problems with the elimination of sharps that represent a risk for health workers and for the community.

SUMMARY OF FINDINGS

We found that single use injection equipment was always available in village pharmacies located close to health centres. The satisfactory availability of single use equipment may have contributed to improved injection safety during 1995-2000 and it appeared to be the result of community management of pharmaceutical depots. However, the cost of single use injection equipment may limit access to certain essential injections, because some patients are unable to afford it.

Despite increased use of single use injection equipment since 1995, we observed syringes reused without sterilization in two centres and the use of new, clean reusable needle that had not been sterilized in one. Although isolated, such practices must be vigorously eliminated because they represent a high risk of transmission of bloodborne diseases.

Health care workers in Burkina Faso are exposed to risks. Two-handed recapping of needles, which is a risk for needle-stick injury, is still common practice in more than half the health centres. Safety boxes, which we found in almost half the centres, are rarely used. In most centres, sharps are collected in open boxes, putting health workers at risk. In contrast to injection equipment, there is no supply system for sharps safety boxes for health care centres. In most cases, both the safety boxes and the injection equipment in the centres represented leftovers of stocks distributed free during the most recent mass vaccination campaign in December 1999. These unused safety boxes suggest that without proper training in use, supply of safety boxes is not enough to change behaviour with regard to disposal of sharps.

Our findings on sharps waste disposal show that communities are still at risk from needle-stick injury or reuse of equipment intended for disposal.

LIMITATIONS

There were two major limitations to this assessment: First, 13 health centres deemed inaccessible because of the poor state of the roads were replaced by centres from the standby list. This may have led to over-estimation of the frequency of safe injections if the less accessible centres were also those in which injections are less safe. Second, we did not evaluate the quality of the single use injection equipment available in the pharmacies. Although most of the equipment seen came from manufacturers located in countries with functional regulatory authorities, the possibility that below-standard injection equipment was sold in sealed packages in Burkina Faso may not be excluded.

RECOMMENDATIONS

There has been a marked improvement in injection safety in Burkina Faso between 1995 and 2000. The population has better access to single use injection equipment. However, further improvements are required to improve injection safety for patients, health workers and the population. Injection safety in Burkina Faso would benefit from measures to change the behaviour of health workers, to ensure regular supplies of injection material and security boxes and to deal with waste properly.

BEHAVIOUR CHANGE

Training should be provided in the different areas recognized as representing a risk. Reuse of single use syringes or needles should be absolutely avoided, as should two-handed recapping. Sterilizable material distributed for BCG vaccination should always be sterilized before use. Health care workers should be reminded of the importance of the cold chain and urged to use security boxes for sharps. Sharps should be banned from the vicinity of health centres.

SUPPLIES

To reduce the number of vaccinations missed by families who are unable to pay for injection equipment and to ensure that all immunizations are carried out using new single use equipment, Burkina Faso authorities should examine a system to ensure joint and regular supplies of vaccines, injection material and safety boxes. [66]

In the case of therapeutic injections, a small tax on the sale of syringes and needles could enable depots to finance safety boxes. The price of a cardboard security box could be spread over 100 injections, requiring a minimal increase in the price of each of them. The successful experience with the supply of syringes and needles could serve as an example for the supply of security boxes.

WASTE DISPOSAL

A national directive should be issued to define the principles for safe waste disposal in order to reduce risks to communities. Waste disposal should consider all waste produced by health centres, training at all levels and the selection of disposal methods that are suitable, simple, efficacious, affordable and environmentally friendly.

ACKNOWLEDGEMENTS

VI.2. SURVEY OF INJECTION SAFETY IN NIGER

August 2000

John Painter[*]

*Epidemic Intelligence Service, CDC, Atlanta, GA, USA.

INTRODUCTION

In 1994, the Ministers of Health from 51 African countries, meeting in Yamoussoukro in the Republic of Ivory Coast, signed a declaration to ensure that injections are administered safely. Nevertheless, unsafe injections remain a threat for patients (because of use of contaminated equipment), health workers (because of needle-stick injuries) and the community (because of unsafe disposal of health care waste).

Niger (2000 population: 11 million) has a total of 683 private and public health clinics. The country is organized into eight provinces and 40 districts. To assess injection safety in Niger, the Ministry of Health proposed an assessment of injection practices, with the objectives of (a) estimating the proportion of clinics engaging in unsafe injection practices and (b) formulating evidence-based recommendations to improve practices.

METHODS

A cross sectional, observational survey, based on standardized data collection instruments[15], was used to assess injection safety. A two-stage cluster sample methodology adapted from immunization coverage surveys was used to select eight clusters of 10 health clinics. Clusters were drawn from official health districts; districts with less than 15 clinics were combined with neighbouring districts to form strata that contained at least 15 clinics. Hence, the 40 health districts were grouped into 25 strata. We selected eight strata – or clusters – for the survey using a probability proportional to the population size. Subsequently, within each of the eight clusters, we selected 10 clinics at random. Ten additional clinics within each cluster were selected as possible replacement clinics in the event that a clinic was unavailable during the field work period.

Information was collected in clinics using three standardized, pre-tested data collection instruments for: (1) observation of available supplies and equipment, (2) observation of therapeutic and immunization injections and (3) interviews with injection providers and clinic supervisors. Two teams consisting of two interviewers collected data during 19-30 August 2000. Each team attempted to visit ten clinics in each of four clusters. Clinics that could not be reached by car or that were closed during the visit were replaced by clinics chosen at random from a replacement list of clinic from within the same cluster. In some cases the available personnel could not arrange observations or provide answers during visits. In those cases, we assigned missing values and removed those records from the analysis of that data element.

All data entry and data analysis was conducted using the Epi-Info software, version 6.04b (CDC, Atlanta, GA, USA). Point estimates for proportions and design effects were calculated using the CSAMPLE module. Confidence intervals for proportions were calculated with the EPITABLE module on the basis of the design effect calculated with CSAMPLE. Health care clinics were considered as the sampling unit. If an unsafe practice was observed during any injection in the clinic, it was coded as

unsafe for that practice. For example, if recapping a needle with two hands was observed during one of two immunization injections observed, the clinic was counted as recapping with two hands.

<div align="center">RESULTS</div>

Seventy-nine clinics were visited and observed. Three clinics were unreachable by car and were replaced by an alternate clinic in the cluster. One clinic was under construction and could not be replaced because of logistic constraints. We observed 86 injections (26 vaccinations and 60 treatments) at 45 (57%) of 79 clinics. We interviewed 78 (98%) of 79 injection providers and 77 (97%) of 79 supervisors. Clinic personnel who did not participate were either unavailable or unwilling to respond.

INJECTION PRACTICES REFLECTING RISK TO THE PATIENT

Clinics used standard single use, auto-disable and sterilizable injection equipment (Table 37). Forty-two (53%) clinics used sterilizable equipment, of which 39 (93%) of 42 examined had a functioning heater; 22 (61%) of 36 had a steam sterilizer that could function without leaking and none of 42 documented sterilization using Time-Steam-Temperature (TST) spot indicators.

Single use syringes were available at 61 (85%) of 72 clinics, including 40 (56%) with auto-disable syringes. Only 28 (54%) of 52 clinics reported no shortages of single use syringes in the last twelve months and 42 (76%) of 55 reported no shortages of energy for sterilization. With respect to immunization supplies, 16 (29%) of 56 clinics reported receiving injection equipment in quantities that matched vaccine supplies. Based on the average number of immunization and treatment injections per week at each clinic, only 14 (18%) of 77 had a one-week supply of single use syringes and only 24 (32%) of 76 had a two-day supply of sterilizable equipment.

We observed attempted injections with a non-sterile syringe or needle in five (11%) of 45 clinics, including both curative injections (4/39, 10%) and vaccinations (1/16, 6%). In all cases, the procedure was interrupted tactfully before the injection. Attempts to use non-sterile syringes were more common than attempts to use non-sterile needles (11% versus 2%, two-tailed Fisher's exact test, $P = 0.20$). Patients were required to purchase injection equipment for treatments. When they could not afford them or when they were not available, attempts were made to boil injection equipment designed for single use at eight (10%) of 79 clinics.

Based on 49 clinics reporting complete information, the mean number of injections given per week was 153 (median 103). Extrapolating to 683 clinics nationally, approximately 5 400 000 injections were given per year in all clinics of the public sector in Niger. The reported weekly number of therapeutic injections (mean = 110, standard error = 12.2) exceeds vaccinations (mean = 73, standard error = 11.7). Hence, curative injections accounted for approximately 60% of all injections in government clinics. However, people may receive more curative injections outside of government clinics.

We examined the procedures used to prepare injections. In 31 (69%) of 45 clinics where an injection was observed, the injection was prepared in a clean, dedicated area, separate from areas potentially contaminated with blood. In 35 (95%) of 37 clinics where a multi-dose medication vial was used for several injections, the needle was removed from the vial between injections. All temperature-sensitive products were kept cool during injection preparation. While six (100%) of six vaccinations observed were prepared with the recommended diluent, only 21 (88%) of 24 curative injections were prepared with the recommended diluent. Only 31 (94%) of 33 injections were reconstituted with a sterile syringe and needle. The skin was wiped with disinfectant prior to 36 (95%) of 39 therapeutic injections and two (13%) of 16 vaccinations.

Table 37: Elements reflecting safety or risk to the patient, injection safety assessment, Niger, 2000

Instrument used (Number) [*]	Information item	Clinics with factor		
		N/ Total [†]	%	95% CI
Supplies (1)	Use of steam sterilizer	42/79	53	31–74
Supplies (1)	Had a functioning heater	39/42	93	69–98
Supplies (1)	Presence of steam sterilizers without observed leaks	22/36[‡]	61	44–76
Supplies (1)	Presence of replacement seals for steam sterilizer	14/41[‡]	34	23–47
Supplies (1)	Documented sterility using a TST indicator	0/42	0	0–10
Supplies (1)	Disposable syringes and needles available	61/72[§]	85	59–96
Supplies (1)	Auto-disable syringes available	40/72[§]	56	30–79
Interview (3)	No shortages of single use injection equipment	28/52[ǀ]	54	42–65
Interview (3)	No shortages of energy source for sterilization	42/55[ǀ]	76	53–91
Interview (3)	Receive matching quantities of syringes with vaccines	16/56[ǀ]	29	16–46
Supplies (1)	Presence of a week's supply of single use equipment	14/77	18	10–26
Supplies (1)	Presence of a two-day supply of sterilizable equipment[¶]	24/76	32	17–46
Practices (2)	Administration with a sterile syringe and needle	40/45	89	72–97
Interview (3)	Mean number of injections give per week (range: 4-906)	153	NA	106-200
Practices (2)	Preparation in a clean dedicated area	31/45	69	52–82
Practices (2)	Removal of needles from multi-dose vials between injections	35/37	95	78–99
Practices (2)	Reconstitution with recommended diluent (vaccine)	6/6	100	52–100
Practices (2)	Reconstitution with recommended diluent (curative)	21/24	88	78–94
Practices (2)	Reconstitution with a sterile syringe and needle	31/33	94	82–99
Practices (2)	Skin prepared with alcohol before injection (curative)	36/39	95	78–99
Practices (2)	Skin prepared with alcohol before injection (vaccine)	2/16	13	1–55
Practices (2)	Temperature sensitive products kept cool during preparation	17/17	100	77–100
Practices (2)	Immediate flushing and disassembling of re-usable syringes	6/30	17	5–52

NA: Non available.

[*] Number of the instrument for standardized data collection.[15]

[†] [Clinics found with the factor]/[clinics for which information on the factor was available].

[‡] Information was not available from all 42 clinics with sterilizers.

[§] Information on inventory was not complete from seven clinics.

[ǀ] Interviews were not complete for all clinics.

[¶] Two-day need for syringes extrapolated from number of treatment injections per week.

RISK TO THE HEALTH CARE WORKER

According to interviews with injection providers and clinic supervisors, only 17 (22%) of 79 clinics reported no accidental needle-stick injuries to clinic workers during the last 12 months. The mean number of needle-stick injuries in the last 12 months was 3.5 (95% confidence interval [CI]: 1.3–5.3) among those who reported at least one, and 1.2 (95% CI: 0.5–2.0) overall.

Only 27 (34%) of 79 clinics had at least one puncture- and liquid-proof container (safety box, Table 38). In addition, only nine (23%) of 40 clinics reported no shortages of safety boxes during the last year and only two (3%) of 65 reported that a matching quantity of safety boxes was delivered with vaccine supplies. However, only 22 (81%) of 27 clinics with safety boxes used them. Sharps were collected and stored in safe containers at four (5%) of 77 clinics. For the 73 clinics that did not do so, 25 (34%) had a least one unused safety box and 16 (22%) had at least 10. Needles were placed in a safety box after use

in only six (16%) of 37 clinics where injections were given with single use equipment. In addition, health care workers were observed recapping with two hands at seven (16%) of 45 clinics.

Table 38: Information elements reflecting risk to the provider, injection safety assessment, Niger, 2000

Instrument used (Number) *	Information item	Clinics with factor		
		N/Total †	%	95% CI
Interview (3)	Absence of needle-stick injuries in the last 12 months ‡	17/79	22	13–34
Supplies (1)	Presence of at least one safety box	27/79	34	49–79
Interview (3)	No shortage of safety boxes during last 12 months	9/40	23	7–50
Interview (3)	Receive matching quantities of sharps containers with vaccines	2/65	3	1–10
Supplies (1)	Used at least one safety box	22/27	81	52–96
Supplies (1)	Sharps always collected and stored in safe containers	4/77	5	1–14
Practices (2)	Absence of two-hands recapping	38/45	84	68–94
Interview (3)	Knowledge of risks of associated with needle-stick injuries	78/78	100	94–100
Interview (3)	Received injection safety training	4/79	5	1–13
Interview (3)	Presence of an injection safety management policy	5/77	7	2–15

* Number of the instrument for standardized data collection.[15]

† [Clinics found with the factor]/[clinics for which information on the factor was available].

‡ Any needle-stick reported by either injection provider or supervisor.

We examined the association between needle-stick injuries and unsafe injection practices. The relative risk of needle-stick injury in the last 12 months was 1.4 (95% CI: 0.9–2) among health care providers who were observed recapping needles with two hands and three (95% CI: 0.5-16) in facilities where needles were not collected in a puncture-proof container. The median number of needle-stick injuries reported by injection providers per year was higher at clinics where used needles were stored in open containers instead of safety boxes (1.0 versus 0.0, P = 0.11, non parametric test).

Health care workers were aware of the risk of infection with bloodborne pathogens associated with needle-stick injuries. All health care workers were knowledgeable about at least one pathogen transmitted through unsafe injection practices or needle-stick injuries, including HIV (100%), hepatitis (77%) and others. Only four (5%) of 79 injection providers reported any training on safe injection practices and only five (7%) of 77 clinics had a written injection safety management policy.

RISK TO THE COMMUNITY

Contaminated sharps were not observed in places that would pose a risk to the community, such as on the grounds of the clinic, at 27 (39%) of 70 clinics (Table 39). In 39 (50%) of 78 clinics, sharps waste was mixed and dumped with ordinary paper waste. Other reported methods for contaminated waste disposal included open burning (19 clinics, 29%), incineration (five clinics, 6%), burial (seven clinics, 9%) and dumping into latrines (four clinics, 5%). Only three (4%) of 75 clinics had a written health care waste management policy.

Table 39: Information elements reflecting safety or risk to the community, injection safety assessment, Niger, 2000

Instrument (number)[*]	Information element	Clinics with factor		
		N/Total[†]	%	95% CI
Supplies (1)	Absence of sharps found on ground around the clinics	27/70	39	18–64
Interview (3)	Presence of a health care waste management policy	3/75	4	1-10

[*] Number of the instrument for standardized data collection.[15]
[†] [Clinics found with the factor]/[clinics for which information on the factor was available].

DISCUSSION

A safe injection is one that does not harm the recipient, the provider or the community.[67] To assess the level of injection safety in Niger, we conducted an assessment using the new WHO standardized injection safety assessment tool. The survey involved observation of stocks of injection equipment, observation of immunization and curative injections and interviews with injection providers and supervisors. We observed unsafe injection practices, including harm to patients because of injections performed with non-sterile equipment, harm to injection providers because of needle-stick injuries and harm to the community because of the presence of infectious medical waste around the clinics.

RISK TO PATIENTS

Unsafe preparation and administration of injections are the practices that expose patients to infections. Only 90% of curative injections and 94% of vaccinations were administered with a sterile needle and syringe. Many injections were prepared in areas contaminated with blood, a practice associated with the transmission of bloodborne pathogens.[68] In addition, only 94% of injections requiring reconstitution were prepared with a sterile syringe and needle. Our assessment suggests that the cause for these unsafe practices includes lack of supplies and training.

Lack of supplies

The supplies of needles and syringes in Niger were not adequate in view of the number of injections administered. While single use and sterilizable equipment are used, only a third of clinics had adequate quantities. Some clinics that did not have adequate supplies of 0.05 ml syringes or needles for BCG immunizations substituted either 2 ml syringes or larger gauge needles. Thus, a comprehensive plan to supply clinics with equipment – with attention to specific needs – should be formulated, costed, budgeted and funded.

Injection providers have the option of single use or sterilizable syringes. Since many clinics in Niger have abandoned sterilizable equipment in favour of single use equipment, it may be difficult to ensure that clinics have adequate supplies and the necessary training to use sterilizable equipment. A dual system of single use and sterilizable equipment creates conditions that promote reuse without sterilization.[65] Therefore, Niger should plan to have adequate supplies of single use needles, including auto-disable for immunization and standard single use for curative services. In Burkina Faso, community pharmacies selling single use injection equipment to patients contributed to improved availability of equipment. In Burkina Faso, 0% of clinics reported shortages versus 46% in Niger. (See).

Auto-disable syringes – that make reuse difficult or impossible – may reduce the risk of person-to-person transmission of bloodborne pathogens, including HBV, HCV and HIV.[66] While auto-disable syringes cost more than conventional single use syringes, the difference is small compared with the cost of treating illness due to unsafe injections.[69] The cost-effectiveness of this approach is even greater among children who are at increased risk of dying from causes related to chronic hepatitis infection.[70] WHO's "bundling" policy recommends that auto-disable syringes be supplied with vaccines in all routine immunization services and campaigns.[66] According to the "bundling" policy, equipment are supplied together, but they might not be physically attached.

From this survey, we could not establish the causes of the limited availability of injection equipment in clinics. Potential explanations include an overall lack of equipment in Niger, either secondary to cost or supply issues and problems in the management of distribution. Anecdotally, we observed several regional clinics that had large stocks of injection equipment, including leftovers from a recent mass vaccination campaign, which could have been redistributed to health clinics to alleviate shortages.

Historically, health clinic managers have not expressed a clear preference and demand for auto-disable syringes and the push for auto-disable syringes has been viewed as an external rather than an internal pressure. However, this perception may change with increasing public awareness of the consequences of unsafe injections and a stronger demand for safety from the user.

Lack of training

Lack of supplies could not explain all the unsafe practices that we observed during our assessment. At least one health care worker believed only a sterile needle, not a sterile needle and syringe, was necessary to protect a patient and we noted that some clinics choose to replace needles but not syringes. Injection with new but non-sterile equipment was attempted, which indicated a lack of training regarding the difference between clean and sterile. In addition, we observed several deficiencies in injection preparation, including not having a clean and dedicated work area, not using the recommended diluent and not using sterile technique. We also noted unnecessary curative injections, i.e., injections of medications, including antibiotics, where oral medications could have been prescribed. To correct these problems, the Ministry of Health will need to assign resources to train and supervise injection providers.

RISK TO PROVIDERS

Unsafe collection of sharps waste poses a risk to injection providers and the community. In Niger, most clinics collected contaminated waste in open containers and the number of needle-stick injuries was high. Shortages of safety boxes were reported and observed. However, many did not use the boxes they had, suggesting additional behavioural issues. We did not explicitly ask when health care workers were most likely to receive needle-stick injuries, but we did observe high-risk practices. The behaviour of injection providers needs to change toward immediately discarding used equipment – without recapping – into puncture- and liquid-proof containers. The health system should procure sufficient quantities of safety boxes to match quantities of new, single use injection equipment distributed through immunization and curative services.

RISK TO THE COMMUNITY

To improve the safety to the community, discarded injection material must be disposed of so that there is no risk of needle-stick injury. In Niger, contaminated sharps were observed in the environment

surrounding health care facilities. Needles and other contaminated equipment disposed in dumpsters and open trash heaps will cause injury. Burying needles proved to be a temporary solution, as needles re-emerged, particularly in sandy soil. We observed burned and buried needles sticking out of the ground, suggesting that open burning was an inappropriate method for sharps disposal. To manage sharps waste appropriately, clinics should accept the responsibility of managing health care waste as part of their work. Waste production should be quantified, streamlined and minimized. Training should be conducted at all levels. Safe, efficient and cost-effective waste treatment options should be made available. Wood-burning incinerators seen at several clinics could serve as a model for other clinics.

LIMITATIONS

This assessment has several limitations. Injections were observed at only 57% of clinics. Health care workers may have wanted to avoid being observed. The survey team perceived that some clinics avoided observers unless providers could give injections under ideal circumstances. This suggests that in the absence of observation some injection providers may use unsafe practices and our results may be biased towards a higher frequency of safe injection practices.

The quality of single use injection equipment available in clinics was not evaluated. Although most of the material observed during the investigation was manufactured in countries having functional national regulatory authorities, we did not examine the quality or sterility of the injection equipment. It is possible that single use equipment sold under sealed packing was repackaged or damaged.

CONCLUSIONS AND RECOMMENDATIONS

Needles and syringes used to deliver life-saving medication should not themselves be vectors for life-threatening pathogens. Improving the level of injection safety will require direction from the Ministry of Health, training of injection providers and educating patients to demand safe injection practices. The holistic approach to injection safety (Figure 8, Page 90, adapted from Dicko) illustrates what is required to improve injection safety. Experience indicates that in the absence of a national policy, unsafe injections occur.[71] Immunization and other specific health services may have difficulty promoting injection safety for several reasons. First, they are not in a position to direct what happens at health clinics, nor the general direction of health clinics. Second, money spent on injection safety may take away from vaccine coverage and therefore may not be viewed as part of EPI's mission.[65] Thus, injection safety needs to begin with a policy from the Ministry of Health, which manages the budgets of EPI and other health services, including district health clinics.

The following four recommendations propose elements for a Ministry of Health initiative for the safe and appropriate use of injections:

1. Formulate a national policy for injection safety, with specific attention to bundling supply of single use injection equipment (including auto-disable syringes for immunizations) and safety boxes with supply of prophylactic or therapeutic injection materials. Introduce these changes with management quality assurance procedures, which includes planning, implementing, monitoring, evaluating and then updating the plan.

2. Require that clinics have an injection safety policy that covers sterile injection procedures, immediate disposal of syringes and safe elimination of medical waste. Improve training for injection providers on safe injection practices including sterile preparation, to protect the patient and safe disposal to protect against needle-sticks.

3. Implement a health care waste management plan following WHO's recommended principles that include assignment of waste management responsibilities to personnel, allocation of resources, safe handling and storage, and safe treatment and disposal.[72]

4. Promote behaviour change among patients that creates a consumer demand for safe injections. Create a public education campaign to promote patients' understanding of injection safety in order to create a consumer demand for safety.

ACKNOWLEDGEMENTS

Ministry of Health
Planning and budgeting
Training and supervision

Injection Providers
Giving injections
Reporting problems

Patients
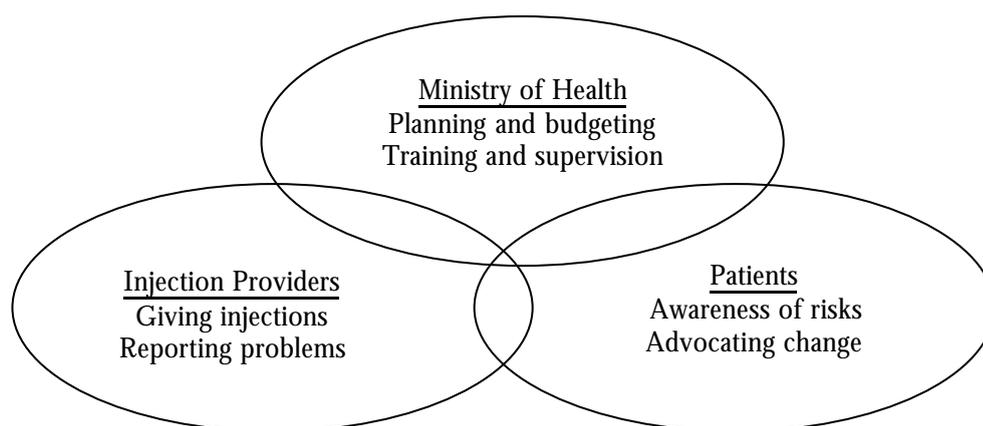Awareness of risks
Advocating change

Figure 8: Holistic approach to improving injection safety (adapted from Dicko et al.) [65]

Section V: The tool to assess the association between injections and infections

V.1. RISK FACTORS FOR ACUTE HEPATITIS B VIRUS INFECTION IN KARACHI, PAKISTAN

2000-2001

H. R. Usman, [†] S. Akhtar, [†] M. H. Rahbar,[†] S. Hamid,[‡] T. Moattar,[§] and S. P. Luby[|]

*The paper is abstracted with permission from: Usman HR, Akhtar S, Rahbar MH, Hamid S, Moattar T, Luby SP. Injections in health care settings: A risk factor for acute hepatitis B virus infection in Karachi, Pakistan. Epidemiol Infect 2003; 130: 293-300.

[†] Division of Epidemiology and Biostatistics, Department of Community Health Sciences, the Aga Khan University, Karachi, Pakistan.

[‡] Department of Medicine, the Aga Khan University, Karachi 74800, Pakistan.

[§] Department of Pathology, the Aga Khan University, Karachi, Pakistan.

[|] Centers for Disease Control and Prevention, Atlanta, GA, USA.

INTRODUCTION

Hepatitis B virus (HBV) infection is highly endemic in most countries in the Western Pacific and South and East Asia, with prevalence of HBV surface antigen (HBsAg) ranging from 5% to 15%.[73] WHO classifies Pakistan in an intermediate endemicity category of 2-7% HBsAg prevalence. In 1994, a cross-sectional survey conducted in Punjab estimated the prevalence of HBsAg in the general population to be 4.3%.[22] Up to 10% of adults carry HBsAg.[74] In a series of acute viral hepatitis patients admitted to the medical unit of a tertiary hospital in Punjab, 71% were HBsAg positive.[75]

Therapeutic injections are considered to be a major source of HBV infection in developing countries. A parallel evaluation of the role of therapeutic injections as a risk factor for HBV infection in Pakistan is still awaited. This case-control study therefore evaluated therapeutic injections given in health care settings as an independent risk factor for acute HBV infection in Karachi, Pakistan.

SUBJECTS AND METHODS

STUDY DESIGN AND SETTING

A case-control design was used to identify the risk factors for HBV infection. The study was conducted in Karachi, Pakistan, the capital of Sindh Province. Study subjects were enrolled from four tertiary care hospitals of Karachi. Generally, people from lower and middle socioeconomic classes seek treatment from these hospitals.

SAMPLE SIZE

The sample size was calculated to detect the odds ratio (OR) of 2.5 with 80% power, specifying alpha at 5% and assuming 9% frequency of exposure among the controls.[52] As we expected to recruit fewer cases of acute hepatitis B, the sample size was adjusted for 1:3 case to control ratio. The calculated sample size was 103 cases and 309 controls.

SELECTION OF CASES AND CONTROLS

We selected as cases patients with acute viral hepatitis who tested positive for anti-HBc IgM, indicating an infecting event within the last six weeks to six months. Consecutive patients with acute viral hepatitis were enrolled when they came to collect their liver function test reports. We interviewed and collected 10cc blood from 229 patients and tested for IgM HBc antibodies. A case was excluded if the patient was not living in Karachi for the six months prior to the onset of illness or was not able to respond to questions.

We selected as controls patients of the selected hospitals with conditions other than acute viral hepatitis and who tested negative for total anti-HBc. Individuals with anti-HBc total are considered naturally immune to HBV and so not acceptable as controls. A control was excluded if he or she was not living in Karachi for six months prior to the interview.

THE QUESTIONNAIRE

A questionnaire was prepared to obtain information about the exposure to various risk factors during six months to six weeks prior to the onset of illness for the cases and during six months to six weeks prior to the time of interview from the controls. We collected information on demographic variables, history of jaundice and the following risk factors: therapeutic injections, blood transfusions, surgical treatment and hospitalization, dental treatment, presence of any liver disease patient in the household, health care occupation, services from barbers, ear piercing and tattooing and injecting drug use.

DATA COLLECTION AND ANALYSIS

Data collection took place during July 2000 to June 2001. Formal permission was taken from the heads of study hospitals and concerned departments. Persons in charge of data collection were stationed in the laboratories of the selected hospitals during working hours. Interviews were carried out in optimal privacy. Study subjects were explained about the study and an informed verbal consent was taken. They were also ensured about the confidentiality of information. Interviews were carried out with the accompanying parent (preferably mother) of the study subjects who were less than 13 years of age.

The data were analyzed using the Statistical Package for Social Sciences (SPSS) version 8.0. Univariate analysis was performed to evaluate the association of each potential risk factor with acute HBV infection. For each categorical potential risk factor, the odds ratio (OR) and 95% confidence interval (CI) were computed by univariate logistic regression model.

Multivariate analysis was performed to adjust for confounding and to identify interaction between variables. Independent variables with a P-value of less than 0.2 in univariate analysis or of known biological significance were considered for multivariate analysis. Variables were entered in the model one by one, starting with the most significant variable in the univariate analysis. Significance of each individual independent variable in the multivariate analysis was assessed by its confidence interval and Wald statistic. Variables found not significant (P > 0.05), not confounding the relationship of other variables or biologically not important were subsequently removed from the model. The overall significance of the variables in the model was assessed by G statistic.

Table 40: Socio-demographic characteristics of cases and controls, Karachi, 2000-2001

Characteristics	Cases (N= 67)		Controls (N= 247)	
	n	(%)	n	(%)
Enrolment hospital				
SSHL [*]	27	(40.3)	85	(34.4)
K V SITE [†]	16	(23.9)	64	(25.9)
JPMC [‡]	12	(17.9)	63	(25.5)
Civil hospital [§]	12	(17.9)	35	(14.2)
Age in years by category				
1-18	12	(17.9)	65	(26.3)
19-25	27	(40.3)	60	(24.3)
26-35	12	(17.9)	70	(28.3)
36-72	16	(23.9)	52	(21.1)
Gender				
Male	45	(67.2)	143	(57.9)
Female	22	(32.8)	104	(42.1)
Ethnicity				
Urdu	12	(17.9)	93	(37.7)
Sindhi	8	(11.9)	13	(5.3)
Punjabi	7	(10.4)	39	(15.8)
Pashto	30	(44.8)	67	(27.1)
Hindko	5	(7.5)	12	(4.9)
Others	5	(7.5)	23	(9.3)
Marital status				
Never married	25	(37.3)	118	(47.8)
Ever married	42	(62.7)	129	(52.2)
Years of formal schooling				
Nil	24	(35.8)	90	(36.4)
1-8 years	30	(44.8)	76	(30.8)
9-12 years	13	(19.4)	71	(28.7)
Above 12 years	0	(0.0)	10	(4.0)
Occupation				
Non-earning	30	(44.8)	136	(55.1)
Business	6	(9.0)	23	(9.3)
Government service	5	(7.5)	12	(4.9)
Factory worker	19	(28.4)	50	(20.2)
Service providers	7	(10.4)	20	(8.1)
Professionals	0	(0.0)	6	(2.4)
Number of household members				
1-6	16	(23.9)	94	(38.1)
7 or more	51	(76.1)	153	(61.9)
Monthly household income [††]				
< Rs 2500	12	(17.9)	20	(8.1)
Rs 2500-5000	39	(58.2)	163	(66.0)
> Rs 5000	16	(23.9)	64	(25.9)

[*] Social Security Hospital Landi, Karachi

[†] Kalsoom Bai Valika Hospital SITE, Karachi.

[‡] Jinnah Postgraduate Medical Center, Karachi.

[§] Civil Hospital, Karachi.

[ǀ] Mean with standard deviation.

[**] Presently married subjects (41 cases & 129 controls).

[††] Rs 63 = 1 US Dollar

RESULTS

We enrolled a series of 229 patients with acute viral hepatitis in the four tertiary care hospitals of Karachi. These patients were tested for IgM HBc antibodies to identify cases. The analysis was based upon 67 cases (29% of the total number of patients with acute hepatitis). We also recruited a series of 373 potential controls from the same hospitals. We excluded 126 subjects (34%) who were positive for total anti-HBc, leaving 247 controls (Table 40).

UNIVARIATE ANALYSIS (TABLE 41)

Cases were more likely to receive at least one therapeutic injection during the exposure period as compared to controls (OR = 5.6; 95% CI: 3.1, 10.0). Taking those who did not receive any injection as a reference category, cases were more likely to receive one injection (OR = 3.0; 95% CI: 1.2, 8.0) or more than one injection (OR = 6.7; 95% CI: 3.6, 12.4). Cases were more likely to receive therapeutic injections from a doctor (OR = 4.9; 95% CI: 2.7, 9.0) or non-doctor (OR = 11.7; 95% CI: 3.8, 35.7). Adult male cases were more likely to get their armpits shaved by the barber (OR = 2.2; 95% CI: 0.98, 4.7), but there was no significant association between facial shaving by the barber and HBV infection (OR = 1.5; 95% CI: 0.74, 3.1).

Exposures including intravenous infusions, hospitalization, blood transfusion, dental treatment and injury causing bleeding were not frequent enough among cases to show statistically significant association with acute HBV infection. The effect measure for other exposures including personnel handling blood/syringes, tattooing and injecting drug use could not be estimated because of zero frequency in some categories.

Table 41: Risk factors[*] for acute HBV infection from univariate analysis, Karachi, Pakistan, 2000-2001

Exposures	Cases = 67		Controls = 247		OR	95% C.I.	
	n	**(%)**	**n**	**(%)**			
Number of injections							
Nil	24	(35.8)	187	(75.7)	1		
One	7	(10.4)	18	(7.3)	3	1.2,	8.0
More than one	36	(53.7)	42	(17.0)	6.7	3.6,	12.4
Injection received from							
Physician	34	(50.7)	54	(21.9)	4.9	2.7,	9.0
Non-physician	9	(13.4)	6	(2.4)	11.7	3.8,	35.7
No injection	24	(35.8)	187	(75.7)	1		
Syringe source							
Closed packet	32	(47.8)	54	(21.9)	4.6	2.5,	8.5
Open	7	(10.4)	3	(1.2)	18.2	4.4,	75.1
Don't know	4	(6.0)	3	(1.2)	10.4	2.2,	49.3
No injection	24	(35.8)	187	(75.7)	1		
Intravenous infusion	9	(13.4)	18	(7.3)	2	0.84,	4.6
Hospitalization	4	(6.0)	8	(3.2)	1.9	0.55,	6.5
Blood transfusion	2	(3.0)	1	(0.4)	7.6	0.67,	84.8
Dental treatment	4	(6.0)	9	(3.6)	1.7	0.5,	5.6
Professional blood/syringe contact [†]	0	(0.0)	0	(0.0)	-	-	-
Facial shave from barber [‡]	20	(47.6)	46	(37.7)	1.5	0.74,	3.1
Armpit shave from barber [‡]	14	(33.3)	23	(18.9)	2.2	0.98,	4.7
Tattooing	0	(0.0)	1	(0.4)	-	-	-
Ear piercing	1	(1.5)	5	(2.0)	0.73	0.08,	6.4
Injecting drug use	2	(3.0)	0	(0.0)	-	-	-
Liver disease patient in household	5	(7.5)	18	(7.3)	1.02	0.36,	2.9

[*] History of potential risk factors was recorded for the period of six weeks to six months prior to the onset of illness for cases and to the time of interview for controls.

[†] 59 cases and 204 controls (adults only).

[‡] 42 cases and 122 controls (male adults only).

MULTIVARIATE LOGISTIC REGRESSION MODEL (TABLE 42)

The final logistic regression model included the number of injections, the number of household members, ethnicity, age, gender and enrolment hospital. After adjusting for the effect of other variables in the model and taking no injections as a reference category, the cases were more likely to receive one injection (OR = 4.0; 95% CI: 1.4, 11.1) or more than one injection (OR = 6.3; 95% CI: 3.2, 12.4). The number of household members was also independently associated with acute HBV infection, as the cases were more likely to have household size of seven or more people (OR = 1.9; 95% CI: 0.95, 3.9) when compared to controls, taking 1-6 people in a household as reference category. Cases compared to controls were more likely to be Pathans (OR = 2.5; 95% CI: 1.1, 5.8), Sindhi (OR = 5.4; 95% CI: 1.7, 18.0) or Hindko (OR = 3.7; 95% CI: 097, 14.0) than Urdu speaking while adjusting for other variables in the model. The estimated population attributable risk (PAR) for therapeutic injections was 53%.

Table 42: Multivariate logistic regression model of risk factors for acute HBV, Karachi, Pakistan, 2000-2001

Exposures *	Adjusted OR	95% CI	
Number of injections [†]			
Nil	1		
One	4.0	1.4,	11.1
More than one	6.3	3.2,	12.4
Number of household members			
1-6	1		
7 or more	1.9	0.95,	3.9
Ethnicity			
Urdu	1		
Sindhi	5.4	1.7,	18.0
Punjabi	1.3	0.44,	4.1
Pashto	2.5	1.1,	5.8
Hindko	3.7	0.97,	14.0
Others	1.4	0.41,	4.9

[*] Variables of age, gender, and enrolment hospitals were included in the model to adjust for any selection bias introduced while selecting controls.
[†] During the period of six weeks to six months prior to the onset of illness for cases and to the time of interview for controls.

DISCUSSION

Our study identified the association of therapeutic injections, ethnicity and number of household members with acute HBV infection among the patients seeking treatment in major tertiary hospitals of Karachi. Besides the association of therapeutic injections with acute HBV infection, the data shows a dose response relationship between number of injections and HBV infection. Other studies in developing countries have also identified therapeutic injections as a risk factor for HBV infection.[76,77,78,79,80] The estimated fraction of acute HBV infection attributable to therapeutic injections in our study was 53%, which is similar to 52% estimated in Moldova.[76] Our study gives a baseline attributable fraction before the implementation of safe injection interventions in Pakistan and can be repeated later to evaluate the effectiveness of these interventions.

Cases were more likely to be living in households of a size of seven or more members. The association between household size and HBV infection has been documented in several studies.[81,82,83,84] Larger household size, i.e., people living in overcrowded conditions, may facilitate person-to-person transmission of HBV infection. Ethnicity also showed association with HBV infection, which needs to be further explored by studying their lifestyle and sexual behaviours.

We enrolled our controls from the same hospitals from where we selected our cases.[85,86] We preferred controls from hospital over neighbourhood for two reasons. First, we could not identify final cases (HBc IgM-antibody positive) at the time of enrolment as we tested for anti-HBc IgM at end of enrolment. It was therefore not possible for us to enrol controls matched on neighbourhood. Secondly, it was more feasible for us to interview and take blood samples from controls in the hospital.

History of multiple sex partners has been identified as risk factor for HBV infection among adults.[87] However, we could not evaluate this risk behaviour in our study. People in Pakistan are socially and

culturally constrained in talking about their sexual behaviours. Thus, we could not collect information on the sexual behaviours of our study subjects and sexually acquired infection cannot be excluded as a source of acute HBV infection in the cases.

We were not able to achieve the calculated sample size of 113 cases with 1 to 3 case control ratio. Consequently we were not able to identify less frequent factors as statistically significant.

Household contact with HBsAg carrier has been identified as a risk factor for HBV infection.[88] It was not feasible for us to ascertain the HBsAg status of study subjects' household members, although we asked for the presence of any household member suffering from liver disease and his or her viral status if known.

RECOMMENDATIONS

We recommend interventions to educate health care providers on the indications for injections to reduce injection frequency. Further research is recommended to estimate the proportion of unnecessary injections and the economic burden it imparts on the healthcare system. Research is also needed to identify factors for horizontal transmission of HBV infection.

ACKNOWLEDGEMENTS

THE WHO RAPID ASSESSMENT AND RESPONSE GUIDE

INJECTION PRACTICES INDICATORS AT A GLANCE

PROGRAMME INDICATORS (INPUTS)	INDICATOR	SOURCE
HIV/AIDS prevention and care programme communicating the risk of HIV infection associated with injections	Yes / No	MoH
National drug policy discouraging injection overuse	Yes / No	MoH
Number of injectable medications on the national essential drug list	_____	MoH
Essential drugs programme supplying syringes, needles, diluent and safety boxes in quantities matching supplies of injectable medications	Yes / No	MoH
Immunization and family planning services supplying auto-disable syringes and needles in quantities matching supplies of injectable vaccines and contraceptives	Yes / No	MoH
Health care waste management plan within the health system	Yes / No	MoH

DETERMINANTS OF INJECTION PRACTICES (PROCESS)	INDICATOR	SOURCE
INJECTION USE		
Proportion of the population reporting a preference for injections in the case of fever	__ / __ (%)	Population
Proportion of prescribers reporting a preference for injections among patients in the case of fever	__ / __ (%)	Prescribers
Proportion of the population recalling that the last injection received has been given at home	__ / __ (%)	Population
INJECTION SAFETY		
Proportion of the population spontaneously reporting the risk of HIV infection associated with unsafe injections	__ / __ (%)	Population
Proportion of prescribers spontaneously reporting the risk of HCV infection associated with unsafe injections	__ / __ (%)	Prescribers
Proportion of health care facilities using sterilizable injection equipment	__ / __ (%)	Providers
Proportion of health care facilities using single use injection equipment	__ / __ (%)	Providers
Proportion of health care facilities using auto-disable injection equipment	__ / __ (%)	Providers
Proportion of health care facilities with stocks of single use injection equipment (in the facility or in a nearby public or community pharmacy)	__ / __ (%)	Providers
Proportion of injections administered by unqualified or family providers	__ / __ (%)	Population

INJECTION PRACTICES (OUTCOMES)	INDICATOR	SOURCE
INJECTION USE		
Proportion of prescriptions including at least one injection	__ / __ (%)	Prescriptions
Average number of injections per prescription for prescriptions containing at least one injectable medication	__ / __ ( )	Prescriptions
Average number of injections per person and per year	__ / __ ( )	Population
INJECTION SAFETY		
Proportion of health care facilities where injections are given with a sterile syringe and needle	__ / __ (%)	Providers
Proportion of health care facilities where used injection equipment can be observed in places where they expose health care workers to needle-stick injuries	__ / __ (%)	Providers
Annual number of needle-stick injuries per injection provider	__ / __ ( )	Providers
Proportion of health care facilities where used injection equipment can be seen in the surrounding environment	__ / __ (%)	Providers

INTRODUCTION

INJECTION OVERUSE AND UNSAFE PRACTICES CAUSE INFECTIONS

In developing countries, the estimated proportion of injections administered with injection equipment reused in the absence of sterilization ranges from 15% to 50%.[10] Surveys conducted in various settings have also indicated that the proportion of prescriptions including at least one injection is high (up to 56%), suggesting that injections are overused to administer medications.[89] As a result of unsafe practices and overuse, injections transmit bloodborne pathogens on a large scale.[11] Annually, worldwide, injections cause an estimated 8-16 million cases of HBV infection, 2.4-4.5 million cases of HCV infection and 80 000 to 160 000 cases of human immunodeficiency virus (HIV) infections. These infections lead to a high burden of chronic disease, disability and death.[70]

A STRATEGY FOR THE SAFE AND APPROPRIATE USE OF INJECTIONS

To prevent injection-associated transmission of bloodborne pathogens, injection frequency should be reduced and safe injection practices should be carried out on a regular basis. At country level, these goals should be reached through a multidisciplinary three-element approach that includes:[90]

1) Behaviour change among patients and health care workers to reduce injection overuse and implement safe practices;

2) Provision of sufficient quantities of injection equipment and infection control supplies;

3) Sharps waste management.

This policy may be implemented with greater effectiveness and at lower cost if an initial assessment is conducted to describe injection practices, their determinants and their adverse effects. This guide proposes a standardized, six step approach[91] to conduct a rapid assessment of injection practices and propose a public health response.

WHO SHOULD USE THIS GUIDE?

Engaging all to ensure that assessment is followed by action

This guide was not designed to be used by a single person conducting an assessment to produce data. Rather, it is intended as a framework for partners to examine injection practices, their determinants and their consequences so that an action plan can be formulated. Thus more than one type of user may use different portions of this guide.

PERSONS CONDUCTING INJECTION PRACTICES ASSESSMENTS AT A NATIONAL OR REGIONAL LEVEL

Epidemiologists, anthropologists and other public health workers seeking to conduct comprehensive or specific assessment of injection practices constitute the primary audience of this guide.

INTERNATIONAL EXPERTS

International experts, including staff of or consultants to health organizations, will find this guide useful when being asked to assess or evaluate injection practices in countries where unsafe injection practices are suspected or targeted by prevention efforts.

NATIONAL POLICY-MAKERS OR SENIOR MANAGEMENT PERSONNEL

Senior management personnel and national policy-makers may use this guide as a reference to better understand the information needed to develop policies and plans for the safe and appropriate use of injections.

S TEP 1 - E NGAGE S TAKEHOLDERS

The safe and appropriate use of injections does not require a specific programme, let alone a vertical one. Rather, prevention activities can be integrated into already existing initiatives and services.

1.A - IDENTIFYING STAKEHOLDERS

Key stakeholders include (1) programme for HIV/AIDS prevention and care, (2) essential drugs, (3) immunization, (4) family planning and (5) other curative services (Table 43). Additional stakeholders may also be approached, including those working with the national regulatory authority, Integrated Management of Childhood Illnesses (IMCI), infection control, professional health care workers' associations, United Nations agencies and programmes (e.g., WHO, UNICEF and UNAIDS), the World Bank and nongovernmental organizations (NGOs).

Table 43: Key programme areas in the Ministry of Health and proposed role in a national safe and appropriate use of injection policy

Key programme areas	Role in a national safe and appropriate use of injection policy
HIV/AIDS prevention and care	✓ Communicating the risk of unsafe injections to patients and health care workers
Essential drugs	✓ Ensuring availability of safe injection equipment, diluent and safety boxes ✓ Promoting rational use of injections within the national drug policy
Immunization and family planning services	✓ Making auto-disable injection equipment and safety boxes available with vaccines and injectable contraceptives [66]
Health care services	✓ Management of sharps waste within the health care waste management plan

1.B - RECOGNIZING THE PROBLEM

Approaching stakeholders from the perspective of their activities will help them recognize the problem (Instrument 1, Page 121). Interviews with stakeholders should be carried out to achieve some broad objectives, including engagement of stakeholders, descriptions of problems and initiatives regarding injection practices within their respective areas and development of an understanding of stakeholders' perceptions regarding injection practices. This understanding will help in communicating the actual results of the rapid assessment back to them.

Stakeholders should be engaged in the preparation and sampling for the assessment. They may want to participate in the data collection and analysis. They must be involved during the development of recommendations.

STEP 2- DESCRIBE THE SITUATION

2.A- IDENTIFYING AVAILABLE INFORMATION, PLANNED STUDIES AND SURVEYS

Stakeholders and key informants can assist the organizers of the assessment in obtaining information already available regarding injection practices, their determinants and their consequences. In addition, they can identify population or health care facility-based surveys that are at the planning stage and that can be used to collect information about injection practices.

CONSEQUENCES OF UNSAFE INJECTIONS AMONG RECIPIENTS

Potential sources of information regarding infections with bloodborne pathogens, abscesses, and other injection-associated adverse events include published and unpublished reports. Reports may be available that describe the frequency of infection with bloodborne pathogens in the general population (e.g., reports from blood transfusion services regarding the prevalence of infections with bloodborne pathogens among first-time blood donors; population-based surveys; infectious disease surveillance data). Other reports may estimate the frequency of occurrence of injection-associated adverse events (e.g., EPI injection safety reviews reporting the incidence of injection-associated abscesses). Finally, there may be studies that evaluate the strength of the epidemiological association between exposure to health care injections and infection with bloodborne pathogens.

INJECTION PRACTICES AMONG INJECTION PROVIDERS

Besides published and unpublished reports, other information sources regarding both the frequency and safety of injection may include the following:

POTENTIAL DATA SOURCES ON INJECTION FREQUENCY

Reports citing the proportion of prescriptions that include at least one injection

Data may be available regarding the proportion of prescriptions that include at least one injection (WHO/DAP OT8 indicator).[92,93] This indicator is a rapid method of assessing injection use in health care facilities. More information about this indicator can be found on page 112.

Population-based surveys

Population-based surveys (e.g., Multi-Indicator Cluster Surveys [MICS], Demographic and Health Surveys [DHS], vaccine coverage surveys and community IMCI surveys) are potential sources of information to estimate the frequency of injections in the population.

Planned surveys that can be used to estimate injection frequency:
Identification of planned community surveys may provide opportunities to add items regarding injection use. Such items may be extracted from Instrument 5, Page 125.

Surveys already conducted that may provide information on injection use:
   IMCI community surveys
IMCI community surveys are designed to evaluate 12 household-level key practices relating to IMCI. Some of the community IMCI survey tools currently under development contain items regarding health care-seeking behaviour of potential relevance to injection practices.

DHS

DHS surveys are national surveys of women of reproductive age and their children under five years of age. DHS collects information of potential interest to investigators attempting to describe injection practices, including:

1) Immunization history;

2) Illnesses among children in the last two weeks (including health care-seeking behaviour and use of injections to treat diarrhoea if applicable);

3) Family planning methods;

4) Low risk behaviours to prevent HIV infection (including avoidance of injections).

Some countries may collect additional information relating to:

1) Behaviours that place the individual at increased risk of HIV infection, including the number of injections received in the last three months and the person who administered the last injection received;

2) Malaria, including health care-seeking behaviour during the last episode of malaria and medication used for treatment (without a specific reference to injections);

3) Health expenditures, which may include information on health care-seeking behaviours.

POTENTIAL DATA SOURCES ON INJECTION SAFETY

Potential information sources regarding unsafe injection practices include the WHO tool to assess injection safety, [15] EPI injection safety reviews, Global Alliance for Vaccine and Immunization (GAVI) assessments and other health care facility surveys. Planned facility surveys may provide an opportunity to add items regarding injection safety to the data collection instruments.

DETERMINANTS IN THE SYSTEM

There are few potential information sources regarding the behavioural and system determinants of poor and good injection practices. A recent article reviewed studies that aimed at identifying the determinants of unsafe injection practices.[94] In addition, a qualitative assessment tool is available from WHO to identify the determinants of unsafe injection practices in the system.[13]

2.B- ORGANIZING AVAILABLE INFORMATION

Information gathered from key stakeholders can serve as the basis for a preliminary description of current injection practices, their determinants and their consequences (Figure 9). Once collected, such information needs to be organized to address the following issues:

1) **What are the consequences to injection recipients of poor injection practices?**
   These may include infections with bloodborne pathogens or other infectious agents, injuries and abscesses.

2) **What are the practices among injection providers in terms of safety and frequency**? Injection providers may include recipients themselves (self-injection), the

family, formally trained health care workers, health care workers who were not formally trained, informal injection providers (e.g., drug sellers) and traditional health care workers (e.g., traditional healers or traditional birth attendants).

3) **What are the determinants of good and bad injection practices within the larger system?** This system includes government ministries, NGOs, professional associations, consumers, corporations (e.g., manufacturers of drugs or of injection equipment and their representatives) and universities that influence injection recipients and injection providers to perpetuate poor injection practices. Behavioural, supply and waste management issues should be addressed (e.g., absence of awareness that unsafe injections cause infections, absence of sharps boxes, absence of waste treatment facilities).

Figure 9: Injection-associated adverse events are caused by poor injection practices that are a consequence of behavioural and system determinants

Lack of equipment and supplies	Lack of awareness	Lack of sharps waste management

Unsafe injection practices	Injection overuse

Injection adverse event
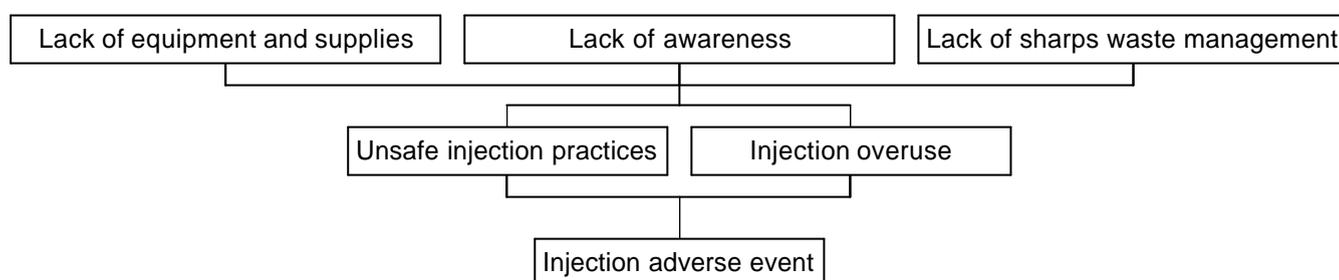
STEP 3- MAKE ASSESSMENT PLANS

3.A- RATIONALE

Review of the information available will determine information needs in the area of:

1) The determinants of poor and good practices in the system;

2) Injection practices, including injection overuse and proportion of unsafe injections among injection providers;

3) The consequences of poor practices among recipients.

The proposed rapid assessment methods consist of information collection from:

1) Prescribers (e.g., physicians), using interviews and reviews of prescriptions;

2) Injection providers (e.g., nurses or other providers administering the majority of injections in the public sector), using interviews and observations in health care facilities;

3) The general population, using interviews.

3.B- PROPOSED TIMELINE FOR DATA COLLECTION

Table 44 describes a proposed timeline for a three-week assessment for one team to collect data from 20 health care facilities distributed across four districts. Other timelines may be constructed on the basis of this template according to the proposed sample size and the human resources available.

Table 44: Proposed scope of work for a three-week data collection of injection practices using a convenience sampling in four districts

Day	Monday	Tuesday	Wednesday	Thursday	Friday	Week End
Week 1	Meeting stakeholders	Meeting stakeholders	Travel to site 1	Fieldwork site 1	Fieldwork site 1	Travel to site 2
Week 2	Fieldwork site 2	Fieldwork site 2	Travel to site 3	Fieldwork site 3	Fieldwork site 3	Travel to site 4
Week 3	Fieldwork site 4	Fieldwork site 4	Travel back	Preliminary analysis	Debriefing	--

S TEP 4 - G ATHER E VIDENCE

4.A- OBJECTIVE OF THE DATA COLLECTION

The objective of the data collection is to collect information regarding a core set of indicators reflecting injection practices, their determinants and their consequences in a way that will make the results generalizable to a wider national context.

4.B- INFORMATION SOURCES

The rapid assessment method entails the collection of information from three different sources:

1) Prescribers;

2) Injection providers;

3) The general population.

4.C- PROPOSED METHODS

SAMPLING STRATEGY

Health care facilities will be used to identify prescribers, injection providers and members of the general population.

The sampling strategy includes two steps:

1) Sampling of primary health care facilities from the list of primary care facilities[*] in the country;

2) Selection of prescribers, injection providers and members of the general public on the basis of the sampled primary health care facilities.

SAMPLING OF PRIMARY HEALTH CARE FACILITIES

A number of potential options may be chosen, according to the level of data quality required. Stakeholders who will be the primary users of the information need to be engaged in any decisions regarding the level of data quality desired and the resources needed for the data collection.

---

[*] The majority of injections are usually administered in primary care facilities. In addition, assessment in hospitals would require different checklists to evaluate the safety of intravenous infusions. The choice of primary health care facilities is not meant to represent all injections given in the country. However, injections given in health care facilities are probably a useful reflection of all injections given in a country.

Box 1: A compromise between data quality, feasibility and costs

In an ideal world, all studies would be conducted perfectly. Advanced planning may allow this rapid assessment to be conducted at low cost if it can be integrated with other surveys. However, if it cannot be integrated, stakeholders must decide the price they can pay for the data quality they will want in order to make decisions.

Option 1: Statistically representative samples

Option 1a: Representative cluster sample of 80 primary health care facilities
In this method that uses a cluster sampling approach, 10 facilities are selected in each of eight clusters, using the approach proposed in the WHO tool to assess the safety of injections.[15] In short, this sampling procedure involves two steps: first, eight districts are selected using a probability proportional to their population sizes. Second, within each of the eight districts, 10 facilities are selected at random from the list of primary health care facilities. This cluster sample design provides a +/- 10% precision around the estimate and may be adapted to large countries as it factors in travel to a small number of districts.

Option 1b: Representative random sample of 20 primary health care facilities
Using a random sample approach, 20 facilities may be selected from the national list of primary health care facilities. Random sampling may be more adapted in selected geographical settings. The sample size of 20 has been proposed to assess prescriptions in health care facilities. [93] If a random sample of 20 health care facilities is chosen, this option will provide less precision than option 1a.

Option 2: Convenience sample of health care facilities

When a statistically-representative sample of health care facilities cannot be conducted, a convenience sample may be used. In this case, a number of health care facilities are selected in a way that (1) is believed by the investigators to be representative of the national situation and (2) will be considered acceptable and believable by the stakeholders who will be using the results of the assessment. Overall, visiting 20 health care facilities should be considered a minimum.

Box 2: Example of convenience sampling of health care facilities

Choice of districts

In a situation of limited resources for the rapid assessment where only four districts can be visited, a choice may be made to visit the capital city, two semi-rural districts chosen to be representative of the average conditions in the country and one remote district thought to representative of the worst conditions seen in the country.

Choice of health care facilities

If only 20 facilities can be visited, a choice may be made to select five facilities in each district.

SELECTION OF PRESCRIBERS, INJECTION PROVIDERS AND INDIVIDUALS

Selected health care facilities are used to select prescribers and injection providers. Individuals from the general population should be sampled from the catchment area of the health care facility.

Selection of prescribers

In each health care facility, one or more prescribers are selected at random. For each prescriber, 30 prescriptions selected at random will be reviewed.

Selection of injection providers

In each health care facility, one or more injection providers are selected at random.

Selection of individuals from the general population

A pre-set number of individuals are selected at random from the population using the health care facility (i.e., catchment population). This may be achieved through a number of methods proposed that are presented here in order of decreasing data quality:

1) Sampling from a list of households available in the villages or communities that constitute the catchment population;

2) Sampling using field methods of randomization (e.g., spinning a bottle) in the villages or communities that constitute the catchment population;

3) Sampling from a list of health care facility users maintained at the facility; [*]

4) Selecting a convenience sample of the population in the street or at the market of the village where the facility is located;

5) Selecting patients at random among those waiting for health care at the facility. [†]

If the fourth or the fifth options are chosen, the sample can be made more representative by recruiting participants by age and gender in proportion identical to the general population.

SAMPLE SIZE

Sample size calculations may be conducted to optimize the sample size according to the desired precision and operational constraints. At a minimum, the final sample should contain at least 20 prescribers, 20 injection providers, 100 participants from the general population and 600 prescriptions.

DATA COLLECTION

DATA COLLECTION FROM PRESCRIBERS

A standardized instrument is proposed to interview prescribers (see Instrument 2: Guide for interviewing prescribers, Page 122). In addition, a random sample of prescriptions from each prescriber should be reviewed to calculate the proportion of prescriptions including at least one injection (see Instrument 3: Sample data collection form for the indicator OT8, Page 123).

---

[*] This can only be done when all patients' records are kept in the health care facility (e.g., in former socialist economies of Eastern and Central Europe).

[†] This choice will create a bias and over-represent the population using the sampled health care facilities.

Box 3: Estimating the proportion of unnecessary injections

This rapid assessment does not propose to estimate the proportion of injections that are unnecessary. Tools to assess the proportion of unnecessary injections have been proposed. These tools, which are methodologically more complicated, are based upon:

- The percentage of injection use for tracer conditions (cough, cold, and diarrhoea);

- The proportion of unnecessary injections calculated using standard treatment guidelines.[95]

Assessing the appropriateness of injections is not simple and is beyond the scope of any rapid assessment. However, more information about the tools to assess appropriateness of injection use can be found elsewhere.[9,41]

DATA COLLECTION FROM INJECTION PROVIDERS

A standardized instrument is proposed to collect information from injection providers (see Instrument 4: Guide for interviewing and observing injection providers, Page 124). Because the sterility of a newly opened package of syringes/needles depends on the quality of the equipment, it is recommended to record the trademark and country of manufacturers for the sets observed in use. In addition, it may be useful to purchase a few sets of each trademark to (1) collect information on retail prices and (2) keep samples of equipment for which the quality is doubtful. If an additional level of detail is needed regarding various specific infection control steps while giving injections, advanced instruments to describe injection practices more extensively are available from the WHO tool to assess the safety of injections. These instruments can be substituted for Instrument 4. [15]

Box 4: The challenge of describing unsafe injection practices outside the public health care system

In selected situations (e.g., Middle East, South Asia and some parts of Africa), a high proportion of injections are administered outside the formal, public health care system. These injections may be administered by a variety of injection providers, including recipients themselves (self-injection), the family, formally-trained health care workers, health care workers who were not formally trained, informal injection providers and traditional health care workers. The safety of injections administered by these injection providers may differ substantially from those given in the public health care system. If interviews from individuals in the general population suggest that injections given outside of the public health care system are common, an attempt should be made to describe –at least qualitatively- the safety of these injections through interviews and observation of these private or informal injection providers, using Instrument 4, Page 124.

DATA COLLECTION FROM THE POPULATION

A standardized instrument is proposed to collect information from the members of the general population (see Instrument 5: Guide for interviewing the general population, Page 125). Adult respondents should be asked to answer questions pertaining to children under 15 years of age. To allow comparisons across settings using an annual number of injections per person, collection of information at the individual level is preferred to collection of information at the household level (household sizes and age structure may differ).[96,97]

STEP 5 - DEVELOP CONCLUSIONS

5.A - DATA ANALYSIS

Close collaboration with national stakeholders in analyzing the data will facilitate future use of the evidence (see Injection practices indicators at a glance, page 100)

ANALYSIS OF QUANTITATIVE DATA

Indicators to be calculated on the basis of data collected from prescribers, including prescription review

Proportion of prescriptions including at least one injection (OT8 indicator)
This indicator belongs to a set of structural, process and outcome indicators developed by WHO to monitor national drug policies. [92,93] Among outcome indicators, indicator OT8 provides information regarding rational use of injections. OT8 is defined as "the number of prescriptions with at least one injection, out of the total of prescription surveyed". The numerator is obtained by adding the number of prescriptions with at least one injection (excluding immunizations [93]). The denominator is the total number of prescriptions studied.

$$\text{OT8} = \frac{\text{Prescriptions with at least one injection}}{\text{Total number of prescriptions surveyed}} \times 100$$

The OT8 indicator is calculated on the basis of prescription review (reference method). However, calculation of the self-reported proportion of the prescriptions that include at least one injection may be useful in some settings to triangulate and verify the results (e.g., in some settings where the prescriber administers injections himself, he may not actually record them as a prescription).

Other indicators
- Average number of injections per prescription for prescriptions containing at least one injectable medication.

- The proportion of prescribers reporting a patient's preference for injections in the case of fever.

- Proportion of prescribers spontaneously reporting the risk of infection with HBV, HCV and HIV associated with unsafe injections.

Indicators to be calculated on the basis of data collected from injection providers

- The proportion of health care facilities where injections are observed to be given with a sterile syringe and needle.

- Proportion of health care facilities where used injection equipment can be observed in places where they expose health care workers to needle-stick injuries.

- The reported annual number of needle-sticks per injection provider.

- The proportion of health care facilities where used injection equipment can be seen in the surrounding environment.

- The ratio of therapeutic to immunization injections (reported work load).

- The proportion of providers spontaneously reporting the risk of infection with HBV, HCV and HIV associated with unsafe injections.

- The proportion of health care facilities using sterilizable injection equipment.

- The proportion of health care facilities using single use injection equipment.

- The proportion of health care facilities using auto-disable injection equipment for immunization injections.

- The proportion of health care facilities using auto-disable injection equipment for curative injections.

- The proportion of injection providers having stocks of single use injection equipment in their health care facility or in a nearby public or community pharmacy.[*]

- The proportion of injection providers reporting sufficient supplies of sharps containers.

Indicators to be calculated on the basis of data collected from the general population

- The proportion of patients questioned who report a preference for injections for the treatment of fever.

- The proportion of persons questioned spontaneously reporting the risk of infection with HBV, HCV and HIV associated with unsafe injections.

- The average number of injections per person and per year (self-reported injections)[†].

- The ratio of therapeutic to immunization injections (self-reported injections).

- The proportion of the population questioned who recalled that the last injection received had been given by an informal provider.[‡]

- The proportion of the population who recalled that the last injection received had been given at home, in a primary care facility and in a hospital.[§]

---

[*] At the time of the visit.

[†] The distribution of the frequency of injections received is usually skewed to the right. A small proportion of the population (e.g., diabetics) receives a substantial proportion of all injections. Thus, population surveys using a small sample size may underestimate the annual number of injections per person because none of the persons receiving many injections were included in the sample.

[‡] Injections received more than one year ago should be excluded from this analysis.

[§] Injections received more than one year ago should be excluded from this analysis.

- The proportion of the population who recalled receiving their last injection with new, single use injection equipment coming from a sealed packet or fitted with two caps. [‡]

ANALYSIS OF QUALITATIVE DATA

Programme inputs

- Programme for HIV/AIDS prevention and care communicating the risk of HIV infection associated with injections.

- Existence of elements discouraging injection overuse in national drug policy.
  This includes: (1) review of the essential drug list to remove unnecessary injectable medications and (2) review of standard treatment guidelines to eliminate use of unnecessary injections.

- Essential drug programme supplying syringes, needles, diluents and safety boxes in quantities matching supplies of injectable medications.

- Number of injectable drugs on the national essential drug list.

- Immunization and family planning services supplying auto-disable syringes and needles in quantities matching supplies of injectable vaccines and contraceptives (the "bundling" policy recommends that donors and lenders supplying injectable vaccines and contraceptives should cover these costs).[66]

- Health care system managing sharps waste.

Other qualitative information

- Top reported conditions for which injections are used (prescribers). [*]

- Top reported medications administered most commonly (prescribers). [*]

- Other qualitative information collected on open-ended questions on the questionnaire.

- Quality of the syringes sampled in the field (see Box 5).

Box 5: Quick checklist to assess the quality of single use injection equipment in the field

---

✓ Mention of the name and address of manufacturer or supplier
✓ Mention of the country of production
✓ Mention of the word "sterile", "For single use" and/or single use logo (a number "2" crossed out)
✓ Mention of the lot number prefixed by "LOT"
✓ Mode and date of sterilization
✓ Sealed package [or sealed caps on the needle and on the plunger]
✓ Visible graduations
✓ Absence of stains and moisture on the syringe
Note: Any other element suggesting that the syringe and needle set is not sterile should be noted.

---

[*] Information about this is best obtained by review of records and/or observation. Thus, these findings are only part of an explorative survey of prescribers' opinion using qualitative interviews.

TRIANGULATION AND COMPARISONS

A number of the proposed indicators use data from different sources to estimate the same figures. Comparing these estimates permits a triangulation that may either validate or call into question the results. In addition, the proportion of prescribers, members of the general population and injection providers spontaneously reporting risks associated with unsafe injections can be compared across population groups.

Table 45: Proposed triangulations and comparisons to better understand the results of the rapid assessment

1. To understand the situation regarding the topics below:	2. Review data from these information sources:		
	Prescribers' data	**Population data**	**Injection providers' data**
Prescriptions including injections	Prescription review is the reference method	N/A	N/A
	Prescriber interviews is an alternative method		
Ratio of immunization to therapeutic injections	N/A	Interviews regarding last injection is the reference method	Reports from injection providers is an alternative method
Reuse of equipment	N/A	Interviews regarding last injection is an alternative method	Observation of injections is the reference method
Preference for injections in the case of fever	Preference for injection among patients can be compared as expressed by the population and as perceived among prescribers		N/A
Spontaneous report of the risk of infection with bloodborne pathogens associated with injections	The proportion of prescribers, members of the general population and providers spontaneously reporting the risk of HBV, HCV and HIV infection may be compared		

5.B- REPORT WRITING

The following outline may be used as a template for concise, efficient report writing.

TITLE (ONE PAGE)

Authors, date and locations.

EXECUTIVE SUMMARY (ONE PAGE)

Including background, methods, results, conclusions and proposed recommendations.

INTRODUCTION (ONE PAGE)

General injection practices issues, reasons motivating the assessment and proposed objectives.

METHODS (ONE PAGE)

National stakeholders interviewed. Study population (including prescribers, providers and population), sampling methods, sample size, data collection and practical organization of the fieldwork.

RESULTS (ONE PAGE)

Salient results may be presented according to (1) unsafe practices, including those exposing the recipient, the health care worker or the community to infections, (2) their determinants and (3) their consequences.

DISCUSSION (ONE PAGE)

Summarizing results, discussing the practices that endanger the injection recipient (identified determinants, proposed solutions), discussing the practices that endanger the injection providers (identified determinants, proposed solutions) and discussing the practices that endanger the community (identified determinants, proposed solutions).

RECOMMENDATIONS (ONE PAGE)

Recommendations can be presented for the categories of (1) behaviour change, (2) provision of equipment and supplies and (3) sharps waste management. To systematically and comprehensively address a range of possible actions, recommendations can be organized around the outline for a safe and appropriate use of injection strategy (Appendix 1). These recommendations represent suggestions from assessment organizers to the various stakeholders and not prescriptive final statements.

APPENDICES

- Three tables summarizing the data collected from (1) providers, (2) prescribers and (3) the general population (see Injection practices indicators at a glance, page 100).

- Data collection instruments.

5.C- PRESENTATION OF THE RESULTS

Results of the assessment should be communicated to all stakeholders immediately after the analysis is completed. Activities may include:

- Assessment debriefing with all stakeholders to discuss results and draft recommendations;

- Communication of a one-page executive summary that includes key indicators and key proposed recommendations; [*]

- Preparation of a slide presentation to stakeholders who can subsequently show it to other audiences.

Availability of a final report within the month following the rapid assessment will increase the chances of efficient use of the evidence.

---

[*] Before the departure from the country in the case of international consultants.

STEP 6- ENSURE USE

6.A- PLANNING

PLAN OF ACTION

Experience with rapid assessments indicates that the formulation of a draft plan of action during a workshop attended by all stakeholders soon after the assessment increases the probability of effective action. Appendix 1, page 127, summarizes the key elements of a national action plan that includes objectives, core interventions, target groups and indicators. Inclusion of realistic, informed costing and budgeting will facilitate the identification of a funding source.

ADVOCACY

Maintenance of communication between all stakeholders ensures long-term usefulness of the initial assessment. Advocacy is needed to persuade stakeholders that the safe and appropriate use of injections is a high enough priority on their agenda and that it is a feasible undertaking. Key components of an advocacy strategy for the safe and appropriate use of injections may include: [98]

1) A summary document describing the full social and economic dimension of poor injection practices in the country. This document, based upon local information, should emphasize that the safe and appropriate use of injections is about (a) reducing the out-of-pocket expenses wasted in unnecessary injections, (b) preventing chronic viral infection leading to substantial disability and death and (c) strengthening health systems through better quality of health care services delivery;

2) Communication with the general public (e.g., through newspaper articles and television reports) to describe poor injection practices, the proposed interventions to improve them and the steps that the public can take to demand safe injections from providers;

3) Local and international success stories that demonstrate the possibility of reducing or eliminating poor injection practices.

6.B-IMPLEMENTING PLANS

Plans to achieve safe and appropriate use of injections should address three broad areas, including (1) behaviour change, (2) provision of supplies and (3) sharps waste management. [90]

BEHAVIOUR CHANGE

The identified determinants of poor and safe injection practices serve as the basis for formulating behaviour change strategies to reduce injection overuse and achieve safe practices. Such strategies aim at promoting six key behaviours. Patients must (1) communicate a preference for oral medications and (2) demand safe equipment when needing injections. Prescribers must (3) prescribe oral drugs whenever possible. Injection providers must (4) use new, single use injection equipment for each injection, (5) collect dirty sharps without recapping immediately after use in a sharps container and (6) manage sharps waste safety.

PROVISION OF EQUIPMENT AND SUPPLIES

Assuring the availability of injection equipment and sharps collection boxes in sufficient quantities at the right time and place helps to provide a working environment that supports safer behaviours. Implementation of plans to increase the availability of supplies needs to integrate the context of the national strategy for pharmaceutical supplies and its financing mechanisms. Logistics systems also need to be revised to ensure that commodities, including safety boxes, are reliably delivered in adequate quantities to all service delivery points, including outreach sites.

Box 6: Choice of injection equipment to be used

The choice of injection equipment to be recommended (sterilizable, single use or auto-disable) may be an issue for which consensus is difficult to reach. It will be most usefully solved through discussions of the results of the assessment with all stakeholders. Two elements should be taken into consideration. First, WHO best practices recommend single use injection equipment (standard or auto-disable) for all injections.[99] Second, WHO and UNICEF recommend that all immunization services should exclusively use auto-disable injection equipment by the end of 2003.[66] **Sterilizable injection equipment should only be considered if (1) sufficient quantities of single use injection equipment can not be made available and (2) if the quality of the sterilization is documented in registers with Time-Steam-Temperature (TST) spot indicators for all injections**. Experience in many developing and transitional countries indicates that this second condition is rarely met and that only single use injection equipment made available in sufficient quantities can ensure the safety of injections.

SHARPS WASTE MANAGEMENT

Sharps waste management is best handled in the general context of the management of all health care waste. An "Aide mémoire" for health care waste management summarizes the key elements of a national strategy, including (1) a national policy framework, (2) an integrated, streamlined system from waste production to final disposal, (3) training at all levels and (4) the availability of waste management options.[72]

6.C- EVALUATING

Using the initial assessment results as a baseline measure, indicators identified as critical by all stakeholders during the initial assessment can be used for ongoing collection of information.

INDICATORS OF INJECTION FREQUENCY AND SAFETY

Indicators of injection frequency

While injection frequency surveys are time-consuming and cannot be conducted regularly to monitor impact, the proportion of outpatient visits followed by an injection (OT8) is an indicator that is easy to use and has been used by WHO for many years. The annual number of injections per person can only be used in a before/after comparison if (1) the sample used is representative and large enough and (2) the sample size is identical in the two surveys and doubled to ensure sufficient statistical power for the comparison.

Indicators of injection safety

A simplified version of the injection safety survey data collection instrument such as proposed in the WHO tool,[15] possibly restricted to practices identified to be unsafe (e.g., frequent two-handed recapping), can be used for routine data collection during supervisory visits to monitor the proportion of unsafe injections.

DATA COLLECTION INSTRUMENTS

INSTRUMENT 1: GUIDE FOR INTERVIEWING STAKEHOLDERS

Concerns have been expressed over the use of injections in your country. I have been invited to assist the Ministry of Health in understanding the situation so that a national policy for the safe and appropriate use of injections can be implemented. The following few questions will help me understand the situation better. Thanks for taking a moment to answer them.

1. Can you describe your activities in the field of public health and/or health care service delivery?

2. Who administers injections in your country?
   - Nurses?
   - Physicians?
   - Dentists?
   - Informal providers?
   - Others?

3. Do you think that injections are overused in your country?
   - What factors among patients and health care workers contribute to injection overuse?
   - How many syringes and needles are sold annually in the country?
   - Are syringes and needles used in the country imported or locally produced?
   - Was the essential drug list reviewed to remove any unnecessary injectable medication?
   - How many injectable medications are there on the national essential drug list?
   - Were standard treatment guidelines reviewed to remove use of unnecessary injections?

4. Do you think that syringes and needles are reused in the absence of sterilization in your country?
   - Is the HIV/AIDS prevention and care programme communicating the risk associated with unsafe injections to patients and health care workers? If yes, by what means do they do so?
   - Is the essential drug programme procuring single use injection equipment, diluent and safety boxes to match deliveries of injectable drugs?
   - Is the Expanded Programme on Immunization (EPI) "bundling" auto-disable injection equipment to match deliveries of vaccine?
   - Does the Family Planning programme "bundle" auto-disable injection equipment to match deliveries of injectable contraceptives?
   - What factors among patients and health care workers contribute to unsafe practices?
   - What kind of injection equipment is used in curative health care services?
   - Do you think that shortages of syringes and needles contribute to unsafe injection practices?
   - Are syringes recycled for plastic or illegal re-packaging? What kind of information supports this?

5. Are syringes and needles immediately discarded in sharps containers in your country?
   - If no:
      - What are the attitudes among health care workers that cause that?
      - Have there been any problems with lack of supplies that have affected their use or non-use?
6. Are syringes and needles appropriately disposed of in your country?
   - Do health care services have a waste management plan?
   - If no:
      - What attitudes explain this situation?
      - What types of constraints explain this situation?

7. Could you please describe any specific information or studies regarding injection practices, their determinants and their consequences in your country?

INSTRUMENT 2: GUIDE FOR INTERVIEWING PRESCRIBERS

Greetings! As we are working here to understand how injections are used, I would like to ask you a few questions about how you prescribe injections. The information I will collect will be recorded anonymously and I will not write your name on this form. As we go through the questionnaire, please feel free not to answer if you don't wish to give additional information.

A. How many outpatients do you usually see during an average week	___ Patients
Of these, for how many would you usually make a prescription that includes at least one injection?	___ Patients
B. For those to whom you prescribe at least one injection, how many injections on average would the total treatment typically include?	___ Injections

C. What are the three diseases for which you prescribe an injection most often?

1-   2-   3-

Comments:

D. What are the three injectable medications that you prescribe most often?

1-   2-   3-

Comments:

E. When you prescribe an injection, who usually gives the injection to the patients?
(One or more answers)

1-   2-   3-

Comments:

F. What kind of medications do patients prefer when they present at an outpatient clinic with a febrile illness?

1- Injections   2- Oral medications   3- Either   9- Don't know
                       or other non injected
                       medications

Comments:

G. Could you name diseases that may be transmitted through unsafe injections?
(Circle when spontaneously mentioned)

1- HIV   2- HCV   3- HBV

Others: List:

H. Do you think that you prescribe too many injections?

1- Yes   2- No   3- Don't know

Why:

If yes, what could help you to prescribe less injections:

INSTRUMENT 3: SAMPLE DATA COLLECTION FORM[*] FOR THE INDICATOR OT8 [†]

Prescription No.	Drug prescribed	Anti-biotic [‡]	From EDL[§]	Not from EDL	Injection [‡]
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

[*] Adapted from a WHO/DAP document. May be used to calculate other rational drug use indicators. [92]

[†] Proportion of prescriptions including at least one injection. Three copies of this form are needed for each prescriber so that information is collected regarding 30 prescriptions.

[‡] Tick if yes.

[§] Essential drug list.

INSTRUMENT 4: GUIDE FOR INTERVIEWING AND OBSERVING INJECTION PROVIDERS

Greetings! We are working to understand how injections are used. I would like to observe how you give injections and to ask you a few questions. Please feel free not to answer if you don't wish. The information collected will be recorded anonymously and I will not write your name on this form.

Fill only one form for each injection provider

Observation of one injection:

A.	Type of injection equipment used in the health care facility for curative injections	☐ Sterilizable ☐ Single use	☐ Auto-disable ☐ N/A
B.	Type of injection equipment used in the health care facility for immunization	☐ Sterilizable ☐ Single use	☐ Auto-disable ☐ N/A
C.	Use of new, single use syringe and needle OR sterilizable syringe and needle sterile according to Time-Steam-Temperature (TST) spot indicator *	1. Yes	2. No

If single use, trademark and country of manufacture of the syringe: _____

D.	Presence of dirty sharps in places where they expose health care workers to needle-stick injuries	1. Yes	2. No

Comments:

E.	Two-handed recapping	1. Yes	2. No

Comments:

F.	Presence of used sharps in the immediate surroundings of the health care facility	1. Yes	2. No

Comments:

Interview of the injection provider:

G.	How many injections do you give in one day?	__ Therapeutic __ Vaccinations

H. Could you name diseases that may be transmitted through unsafe injections?
(Circle when spontaneously mentioned)

1. HIV	2. HCV	3. HBV

Others, list:

I.	How many needle-stick injuries have you had during the last 12 months?	___ Injuries

Comments:

J.	How many doses of hepatitis B vaccine have you ever received?	___ Doses

K. Do you currently have stocks of new, single use syringes and needles in your facility or at a nearby public or community pharmacy?

1- Yes	2- No	3- Don't know

Comments:

L. Do you have sufficient quantities of sharps boxes to dispose of sharps safely?

1- Yes	2- No	3- Don't know

Comments:

M. How are sharps waste disposed of in your health care facility?

1- Open incineration	2- Protected incineration	3- Incinerator	4- Burial in a pit	5- Dumping (regular trash)	6- Other

---

* If an injection is about to be given with non-sterile injection equipment, the procedure should be tactfully interrupted and the form should be filled as if the injection had been given with non-sterile equipment.

INSTRUMENT 5: GUIDE FOR INTERVIEWING THE GENERAL POPULATION

Greetings! As we are working here to understand how injections are used, I would like to ask you a few questions. Please feel free not to answer if you don't wish. The information collected will be recorded anonymously and I will not write your name on this form.

Adult care takers should respond for children under 15 years of age

A. Age: ___ Years	B. Gender : ___ Male ____ Female

C. During the last three months that is between <date> and <date> did you receive an injection or an IV infusion? (Prompt) The potential persons who may have given you an injection or an IV infusion include your doctor, your nurse, your dentist, a relative, any other person or caregiver or yourself.

1 - Yes   If yes, how many? ____   2- No

D. (If yes to question C) How many of these injections were given by a health care worker for the purpose of a vaccination? _____

E. Can you remember the last time that you received an injection?
1 – Yes, Date: _____   2 – No

F. (If yes to question E) Can you remember who gave you this last injection?
1 – A medical doctor   2- A nurse   3- A dentist   4- A traditional healer

5- Someone else   6- Me, myself   7- A pharmacist   8- I don't remember

G. (If yes to question E) Can you remember where you received this last injection?
1- Clinic   2- Hospital   3- Dental office   4- Home   5- Don't know

H. (If yes to question E) Can you remember where the needle and the syringe that were used to give you this last injection came from?
1 – From a blister package   2- It was fitted with two caps   3- From a pot of tepid water

4- From a sterilizer   5- Other (specify)_____   6- I don't know/ remember

I. (If yes to question E) Can you remember what you paid for this injection?

__ For medication +   __ For the syringe +   __ For the service =   ____ Total

J. Have you ever been accidentally stuck by a injection needle that was left in the garbage or in the environment:

1 – Yes ____ Times   2 – No   3- Don't remember

K. When you are sick with a febrile illness, what is the treatment that you prefer to receive?
1 – An injection   2 - A medication by mouth   3- I don't care

L. Do you think that dirty syringes can transmit diseases?
1 – Yes   2 – No   3- I don't know

If yes, which (Circle when spontaneously mentioned)
1- HIV   2- HCV   3- HBV

3- Abscesses   4- Other (specify): _____

APPENDIX 1: TEMPLATE OF A NATIONAL INJECTION SAFETY PLAN

1. BEHAVIOUR CHANGE

HIV PREVENTION AND CARE PROGRAMME TO COMMUNICATE THE RISK OF HIV INFECTION ASSOCIATED WITH POOR INJECTION PRACTICES

Objectives	Core interventions	Beneficiaries/ Target groups	Indicators
Achieve safe injection practices	**Create consumer demand for new, single use injection equipment** • Education materials • Mass media	Patients	√ Proportion of the population spontaneously reporting the risk of HIV infection associated with unsafe injections
	Ensure use of new, single use injection equipment • Pre-service and in-service training	Injection providers (e.g., nurses)	√ Proportion of health care facilities where injections are given with a sterile syringe and needle
	Protect health care workers from needle-stick injuries • Endorsement of best practices by nursing association • Pre-service and in-service training	Injection providers (e.g., nurses)	√ Proportion of health care facilities where used injection equipment can be observed in places where they expose health care workers to needle-stick injuries

NATIONAL DRUG POLICY TO PREVENT INJECTION OVERUSE

Objectives	Core interventions	Beneficiaries/ Target groups	Indicators
Reduce injection overuse	**Promote oral medication** • Education materials • Mass media	Patients	√ Proportion of the population reporting a preference for injections in the case of fever
	Reduce prescription of injectable medications • Standard treatment guidelines • Policy statement from medical association • Interactional group discussions • Reduce financial incentive to provide injections	Injection prescribers (e.g., physicians, medical assistants, including in the private sector)	√ Proportion of prescriptions including at least one injection
	Reduce access to injectable medications • Remove unnecessary injectable medications from the essential drug list	Health facilities, pharmacies and depots.	√ Number of injectable medications on the essential drug list

2. EQUIPMENT AND SUPPLIES

ESSENTIAL DRUG SYSTEM SUPPLIES TO MAKE SYRINGES AND SHARPS BOXES AVAILABLE IN EVERY HEALTH CARE FACILITY

Objectives	Core interventions	Beneficiaries/ Target groups	Indicators
Ensure universal access to safe injection equipment and safety boxes	**Deliver injectable medications with matching quantities of essential equipment and supplies when procuring and distributing essential drugs** ▪ Procure syringes, needles, diluents and safety boxes for the collection of sharps ▪ Strengthen the national regulatory authority to ensure the quality of injection equipment	Public and private health care facilities	√ Proportion of health care facilities with stocks of single use injection equipment (in the facility or in a nearby public or community pharmacy)

IMMUNIZATION AND FAMILY PLANNING TO DELIVER INJECTABLE SUBSTANCES WITH AUTO-DISABLE SYRINGES AND SHARPS BOXES

Objectives	Core interventions	Beneficiaries/ Target groups	Indicators
Make all injectable vaccines and contraceptives available with matching qualities of injection equipment and safety boxes	**"Bundle" injectable vaccines and contraceptives procured by donors and lenders with essential equipment and supplies, including:** ▪ Auto-disable syringes and needles ▪ Diluents ▪ Safety boxes	Immunization and family planning services	√ Immunization and family planning services supplying auto-disable syringes and needles in quantities matching supplies of injectable vaccines and contraceptives of services

3. SHARPS WASTE MANAGEMENT

HEALTH CARE SYSTEM TO MANAGE SHARPS WASTE

Objectives	Core interventions	Beneficiaries/ Target groups	Indicators
Integrate sharps waste management into a comprehensive national health care waste management plan	**National health care waste management plan** ▪ National policy with regulatory framework ▪ Plan from waste production to disposal ▪ Training at all levels ▪ Procurement of waste treatment options	▪ Health care facilities ▪ Injection providers ▪ Communities	√ Proportion of health care facilities where used injection equipment can be seen in the surrounding environment

REFERENCES

1   Drucker E, Alcabes PG, Marx PA. The injection century: massive unsterile injections and the emergence of human pathogens. Lancet 2001; 358: 1989-1992.

2   Ringertz O. Serum hepatitis in Swedish track-finders. Scand J Infect Dis 1972; 4 (suppl 5): 1-25.

3   Bigger JW. Jaundice in syphilitics under treatment. Lancet 1943; i: 457-

4   MacCallum FO, Bauer J. Homologous serum jaundice: transmission experiments on human volunteers. Lancet 1944: i: 622-627.

5   Hutin YJF, Hauri AM, Chiarello L, Catlin M, Stilwell B, Ghebrehiwet T, Garner J and the members of the injection safety best practices development group. Best infection control practices for intradermal, subcutaneous and intramuscular needle injections. Bull World Health Organ, In press.

6   Hauri AM, Armstrong GL, Hutin YJF. Contaminated injections in health care settings. In "Comparative Quantification of Health Risks: Global and Regional Burden of Disease Attributable to Selected Major Risk Factors". Ezzati M, Lopez AD, Rodgers A, Murray CJL. Editors. Geneva: World Health Organization, 2003.

7   Hepatitis C – global prevalence (update). Weekly Epidemiological Record 1999; 74: 425-427.

8   Reeler AV. Injections: A fatal attraction. Soc Sci Med 1990; 31: 1119-1125.

9   Birungi H, Asiimye D, Whyte SR. Injection use and practices in Uganda (WHO/DAP/94.18). Geneva: WHO, 1994.

10   Simonsen L, Kane A, Lloyd J, Zaffran M, Kane M. Unsafe injections in the developing world and transmission of bloodborne pathogens: A review. WHO Bull 1999; 77: 789-800.

11   Kane A, Lloyd J, Zaffran M, Kane M, Simonsen L. Transmission of hepatitis B, hepatitis C and human immunodeficiency viruses through unsafe injections in the developing world: Model-based regional estimates. WHO Bull 1999; 77: 801-807.

12   Basic Support for Institutionalizing Child Survival (BASICS), SIGN, WHO. Injection safety assessment tools workshop: Meeting report, March 6-8, 2000. Unpublished.

13   WHO. Tool "A" to identify determinants of poor and good injection practices. (Draft 2, October 2000). WHO, Geneva, Switzerland.

14   WHO. Tool "B" to estimate the frequency of injections and identify providers. (Draft 2 October 2000).). WHO, Geneva, Switzerland.

15   WHO. Tool for the assessment of injection safety. (WHO/V&B/01.30 or WHO/BCT/01.02.) Geneva: WHO, 2001.

16   WHO. Tool "D" to assess the association between injections and infections. (Draft 2 October 2000).). WHO, Geneva, Switzerland.

17   WHO. Injection practices: Rapid assessment and response guide. WHO Department of Blood Safety and Clinical Technology, WHO/BCT 02.11.

18   Ministry of Health. Albanian Health System Reform. Position Paper on Policy and Strategies for the Albanian Health Sector Reform. Tirana: Ministry of Health, September 1999 (unpublished document).

19   Ministry of Health, WHO, and Merlin. A review of the working conditions of the 41 hospitals in Albania. Tirana: Ministry of Health, July-September 1999 (unpublished document).

20   Stoica A, Hutin YJF, Paun M, Mast EE, Margolis HS. Attitudes of Physicians Regarding the Use of Therapeutic Injections, Arges District, Romania. Abstract presented at the annual meeting of the Society for Healthcare Epidemiology of America, San Francisco, CA, April 1999.

21   WHO. High frequency of therapeutic injections, Republic of Moldova. Wkly Epidemiol Rec. 1999; 11: 84-6.

22   Luby SP, Qamruddin K, Shah AA et al. The relationship between therapeutic injections and high prevalence of hepatitis C infection in Hafizabad, Pakistan. Epidemiol Infect 1997; 119: 349-56.

23   Frank C, Mohamed MK, Strickland GT et al. The role of parenteral antischistosomal therapy in the spread of hepatitis C virus in Egypt. Lancet 2000; 355: 887-91.

24   Prawitasari Hadiyono JE, Suryawati S, Danu SS, Sunartono Santoso B. Interactional group discussion: Results of a controlled trial using a behavioural intervention to reduce the use of injections in public health facilities. Soc Sci Med 1996; 42: 1177-1183.

25   Dentinger CM, Hutin YJF, Pasat L, Mihilescu I, Mast EE, Margolis HS. Knowledge and practices of nurses regarding injection safety and use of universal precautions, Vilcea district, Romania. Abstract presented at the annual meeting of the Society for Health-care Epidemiology of America (SHEA), San Francisco, CA, April 1999.

26   Davaasuren D, Dahgwadori Y, Nymadawa P, Gantuya S, Sarangoo G. Survey results of prevalence for viral hepatitis B, C and D markers among the children in Ulaanbaatar. Mongolian Medical Sciences 2000; 4: 21-24.

27   Kidd-Lunggren K, Broman E, Ekvall H, Gustavson O. Nosocomial transmission of hepatitis B virus infection through multiple-dose vials. J Hosp Infect 1999; 43: 57-61.

28   Minister of Health, Order #A/124, 1995. Appendix 4.

29   Pruss A, Giroult E, Rushbrook P. Safe management of wastes from health care activities. Geneva: WHO, 1999.

30   Hamid S. Burden of end stage liver disease. First national symposium on safe injection and blood practices in Pakistan. Aga Khan University, Karachi, Pakistan, 2000.

31   Aylward B, Kane M, McNair-Scott R, Hu DH. Model-based estimates of the risk of human immunodeficiency virus and hepatitis virus transmission through unsafe injections. Int J Epidemiol 1995; 24: 446-452.

32   WHO. State of the world's vaccines and immunization. WHO/GPV/96.04. Geneva: WHO, 1996.

33   World Bank. Towards a Health Sector Strategy. Washington DC: World Bank, 1997.

34   Hoodbhoy F. An intervention to make injections safe. First national symposium on safe injection and blood practices in Pakistan 2000, Aga Khan University: Karachi, p 17.

35   Ahmed ST. Improvement in injection practices by the private practitioners in rural communities in Karachi, Pakistan. First national symposium on safe injection and blood practices in Pakistan. Aga Khan University, Karachi, Pakistan, 2000.

36   Luby S, Zaidi N, Rehman S et al. Improving private practitioner sick child case management in two urban communities in Karachi, Pakistan. Final project report to BASICS, 1999.

37   Khan AJ, Luby SP, Fikree FF et al. Injections and hepatitis B and C transmission in peri-urban Karachi, Pakistan. WHO Bull 2000; 78: 949-1066.

38   Pasha O, Luby S, Khan AJ, Shah A, McCormick J, Fisher-Hoch S. Household members of Hepatitis C virus infected people in Hafizabad, Pakistan: infection by injections from health care providers. Epidemiol Infect 1999; 123: 515-518.

39   World Bank. Health Sector Study, Islamic Republic of Pakistan: Key Concerns and Solutions. Washington, DC: World Bank, 1993.

40   Nadeem Saeed. Patients prefer private health facilities. Daily Dawn. November 27, 2001.

41   van Staa A, Hardon A. Injection practices in the developing world: a comparative review of the field studies in Uganda and Indonesia (WHO/DAP/96.4; unpublished document, available on request from Essential Drugs and other Biologicals, WHO). Geneva: WHO, 1996.

42   Bennett S, Woods T, Liyanage WM, Smith DL. A simplified general method for cluster-sample survey of health in developing countries. World Health Stat Quart 1991; 44: 98-106.

43   Ko YC, Li Sc, Yen YY, Yeh SM, Hsieh CG. Horizontal transmission of hepatitis-B virus from siblings and intramuscular injection among preschool children in a familial cohort. Am J Epidemiol 1991; 133: 1051-23.

44   Sun CA, Chen HC, Lu CF et al. Transmission of hepatitis C virus in Taiwan: prevalence and risk factors based on a nation wide survey. J Med Vir 1999; 59:290-96.

45   Hersh BS, Popovici F, Jezek Z et al. Risk factors for HIV infection among abandoned Romanian children. AIDS 1993; 7: 1617-24.

46   Baron R, McCormick JB, Zubeir O. Ebola virus disease in southern Sudan: hospital dissemination and intrafamilial spread. WHO Bull 1983; 61: 997-1003.

47   Roa GG, Shahi M. Injections in the Indian subcontinent. BMJ 1987; 295: 1281.

48   Raglow G, Luby SP, Nabi N. Therapeutic injections in Pakistan: from patients' perspective. Trop Med Int Health 2001; 6(1): 69-75.

49   Luby S, Zaidi N, Rehman S, Northrup R. Improving private practitioners sick-child case management in two urban communities in Pakistan. Trop Med Int Health 2002; 7(3): 210-219.

50   Ward B. On the North West Frontier. BMJ 1981; 282: 458-259.

51   Usman HR, Akhtar S, Rhabar MH, Hamid S, Moattar T, Luby SP. Injections in health care settings: a risk factor for acute hepatitis B virus infection in Karachi, Pakistan. Epidemiol Infect 2003 (In press).

52   Bari A, Akhtar S, Rahbar MH, Luby SP. Risk factors of hepatitis C virus infection in male adults in Rawalpindi–Islamabad, Pakistan. Trop Med Int Health 2001; 6(9): 732-738.

53   District Census Report of Karachi 1998. Population Census Organization, Statistics Division. Government of Pakistan Islamabad 1999.

54   District Census Report of Mirpur Khas 1998. Population Census Organization, Statistics Division. Government of Pakistan Islamabad 1999.

55   Expanded Programme on Immunization. EPI coverage survey. Geneva: WHO, 1991. WHO/EPI/MLM/91.10.

56   Anand K, Panadav CS, Kapoor SK. Injection use in a village in North India. Natl Med J India 2001; 14:143-4.

57   Frequency of vaccine- related and therapeutic injections—Romania, 1998. MMWR 1999; 48(13): 271-274.

58   Pakistan Medical Research Council. National Health Survey of Pakistan 1993-94. Ministry of Health, Government of Pakistan, Islamabad 1996.

59   Bahatia JC, Cleland J. Health seeking and expenditure by young Indian mothers in public and private sector. Health Policy Plan 2001; 16(1): 55-61.

60   Wyatt HV. Injections cripple: injection kill. J Indian Med Assoc1986; 84: 193-94.

61   Greenhalgh T. Drug prescription and self-medication in India: an exploratory survey. Soc Sci Med 1987; 25: 307-318.

62   Vissandjee B, Barlow R, Fraser DW. Utilization of health services among rural women in Gujrat, India. Public Health 1997; 111:135-48.

63   Ha NT, Berman P, Larsen U. Household utilization and expenditure on private and public health services in Vietnam. Health Policy Plan 2002; 17(1): 61-70.

64   Vincent-Ballereau F, Lafaix C, Laroche G. Incidence of intramuscular injections in rural dispensaries in developing countries. Trans Roy Soc Trop Med Hygiene, 1989, 83: 106.

65   Dicko M, Oni A-QO, Gavinet S, Kone S, Pierre L, Jacquet B. Safety of immunization injections in Africa: not simply a problem of logistics. WHO Bull 2000; 78: 163-169.

66   WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services. WHO-UNICEF policy statement for mass-immunization campaigns. WHO/V&B/99.25.

67   WHO. Aide-Mémoire for a national strategy for the safe and appropriate use of injections. Geneva: WHO, 2000.

68   MMWR. Injection Practices Among Nurses -- Valcea Romania, 1998. MMWR Weekly 2001; 50: 59-61.

69   Lloyd JS, Milstien JB. Auto-disable syringes for immunization: Issues in technology transfer. WHO Bull 1999; 77: 1001-1007.

70   Miller MA, Pisani E. The cost of unsafe injections. WHO Bull 1999; 77: 808-811.

71   Battersby A, Feilden R, Stoeckel P, Da Silva A, Nelson C, Bass A. Strategies for safe injections. WHO Bull 1999; 77: 996-1000. Battersby A, Feilden R, Stoeckel P, Da Silva A, Nelson C, Bass A. Strategies for safe injections. WHO Bull 1999; 77: 996-1000.

72   WHO (Department of Protection of the Human Environment). Aide-memoire for a national strategy for health-care waste managment. Geneva: WHO, 2000.

73   Gust ID. Epidemiology of hepatitis B infection in the Western Pacific and South East Asia. Gut 1996; 38 (Suppl 2): S18-23.

74   Malik IA, Luqman M, Ahmed A et al. A clinicopathological study of viral hepatitis. Pakistan J Med Res 1987; 26: 4-11.

75   Chaudhry GM, Noor NA, Qazi AW. Frequency of acute viral hepatitis cases in Nishtar Hospital Multan. JCPSP 1995; 5: 6-9.

76   Hutin YJ, Harpaz R, Drobeniuc J et al. Injections given in health care settings as a major source of acute hepatitis B in Moldova. Int J Epidemiol 1999; 28: 782-6.

77   Narandranathan M, Philip M. Reusable needles—a major risk factor for acute virus B hepatitis. Trop Doct 1993; 23; 64-6.

78   Singh J, Gupta S, Khare S, Bhatia R, Jain DC, Sokley J. A severe and explosive outbreak of hepatitis B in rural population in Sirsa district, Haryana, India: unnecessary therapeutic injections were a major risk factor. Epidemiol Infect 2000; 125: 693-9.

79   Singh J, Bhatia R, Patniak SK et al. Community studies on hepatitis B in Rajahmundry town of Andra Pradesh, India, 1997-8: unnecessary therapeutic injections are a major risk factor. Epidemiol Infect 2000; 125: 367-75.

80   Singh J, Bhatia R, Gandhi JC et al. Outbreak of viral hepatitis B in rural community in India linked to inadequately sterilized needles add syringes. WHO Bull 1998; 76: 93-8.

81   Toukan AU, Sharaiha ZK, Abu-el-Rub OA et al. The epidemiology of hepatitis B virus among family members in the Middle East. Am J Epidemiol 1990; 132: 220-32.

82   Stroffolini T, Chiaramonte M, Craxi A et al. Baseline sero-epidemiology of hepatitis B virus
        infection in children and teenagers in Italy. A survey before mass hepatitis B vaccination. J Infect
        1991; 22: 191-9.

83   Pellizzer G, Ble C, Zamperetti N et al. Serological survey of hepatitis B infection in Tanzania.
        Public Health 1994; 108: 427-31.

84   Milne A, Allwood GK, Moyes CD, Pearce NE, Newell K. A seroepidemiological study of the
        prevalence of hepatitis B infections in a hyperendemic New Zealand community. Int J Epidemiol
        1987; 16: 84-90.

85   Wacholder S, McLaughlin JK, Silverman DT, Mandel JS. Selection of controls in case-control
        studies. I. Principles. Am J Epidemiol 1992; 135: 1019-28.

86   Wacholder S, Silverman DT, McLaughlin JK, Mandel JS. Selection of controls in case-control
        studies. II. Types of controls. Am J Epidemiol 1992; 135: 1029-41.

87   Hou MC, Wu JC, Kuo BI et al. Heterosexual transmission as the most common route of acute
        hepatitis B virus infection among adults in Taiwan--the importance of extending vaccination to
        susceptible adults. J Infect Dis 1993; 167: 938-41.

88   Sagliocca L, Stroffolini T, Amoroso P et al. Risk factors for acute hepatitis B: a case-control study.
        J Viral Hepat 1997; 4: 63-6.

89   Quick JD, Rankin JR, Laing RO et al. (Editors). Managing Drug Supply, 1st edn 1997; pp. 430-49.
        West Hartford: Kumarian Press.

90   "Aide Mémoire" for National Safe and Appropriate use of Injections Strategies. WHO document,
        Department of Blood Safety and Clinical Technology, 2000. Document available at
        www.injectionsafety.org.

91   CDC. Framework for program evaluation in public health. MMWR 1999;48: RR-11.

92   WHO, action programme on essential drugs. Indicators for monitoring national drug policies.
        WHO/DAP/94.12.

93   WHO. How to investigate drug use in health facilities. WHO/DAP/93.1.

94   Reeler AV: Anthropological perspective on injections: a review. Bull WHO 2000;78:135-43.

95   WHO. Guide to good prescribing. WHO/DAP/94.11.

96   WHO. Report of two informal workshops on injection practices research. WHO/DAP/92.9.

97   WHO. How to investigate drug use in communities. WHO/DAP/92.3.

98   WHO. How do I become an injection safety advocate? Initial draft, August 2001, available from
        www.injectionsafety.org.

99   Best infection control practices for skin-piercing intradermal, subcutaneous and intramuscular
        needle injections. WHO/BCT/DCT 01.02.