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INJECTION SAFETY IN CENTRAL ASIA

by

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Injections are one of the most common health care procedures. According to WHO data, there are 16 billion medical injections performed annually in developing and transitional countries. In countries where unnecessary injections are common, the average number of injections per person has been estimated to be 3.7 per year and half of them are estimated to be unsafe injections (Hauri AM et al., 2003).

Each year, reuse or unsafe practice of injection devices may cause 20 million infections with hepatitis B virus (HBV), 2 million infections with hepatitis C virus (HCV), and 250,000 infections with human immunodeficiency virus (HIV) worldwide. Like many developing countries, unsafe injection practices are a significant issue for Central Asian countries of Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan, and Uzbekistan. In addition to unsafe injections, overuse of transfusions of blood and blood products, reuse of single use medical equipment, inadequate sterilization, improper disposal of sharps (e.g., needles, scalpel blades, etc.) are also major cause of concern in Central Asia.

The term “injection safety” was initially used when it was recognized that injections—which are typically thought of as being intramuscular—may be an important mode of transmission of HIV or hepatitis viruses. More recently, the term has been broadened to include other means of parenteral injection of substances (intravenously), withdrawing of blood (phlebotomy) or for intravenous/intra-arterial access (catheters in veins or arteries).

WHO’s definition of safe injections is: *A safe injection, phlebotomy, lancet procedure or intravenous device insertion does not harm the recipient, does not expose*

the provider to any avoidable risk and does not result in any waste that is dangerous for other people.”

The HIV epidemic in Central Asian Republics of Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan, and Uzbekistan is primarily driven by injecting drug users (IDUs), however, Ministries of Health (MoHs) estimate that anywhere between 2-15% of the HIV transmissions occur due to nosocomial infections. However, lack of proper monitoring and evaluation systems in the region have led many to believe that a larger proportion of HIV transmission is caused by nosocomial infection in Central Asia.

The first HIV outbreak in the region occurred in 2006 when more than 130 children were infected with HIV in Shymkent, Kazakhstan. Outbreak investigation conducted by the Centers for Disease Control and Prevention (CDC) cited intravenous route of medication, subclavian vein catheterization, and use of blood or blood products as the main risk factors for HIV transmission.

In early 2007, another HIV outbreak was reported in Osh, Kyrgyzstan, where initially it was reported that at least 26 people, mostly children, acquired HIV infection in two local hospitals. CDC was asked again to conduct an investigation and estimated that the number of children infected exceeded 100. The results of the investigation cited intramuscular and intravenous injections to be the primary risk factor for HIV transmission as well. Data from the CDC outbreak investigation is presented below.

Also in 2007, HIV outbreak was reported in Andijan, Uzbekistan among 7 children; however, the government never confirmed the outbreak. Although no evidence exists it is believed that nosocomial infection was the primary cause of the outbreak.

Subsequently, in November 2008, BBC reported that more than 40 children were infected with HIV in Namangan, Uzbekistan. Uzbek government did not request CDC to investigate the outbreak, however, a team of UN agencies, including UNAIDS, UNICEF, and WHO, visited Namangan on a fact finding mission. UN agencies reported unsafe injection practices to be the primary risk factor for HIV transmission among children. Then, in March 2010, an Uzbek documentary was leaked to the media that claimed more than 147 children were infected with HIV between 2007 and 2008 in Namangan alone.

After each of the outbreak that CDC investigated, CDC provided training to physicians and healthcare workers on proper injecting techniques, however, it was evident that localized trainings or interventions would not prevent HIV outbreaks elsewhere in the region. Thus, CDC and Central Asia AIDS Project (CAAP), a regional entity, started to exchange ideas on how best to provide assistance to MoHs.

CAAP and CDC already had a collaborative relationship. Working jointly, CAAP and CDC initiated HIV sentinel surveillance in Central Asian Republics of Kazakhstan, Kyrgyzstan, Tajikistan, and Uzbekistan. In addition to sentinel surveillance, CAAP and CDC also collaborated on laboratory issues in the region.

CDC/Central Asia Regional Office (CAR), based in Kazakhstan, has a long history of working in the region. It was initially established in 1997 and has been actively engaged in providing technical assistance to MoHs on HIV/AIDS since 2002. CAAP was established in 2005 through funding by World Bank and Department for International Development (DFID). Its main purpose is to control the spread of HIV/AIDS in the region by engaging stakeholders in the region and by building capacity of local NGOs. Since prevention of nosocomial infection was an area of overlap between CDC and

CAAP and because of a history of collaborative efforts between the two entities, both entities decided to collaborate in area of injection safety as well.

During the discussions between two entities, it was agreed that the Central Asian countries needed a strategic plan to prevent nosocomial infection. However, the strategy and implementation plan would be based on country specific needs and in order to better understand the conditions in individual countries, it was agreed that additional data was needed.

The first attempt to compile data was using MoHs resources, however, MoHs in the region have a very weak monitoring and evaluating system. Consequently, the type of data that was needed did not exist in most of the countries. It was then decided that there were only two options to gather the necessary data – 1) to conduct rapid assessment in select sites of each of the country or 2) to conduct national baseline assessment.

During discussions with several other stakeholders, a concern was noted that by limiting data collection to a specific region of a given country, it may not accurately represent a national picture. Most of the countries in the region are diverse – their economic development, infrastructure, and other social phenomenon all vary considerably. Another concern which was noted that by limiting any assessment to a specific geographic area, CAAP and CDC may expose healthcare facilities and workers of those geographic area to national government scrutiny, which may jeopardize the intent of the assessment. Central Asia has a history of penalizing healthcare workers that may unintentionally expose patients to risks. Rather than dealing with the root of the problem, such as in-service/pre-service training of physicians, many countries have chosen to penalize their health care workers. One such example is Uzbekistan, where in

2010 a law was passed by the President holding healthcare workers criminally responsible for spreading HIV in medical facilities. Such laws have rarely resulted in reduction of nosocomial infection, instead it generally results in resistance by physicians to diagnose patients with to avoid criminal penalties. Thus, to circumvent both of the issues, it was decided that data should be collected at the national level. Furthermore, it was decided that CAAP would provide the funding for the assessments, whereas, CDC will provide the technical expertise.

The goal identified for the assessment was to collect baseline data in each country to assess the injection practices in hospitals and lower level health care facilities. It was agreed that the baseline assessment will be used to identify gaps in the healthcare system so recommendations could be made to host government on implementation of appropriate interventions.

Consequently, CAAP and CDC followed-up with each of the Central Asian Republics, except Turkmenistan. Although no HIV outbreak had been reported in Turkmenistan, CAAP and CDC wanted to conduct national assessment in Turkmenistan as well. Officially, the government of Turkmenistan has reported only 2 HIV cases and does not acknowledge the existence of HIV in their country, which poses significant challenge in operating there. Despite documentation that other infectious diseases can be transmitted due to unsafe injection practices, the government of Turkmenistan gave no response, thus were excluded from this activity.

The MoHs initially only agreed to hold conferences in each country to highlight and familiarize lead physicians and related public health workers to proper injecting techniques. After further communications with MoH, it was decided that the goal of the

conference will be to introduce international guidelines involving injection safety and related infection prevention and control practices (IPC). Consequently, in June 2009, two national conferences were conducted in Tajikistan and in Uzbekistan each, and by September 2009, another two conferences were conducted in Kyrgyzstan and Kazakhstan each. The conferences were attended by senior representatives of MoHs and included participants from each oblast (province) of each country. As a result of the conferences and discussions that took place during the conference, resolutions by the Ministry of Health were signed that granted CAAP and CDC approval to conduct national assessments with the goal to improve regulatory documents and national standards.

As the first step towards developing an assessment tool, CDC/Central Asia Regional office (CDC/CAR) based in Almaty, Kazakhstan took the lead in developing a protocol and assessment tool for the national assessment in each country. CDC/CAR used the WHO developed injection safety assessment toolkit as a basis of structuring the assessment and adapted it to fit the needs of Central Asia. WHO had initially developed a tool for injection assessment in 2001 (Tool for the assessment of injection safety. Department of vaccines and biologicals. WHO, Geneva, 2001), but it was revised in 2007 to include all vascular access points, such as intramuscular, subcutaneous and intradermal practice injections, phlebotomies, intravascular access devices, and procedures with a lancet (Tool for the assessment of Injection Safety and the Safety of Phlebotomy, Lancet Procedures, Intravenous Injections and Infusions. SIGN/WHO/Essential Health Technologies. 16 July, 2007).

Drafts of protocol and assessment tool were shared with the MoHs at various intervals and many of their recommendations/suggestions were incorporated. Since the

lingua franca in the region is Russian, the protocol and all the questionnaires were written in English and translated into Russian when shared with the MoHs for their feedback. The Russian protocol and questionnaires were also translated back into English and compared to the original English transcribed protocol and questionnaires to verify accuracy of translation.

The toolkit was also piloted at a few hospitals to gain feedback from target audiences and participants. The pilot resulted in a few modifications of the questionnaires to accurately pose the question during the assessment. Once the final changes to the protocol and toolkit were made, they were submitted to MoHs for their final approval. MoH approval was received within a few week of the submission, after which it was submitted to CDC IRB for their approval.

Once IRB approval is received, CDC will hold a two-day training for data collectors/assessors in each of the country. Data collectors will be trained in a classroom setting with an introduction to Injection safety and waste management concepts. This training will include a detailed review of the entire questionnaire including all instructions and steps. Practice sessions will be held at a local hospital and lower level facility which are not included in the sample. This will provide an opportunity to standardize the approach to data collection, to provide feedback on the performance of data collectors, and to field test the questionnaires in the local context. In the first few days of the actual data collection, data collectors will receive close support from technical advisors and hired supervisors to ensure good quality data and to help address any issues that may arise. Data collectors are to be supervised throughout data collection by

supervisors; they will be provided with contact information to have immediate access to a supervisor as needed during data collection.

The report will be written based on the results of the database analysis. It will be prepared by appropriate CDC staff, and will undergo technical review to ensure the overall quality of the report. The report will follow the general outline provided to the analyst and will cover the different topics mentioned in the analysis plan.

The final country-specific survey report will be shared with MoH. MoH will decide the sharing mechanism with other counterparts. Results may also be presented at conferences as lessons learned in the following areas (1) need for changing the behavior of health care workers to ensure safe injection practices through capacity building, behavior change and communications, and policy interventions; (2) ensuring the availability of safe injection equipment and supplies through procurement and logistics interventions; and (3) managing health care waste safely and appropriately; (4) reduction/elimination of unnecessary injections

The results and the assessment will be presented as a report combined with information from other countries at a regional workshop for all countries of CAR. This workshop will include national decision makers, the survey team, directors of large facilities where assessments were conducted and other national or international agencies with an interest in the results. Results to be presented will be shown as aggregated results by CAR region, district or by type of facility (such as grouping all hospitals together, for example). Data from individual countries will be presented only if there is preceding approval from the MoH of each country, and even then the name of the country will not be announced. If a country objects, then all data will be aggregated and shared.

It is hoped that once the data gained from the assessment will serve as advocacy tool that can be used to engage host governments in taking actions to prevent nosocomial infections in the region. The results of the assessment will also guide MoH, CAAP, CDC, and all stakeholders in developing a strategy that can be implemented in each country to avoid nosocomial infections in the region.

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**Injection Practices: A National Assessment of the
Healthcare Facilities in Central Asian Countries of
Kazakhstan, Kyrgyzstan, Uzbekistan and
Tajikistan**

**Ministry of Health of the Republic of Kazakhstan
Ministry of Health of the Kyrgyz Republic
Ministry of Health of the Republic of Uzbekistan
Ministry of Health of the Republic of Tajikistan
Centers for Disease Control and Prevention, USA
Central Asian AIDS Project**

DISCLAIMER

This proctol was submitted to CDC for review and approval by IRB, however, at the time of submission to GSU, the protocol had not been approved by CDC. Conssequently, the procol may undergo further changes before the assessment can start.

ABBREVIATION AND SYMBOLS USED

AIDS – Acquired Immunodeficiency Syndrome

CAR – Central Asia Region

CDC – Centers for Disease Control and Prevention, USA

CDC/CAR - Centers for Disease Control and Prevention, Office in the Central Asia

CAAP – Central Asian AIDS Project

CVC – Central venous catheter

CV – Curriculum vitae

EPI – Extended Program for Immunization

GAP – Global AIDS Program

HCF – Healthcare facility

HCW – Healthcare worker

HIV - Human Immunodeficiency Virus

HBV - Hepatitis B Virus

HCV – Hepatitis C virus

ICU – Intensive Care Unit

IRB – Institutional Review Board

IS- Injection Safety

MOH – Ministry of Health

PEP – Post-Exposure Prophylaxis

RC AIDS – Republican AIDS Center

RSES – Republican Sanitarian – Epidemiological Station

SIGN – Safe Injection Global Network

TOR – Terms of Reference

WHO – World Health Organization

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Central Asian AIDS Project

1. INTRODUCTION

1.1. Literature review

Injections are one of the most common health care procedures. According to WHO data, there are 16 billion medical injections performed annually in developing and transitional countries. In countries where unnecessary injections are common, the average number of health care injections per person has been estimated to be 3.7 per year (Hauri AM et al., 2003). Half of them are unsafe injections (see definition, below). The vast majority of injections, about 95%, are given in curative care (http://www.who.int/injection_safety/toolbox/en/InjectionFactSheet2002.pdf).

WHO definition of safe medical procedures involving injections or other parenteral procedures: *A safe injection, phlebotomy, lancet procedure or intravenous device insertion does not harm the recipient, does not expose the provider to any avoidable risk and does not result in any waste that is dangerous for other people.* (http://www.who.int/injection_safety/Injection_safety_final-web.pdf).

The term “injection safety” was initially used when it was recognized that injections—which are typically thought of as being intramuscular—may be an important mode of transmission of HIV or hepatitis viruses. More recently, the term has been broadened to include other means of parenteral injection of substances (intravenously), withdrawing of blood (phlebotomy) or for intravenous/intra-arterial access (catheters in veins or arteries). Thus, although the term used in this protocol is “injection safety,” the safety of additional medical procedures involving intravascular injection/access will be studied. Injection safety includes practices intended to prevent transmission of infectious diseases between one patient and another, or between a patient and healthcare provider, and also to prevent harms such as needle stick injuries (Joseph F. Perz et al., 2010).

Injection safety is an important problem around the world. While there is disagreement among experts over the precise contribution of unsafe injection practices to global incidence of selected infections, each year, reuse or unsafe practice of injection devices may cause 20 million infections with hepatitis B virus (HBV), 2 million infections with hepatitis C virus (HCV), and 250 000 infections with human immunodeficiency virus (HIV) worldwide, accounting for 30%, 41% and 5% of new infections in 2000, respectively (Hauri AM et al., 2003). The probability of transmission of HBV via blood traces on syringes/needles may be as much as 20-40% in Health Care Facilities (HCF); on average, 6% of needle-stick injuries involving HCV-infected patients has led to infection; and seroconversion risk following HIV-contaminated needle-stick accidents has been estimated as 0.3% (L. Simonsen A. et al., 1999). Also, improperly handled injectable medications such as multi-dose vials may transmit blood borne pathogens (WHO/BCT/DCT 01.02); and the use of multi-dose vials has been

reported to be a potential source of infections in 19 studies (L. Simonsen A. et al., 1999).

Environmental contamination within the HCF is a potential source of infection. For instance, HBV persists for up to seven days on surfaces (CDC. Recommendations for preventing transmission of infection among chronic hemodialysis patients. *MMWR*, 2001). In Romania, a review of injection practices revealed that HBV transmission was probably related to the preparation of injections in contaminated environments (Sautter RL et al., 1984).

There are multiple poor injection practices which could lead to infections. An example is swabbing of vial tops or ampoules with an antiseptic or disinfectant when the disinfecting substances have been stored inappropriately (Nakashima AK et al., 1987; Reiss I et al., 2000). Needle-stick injuries to healthcare workers when administering injections are usually attributable to the brusque movements of patients (Jagger J et al., 1998; Haiduven DJ et al., 1992), and ensuring little movement of the patient or limb is partially preventable. A high proportion of needle-stick injuries are due to the two-handed recapping technique (Jagger et al., 1998), a very preventable practice, and unsafe sharps waste collection causes between 5% and 28% of needle-stick injuries (Khuri-Bulos NA et al., 1997).

A major concern that places both patient and HCW at risk is unnecessary injections. Two studies from the United Republic of Tanzania, one of which was a survey of 66 clinics, concluded that 70% of all curative injections given were unnecessary (Gumodoka B et al., 1996). An Indonesian survey calculated that 82% of curative injections were unnecessary (Hogeboom van Buggenum et al., 1993). In India, a study founded that 96% of all injections given by private doctors were for antibiotics, vitamins and analgesics (Greenhalgh T. et al., 1987). Two studies in Moscow, Russia concluded that 85% and 99% of injections given to hospitalized children were unnecessary (Loukina TN et al., 1993; Stekolschikova IA et al., 1993).

Unsafe injections and vascular access practices are a notable problem for all CAR countries. All findings mentioned above suggest that unsafe medical practices remain a significant health threat in Central Asia today. Among them are unnecessary injections, overuse of transfusions of blood and blood products, reuse of single use medical equipment, inadequate sterilization, improper disposal of sharps (e.g., needles, scalpel blades, etc.). An example of a documented nosocomial HBV and HCV transmission in the region is a CDC/CAR study of HBV and HCV infection in a TB dispensary in 2002 which found that 10% of HBV susceptible persons seroconvert within three months of beginning treatment at the dispensary. The seroconversion rate for HCV was similar.

Nosocomial HIV infection cases have been reported from all countries of the region. One example is the HIV outbreak among children reported in South

Kazakhstan oblast (oblasts are the equivalent of States in America) in May 2006. An epidemiological investigation conducted by CDC/CAR found that the main risk factors for HIV infection among children during the outbreak were a history of blood transfusion and certain invasive procedures (subclavian line insertion). A similar HIV outbreak was reported in the southern part of Kyrgyzstan in 2007. Also Uzbekistan and Tajikistan have registered cases of nosocomial HIV infection. Unfortunately, there are no systematically-collected evidence-based data on injection practices in four of the CAR countries.

WHO developed a tool for the assessment of injection safety in 2001 (Tool for the assessment of injection safety. Department of vaccines and biologicals. WHO, Geneva, 2001). Since then, this tool was used in over 90 national injection safety assessments; results were used to establish national standards for injection safety. A revised tool has been developed, which includes the assessment of intramuscular, subcutaneous and intradermal practice injections, also covers phlebotomies, intravascular access devices, and procedures with a lancet (Tool for the assessment of Injection Safety and the Safety of Phlebotomy, Lancet Procedures, Intravenous Injections and Infusions. SIGN/WHO/Essential Health Technologies. 16 July, 2007).

MOH of have expressed concern about the contribution of hospital acquired (nosocomial) blood borne infections among registered HIV cases in children in three of the five Republics. At the present time, MOH of four countries have expressed the need and willingness to conduct an assessment of injection practices at the national level with the aim of receiving evidence-based data to then make decision with the goal of improving national standards and practices.

Last year, CDC and CAAP discussed the best approach with which to provide technical assistance to each MOH and decided to conduct national conferences in four Central Asian countries. By June 2009, two national conferences were conducted, one in Tajikistan and one in Uzbekistan; by September 2009, another two conferences were conducted, in Kyrgyzstan and Kazakhstan. As a result of the conferences and discussions in working groups, resolutions by the Ministry of Health were signed. With the resolution, MOH of all four countries announced the need for national assessments of injection practices with the aim of using data from the assessments to improve regulatory documents and national standards (Prikazes).

1.2. Justification for the assessment

Recognizing from preliminary work that within CAR there is overuse of injections, unsafe practices, lack of single-use disposable injection equipment in some countries, and large problems with medical waste management, there is a need to conduct baseline assessments in at least four of the countries of CAR; a fifth has not given permission for such a survey. All countries mentioned above will

require a comprehensive approach toward using the data acquired and applying them to solving the problems likely to be encountered in the surveys.

1.3. Intended/Potential use of the study

The information collected during this study will provide baseline data on IS and waste management practices in countries of CAR (Kazakhstan, Kyrgyzstan, Uzbekistan and Tajikistan). The results of the baseline assessment will allow to MOHs to improve injection policies and establish an intervention strategy with the goal of reducing unnecessary injections and improving safe injection practices. A repeat assessment after implementation and completion of activities for improvement of injection practices is then anticipated; this study is statistically powered to allow such an assessment.

2. OBJECTIVES

2.1. Goal and general objectives of the assessment

The goal is to conduct a baseline assessment of injection practices. The assessment will look for gaps in safe injection practices in hospitals and lower level HCFs. These identified gaps will be used for improvement of national policies in injection safety and healthcare waste management, and for the establishment of educational curricula for pre- and in-service trainings (the development of training to be also used as a capacity building exercise for MOH in how to train HCWs, including injection providers and waste handlers).

The general objectives of the assessment include:

1. Assessing the availability of injection equipment/materials.
2. Describing the conditions and practices for administering injections and other related procedures.
3. Assessing the availability of equipment/materials for the collection, transport and elimination of waste, as well as the procedures and practices relative to managing waste from injection and other injection-related procedures and activities.
4. Assessing the existence of reference documents (national policy, standards, and guidelines) in health facilities for injections and other injection related procedures.
5. Assessing the number of accidental needle sticks among health care providers and waste handlers reported in the last 6 months.
6. Assessing the barriers to reporting accidental needles sticks among health care providers.
7. Assessing the knowledge of health care workers about infections transmitted through unsafe injections and accidental needle sticks.
8. Assessing the vaccination status of the health care providers and waste handlers (hepatitis B).

2.2. Specific Objectives and Key Indicators

The survey will seek to answer the following specific questions:

- For each injection given, were the needle and syringe taken from a sterile pack?
- For each phlebotomy, were the needle and syringe taken from a sterile pack or was a new phlebotomy set used?
- For each catheter inserted, were the catheter and stylet taken from a sterile pack?
- For cases where the needle and syringe were NOT taken from a sterile pack: Was there evidence that a used needle and/or syringe were being re-used on the same or a different patient without re-processing?
- After the completion of the injection and other injection related procedure, was the used syringe/device recapped with two hands?
- After each injection and other injection related procedure observed, did the provider immediately dispose of the used needles and syringes in an appropriate sharps container or use a needle remover?

Key indicators to assess safe injection practices have been designed to reflect the goals of the study:

- **Key indicators to assess safe intramuscular injection practices**
- Use of new sterile devices for injections: “Proportion of intramuscular injections given with a new syringe and needle”
- Prevention of the risk of needle stick injuries among providers by eliminating recapping: “proportion of intramuscular injections given by HCWs who dispose of used sharps involving needles without recapping them”
- Prevention of the risk for needle stick injuries among HCWs: “Proportion of intramuscular injections given by HCWs who dispose of used sharps in a safety box or puncture-proof, leak-proof sharps container (or use a needle remover) immediately after injection/injection related procedure”
- **Key indicators to assess safe intravenous injection practices**
- Use of new sterile devices for injections: “Proportion of intravenous injections given with a new syringe and needle”
- Prevention of the risk of needle stick injuries among providers by eliminating recapping: “proportion of intravenous injections given by HCWs who dispose of used sharps involving needles without recapping them”
- Prevention of the risk for needle stick injuries among HCWs: “Proportion of intravenous injections given by HCWs who dispose of used sharps in a safety box or puncture-proof, leak-proof sharps container (or use a needle remover) immediately after injection/injection related procedure”
- **Key indicators to assess safe phlebotomy practices**
- Use of new sterile devices for phlebotomies: “Proportion of phlebotomies given with a new syringe and needle”

- Prevention of the risk of needle stick injuries among providers by eliminating recapping: “proportion of phlebotomies given by HCWs who dispose of used sharps involving needles without recapping them”
- Prevention of the risk for needle stick injuries among HCWs: “Proportion of phlebotomies given by HCWs who dispose of used sharps in a safety box or puncture-proof, leak-proof sharps container (or use a needle remover) immediately after injection/injection related procedure”
- **Key indicators to assess safe IV procedures through CVC and PVC:**
- Use of new sterile devices for phlebotomies: “Proportion of phlebotomies given with a new syringe and needle”
- Prevention of the risk of needle stick injuries among providers by eliminating recapping: “proportion of phlebotomies given by HCWs who dispose of used sharps involving needles without recapping them”
- Prevention of the risk for needle stick injuries among HCWs: “Proportion of phlebotomies given by HCWs who dispose of used sharps in a safety box or puncture-proof, leak-proof sharps container (or use a needle remover) immediately after injection/injection related procedure”

3. EXPECTED TYPES OF RESULTS

The results expected at the end of the baseline assessment are listed below:

3.1. In the area of managing injection equipment and waste management products, data will be collected on:

- The length of time that injection commodities or equipment or safety boxes are out of stock
- The appropriate amount of injection equipment and safety boxes available in the inventory by type and by size

3.2. In the area of injection administration, data will be collected on:

- Packaging of the injection equipment (new and sterile package)
- The reconstitution of medications/ vaccines
- Cleaning or use of an antiseptic at the injection site prior to administration
- The practice of “re-capping” needles after injection
- The use of safety boxes to collect used injection equipment (syringes/needles) (see appendix 3, section 1, Q 1.07)
- The use of needle removers on used injection equipment
- Training on injection safety

3.3. In the area of infection prevention and control, data will be collected on:

- The hygienic conditions of injection preparation and administration (see appendix 3, Section 3, Q 3.1.)
- The hand hygiene practice of HCWs administering the injection

- The number of accidental needle sticks among health care providers and waste handlers reported in the last 6 months
- The knowledge of health care workers of infections transmitted through unsafe injections and accidental needle sticks
- The vaccination status of the health care providers and waste handlers (hepatitis B)

3.4. In the area of estimating needs relative to injection safety, data will be collected on:

- The existence of reference documents on injection safety (national policy, standards and guidelines)
- Forecasting adequacy-the regularity of the supply of products, injection equipment and waste management materials
- The adequacy of the amounts on-site of injectable products, injection equipment, waste management material

3.5. In the area of medical waste management, data will be collected on:

- Medical waste-final disposal methods
- Method of eliminating ashes following incineration (if there is an incinerator)
- Maintenance of the incinerator (if there is an incinerator)
- Problems encountered relative to final medical waste disposal
- Vaccination status of the health workers responsible for waste management (hepatitis B)
- Type of protective equipment available and used
- Training in medical waste management

4. MATERIALS AND METHODS

4. 1. Type and Duration of the Survey

All assessments are cross-sectional surveys. The assessments in Kazakhstan and Kyrgyzstan are being performed with HCF's that will be randomly selected, while the assessments in Tajikistan and Uzbekistan will be done in preselected HCFs (lists of HCFs are provided by MOHs). Data will be gathered via interviews with facility staff, facility-based observations, and review of stock and inventories of materials in the visited HCFs.

The total duration of the assessment starting with training for assessors and finishing with the production of the final report is described in Appendix 1.

4.2. Units of Analysis and Target Populations

The unit and target populations of the injection safety assessment include the following:

- **Survey Units**

The sample will be stratified by facility type to include the following (tailored as appropriate to the country work plan and expansion plan):

- Oblast-level and city-level hospitals, and polyclinics
 - Adult hospitals: intensive care, therapeutical, surgical, obstetrics, outpatient and laboratory
 - Pediatric hospitals: intensive care, therapeutical, surgical, outpatient and laboratory
- Rayon-level hospitals (no separate hospitals for adult and pediatric services)
 - Departments: intensive care, therapeutical, surgical, obstetrics, pediatric, outpatient and laboratory.
- Public health centers, health posts in the rayon level villages (primary health care services).
- Tertiary hospitals (specific for Uzbekistan, as provided by MoH).

- **Target Populations**

The target populations are selected staff and patients of the following types:

- Staff administering injections and phlebotomy
- Supervisors of the staff responsible for administering injections and phlebotomy
- Staff in charge of medical waste management
- Patients of observed departments/facilities

4.3. Sample Size Calculations

This is proposed study protocol for four countries of CAR and thus sample size calculations presented here are country-specific.

Nevertheless, types of procedures and types of HCFs will be same for all countries (table 1).

Table 1. Health care services included in assessment and types of procedures.

Service	Procedures
Outpatient Services: All diagnostic, curative and preventive	1. Injections – IM, IV 2. IV infusions 3. Phlebotomies
Hospitals: Therapeutical, surgical, obstetric-gynecological, pediatric, laboratory,	1. IM injections 2. IV Injections 3. IV infusions, including these

ICU, outpatient departments	through CVC and PVC 4. Phlebotomies
LL HCFs: Both curative and vaccination	1. IM/SC 2. IV injections

Kazakhstan and Kyrgyzstan

The objective of the study, as stated above in Section 2, is to assess injection practices in hospitals as well as lower-level facilities in the country. Statistical testing is planned for the comparisons of data acquired from the baseline assessment, listed in Section 4.4.

The sampling unit is the HCF. Two-stage, cluster-sampling self method through choice in which clusters are selected using probability proportional to population size and equal numbers of sampling units within each cluster. As clusters, rayons and cities were selected. There are a finite number of HCFs in the clusters covered by this survey. Ten HCFs per cluster were selected, including 2 oblast level HCFs to which rayon belongs. We are going to observe four types of injections and related procedures: phlebotomies, IV and IM injections, IV infusions, including these through CVC and PVC. We assume a design effect of 2.0, beta of 0.80 and alpha of 0.05 and calculated the sample sizes as described below using the Power and Sample Size (PASS) software package

For the four types of procedures, we assume (in the absence of data) that 15% of each procedure is unsafe. We assume that our intervention will decrease the proportion of unsafe procedures to 5% after intervention. We calculate a sample size of 320 observations for each procedure. We estimate that two injections (2 curative and 2 immunization) will be observed in each lower-level facility and eight procedures 2 IM, 2 IV, 2 phlebotomies, 2 IV infusions, including these through CVC and PVC, in each of up to seven (7) departments of each of the selected hospitals. These injection observations will be used to evaluate key indicators (table 2a and 2b).

In terms of CVCs, we assume (in the absence of data) that 30% of them are unsafe during baseline assessment. We assume that our intervention—if it is to have a “significant” impact on the proportion of unsafe practices--will decrease the proportion of unsafe CVCs to 5% after intervention. We calculate a sample size of observations for catheterizations of 78 per country. Although we are interested in CVCs, we believe it will difficult to observe enough number of procedures, uncertainty about number and timing of CVC insertion at the facilities, and the length of time (minimum, 25 minutes) required to observe a complete CVC procedure. We will prioritize CVC observation in our visits and learn what we can, although we are uncertain we can achieve the hoped-for number of 78 observations.

The allocated number of injection observations for each of the four procedures by rayon will, unlike for CVC, far exceed the calculated sample size. Given this, injection practices may be analyzed and then presented by higher-level facility (hospital) and lower-level facilities (medical post), provided there are enough cases in each for this level of analysis but such a comparison is not a primary intent of our study.

Uzbekistan and Tajikistan

As it was mentioned above, the MOHs of both countries chose not to use random sampling and, instead, provided CAAP and CDC with preselected list of HCFs. We believe that the assessment of practices using the lists provided by MOHs will provide valuable information.

The sampling unit is the HCF. These HCFs include oblast hospitals, rayon hospitals, city level hospitals/District hospitals (which are lower-level hospitals) and outpatient clinics or LL HCFs (Medical posts) as well. For Uzbekistan, MOH also selected tertiary hospitals.

For Uzbekistan, in which we used 75 HCFs given to us by the country, we have no good way of knowing how representative they are of all HCFs. But, every oblast is represented in the sample with at least one HCF and a range of types of HCFs is included, i.e., oblast level, rayon-level and lower level.

For Tajikistan, in which we used sample of 106 HCFs given to us, all oblast- and rayon-level hospitals were included, as were a variety of lower-level facilities. To attempt to obtain a representative “picture” of practices, a sample will be drawn from across the study area. It is estimated that four injections (2 curative and 2 immunization) will be observed in each lower-level facility and six (2 IM, 2 IV and 2 phlebotomies) in each one of up to seven (7) departments of each of the selected hospitals. These injection observations will be used to evaluate key indicators (table 2c and 2d).

4.4. Sampling Techniques in Health Districts and Health Facilities

Kazakhstan and Kyrgyzstan

The sampling of health facilities assessed will be obtained through a combination of purposeful and random selection. In each cluster to be assessed, the following approach will be used:

- Oblasts are listed haphazardly (using a listing provided by Ministry, which was not alphabetical and Ministry did not know the intent of use of the list) with all their rayons.
- The initial rayon is to be selected by random number from the listing of oblast/rayons. This rayon belongs to an oblast and defines the oblast that will be included in the study.

- *Purposeful selection* will be used for selecting oblast hospitals, rayon hospitals, and lower-level hospitals (so that oblast level, rayon level, and lower-level hospitals are included). There are 1-2 oblast hospitals, 1 (occasionally 2) rayon-level hospitals, and generally lower-level hospitals. All will be included, because it is in hospitals that injections or catheters are used. Selecting lower-level primary HCFs (see next bullet) runs the risk of identifying a HCF but in which there may be no procedures being done the day of the visit.
- *Random sampling* will then be used for selecting lower-level primary HCFs, using a computer-generated random number selection. Nine is generally considered to be a reasonable number of facilities in an assessment of this type and we shall select 10. Each unit of analysis should have this number of facilities at a minimum.
- The second rayon is then selected by PPS and the above process repeats. The sampling interval was the entire population of the country divided by 8. We applied the sampling interval to the cumulative population in the Excel sheet (as described in the first bullet) to select the next rayon. We then repeated the process just described. Our goal was to get 80 HCFs, and to always have the oblast-level, rayon-level, and lower-level hospitals and, then, primary care HCFs.
- Attached (Appendix 8 KZ sampling.doc and Appendix 9 KG sampling.xls) are files that contain the sampling schemes.

Observations or syringe use for injections and phlebotomy will be conducted in the hospital service areas where the majority of syringes and needles are used. In Central Asia health care facilities perform procedures such as phlebotomy, injection and catheter insertion in special areas. These include: ICU, medical department, pediatrics, gynecology-obstetrics, outpatient care, the phlebotomy area of the laboratory, and surgical ward¹, as well as stock room of each department. It is important to note that not all hospitals will have all seven departments. The survey will include all of the areas listed above that exist at each facility.²

The assessment will be carried out in the health districts and numbers of facilities in Kazakhstan and Kyrgyzstan is shown in Table 1a and b.

¹ Surgical department is listed as an area but it should be noted that this refers to pre-operative procedures and post-operative procedures. Data collectors will not attempt to observe actual surgeries.

² The specific types of service departments may vary by hospital. The goal is to include all areas with high numbers of injections or use of injection equipment as well as the stock room. While it is recognized that there may be other locations where injections can occasionally be observed, it is not necessary to visit those areas for this quantitative data collection. However, those areas can and should be visited during supervisory visits. Dental clinics are not a suggested location for data collection because there are usually too few of them for quantitative analysis. Trauma centers and psychiatric departments are not recommended sites of data collection because the data collectors risk interfering with patient treatment.

Uzbekistan and Tajikistan

Assessment will be done in preselected HCFs. Observations of needle/syringe use for injections and phlebotomy will be conducted in the seven departments where the majority of syringes and needles are used. These include: ICU, medical department, pediatrics, gynecology-obstetrics, outpatient care, the phlebotomy area of the laboratory, and surgical, as well as stock room of each department. It is important to note that not all hospitals will have all seven departments. The survey will include all of the areas listed above that exist at each facility.

Table 1a: Health Districts and Facilities in Kazakhstan to be Covered by This Survey

Districts	# Oblast hospitals*	# Rayon hospitals	# District hospitals	# LL HCFs	# City hospitals	# Outpatient clinics	Total # of HCFs
Ulansky rayon (East Kazakhstan Oblast)	1	1	2	6	0	0	10
Shetsky rayon (Karaganda)	2	2	0	6	0	0	10
Ekibastuz city (Pavlodar oblast)	2	0	1	3	1	3	10
Astrakhansky rayon (Akmola Oblast)	2	1	1	5	0	1	10
Makhtaralsky rayon (SKO)	1	4	0	0	0	5	10
Shymkent city (SKO)	1	0	0	2	5	2	10
Kurmangazy rayon (Atyrau oblast)	2	1	4	3	0	0	10
Almaty	0	0	0	0	5	5	10
Total	11	9	8	25	11	16	80

* For each oblast it can have 1 or 2 oblast hospitals; no oblast has more than 2 hospitals.

Table 1b: Health Districts and Facilities in Kyrgyzstan to be Covered by This Survey

Districts	# Oblast hospitals*	# Rayon hospitals	# District hospitals	# LL HCFs	# City hospitals	# Outpatient clinics	Total # of HCFs
Sokoluk (Chu oblast)	1	1	2	5	0	1	10
Batken (Kadamjay)	2	2	5	0	0	2	11
Talas (Karabura)	1	1	0	6	0	2	10
Aravan (Osh)	2	3	0	4	0	1	10
Nookat (Osh)	0	8	0	0	0	2	10
Jalalabat (Bazarkurgan)	1	1	0	7	0	1	10
Issyk-Kul	1	0	0	4	2	2	9
Bishkek	0	0	0	0	3	7	10
Total	8	16	7	26	5	18	80

* For each oblast it can have 1 or 2 oblast hospitals; no oblast has more than 2 hospitals.

The lists of HCFs for Kazakhstan, Kyrgyzstan, Uzbekistan and Tajikistan are presented in Appendix 2.

4.5. Study Populations / Areas

A description of data to be collected from each study population/area can be found below. Details for can be found in Table 3 at the end of this section.

4.5.1 Inventory / Stock Rooms

Each stock room of each department of each hospital (7 departments will be under observation or, if fewer than 7 departments exist, as many as do exist) and each procedure site within each department hand stock will be assessed. In LLHCFs, 1 stock room will be assessed. In total, 7 stock

rooms per hospital (or, if fewer, if there are fewer than 7 departments) and 1 stock room per LLF will be assessed.

4.5.2 Observation of departments and entire HCFs

The observations are conducted in and around the facility and compiled onto 1 questionnaire. Observations outside the facility are limited to the facility grounds. A total of 1 set of observations covering the entire hospital and 1 set of observations per lower-level facility will be completed. These observations will be analyzed by department with a total of 7 sets of observations per hospital and 1 per lower-level facility in each country.

Thus, 7 departments or fewer will be observed per hospital. One department of each type (general, ICU, surgical, obstetric, pediatric, laboratory and outpatient) will be assessed. If, however, a hospital has 3 departments of one type, only one department will be chosen randomly for assessment. If there are more than two departments of one type, the number of these departments will be placed into “a hat” and randomly draw one from the hat; if there are two, assessors will flip a coin.

4.5.3 Injections Observed

The observations are conducted *where the injections are given* (patient bedside, injection room, etc). Usually, these services are concentrated in one or two rooms in lower level facilities. Data will be collected in both inpatient and outpatient settings. In hospitals, observations will be conducted in the departments listed in Section 4.4. If more than one HCW is providing procedures during observations, all HCWs will be observed. Although four injection observations are planned for each lower-level facility and eight injection observations per each department of each hospital, there will be fewer observations if not all hospitals have all 7 departments or if some lower-level facilities or hospital departments have fewer than 4 injections taking place during the time of the data collection visit.

Kazakhstan

A sampling of injections observed will be devised in the following manner:

- **Hospitals: 8 injections and related procedures per service area (department)**, that is, 8 in medicine, 8 in pediatrics, 8 in gynecology-obstetrics, 8 in surgical , 8 in the laboratory, 8 in ICU and 8 in the outpatient department (8 injections per service area x 7 departments x 39 hospitals). Total: 2,184 injections will be observed.

- **City outpatient clinics: 8 injections per service area (department)**, that is, 8 in laboratory and 8 injections where patients receive treatment (8 injections per service area x 2 service areas x 16 HCFs). Total 256 injections will be observed.
- **Lower-level health facilities: 4 injections per facility** of which 2 should be a vaccination, 2 curative³. Note that the goal is to observe 4 injections. Data collectors should observe **no more than 2** immunizations and 2 curative injections. (4 injections per facility x 25 HCFs). Total: 100 injections will be observed (see Table 2).

Table 2a: Total number of procedures to be observed in HCFs, Kazakhstan.

HCFs	# of HCFs	# of departments	# of procedures per department	Total # of procedures
Hospitals	39	7	8	2184
City outpatient clinics	16	2	8	256
Lower level HCFs	25	1	4	100
Total	80			2540

Kyrgyzstan

A sampling of injections observed will be devised in the following manner:

- **Hospitals: 8 injections per service area (department)**, that is, 8 in medicine, 8 in pediatrics, 8 in gynecology-obstetrics, 8 in surgical , 8 in the laboratory, 8 in ICU and 8 in the outpatient department (8 injections per service area x 7 service areas x 36 hospitals). Total 2016 injections will be observed.
- **City outpatient clinics: 8 injections per service area (department)**, that is, 8 in laboratory and 8 in s where patients receive treatment (8 injections per service area x 2 service areas x 18 HCFs). Total 288 injections will be observed.
- **Lower-level health facilities: 4 injections per facility** of which 2 should be a vaccination, 2 curative. Note that the goal is to

³ The purpose of this is to have a sample of each type of HCF and practices for analysis. This way will allow us to have national wide data.

observe 4 injections. Data collectors should observe **no more than** 2 immunizations and 2 curative injections. (4 injections per facility x 26 HCFs). Total 104 injections will be observed (see Table 2b).

Table 2b: Total number of procedures to be observed in HCFs, Kyrgyzstan.

HCFs	# of HCFs	# of departments	# of procedures per department	Total # of procedures
Hospitals	36	7	8	2016
City outpatient clinics	18	2	8	288
Lower level HCFs	26	1	4	104
Total	80			2408

Uzbekistan

A sampling of injections observed will be devised in the following manner:

- **Hospitals: 8 injections per service area (department)**, that is, 8 in medicine, 8 in pediatrics, 8 in gynecology-obstetrics, 8 in surgical , 8 in the laboratory, 8 in ICU and 8 in the outpatient department (8 injections per service area x 7 service areas x 65 hospitals). Total 3640 injections will be observed.
- **City outpatient clinics: 8 injections per service area (department)**, that is, 6 in laboratory and 6 in s where patients receive treatment (8 injections per service area x 2 service areas x 4HCFs). Total 64 injections will be observed.
- **Lower-level health facilities: 4 injections per facility** of which 2 should be a vaccination, 2 curative. Note that the goal is to observe 4 injections. Data collectors should observe **no more than** 2 immunizations and 2 curative injections. (4 injections per facility x 6 HCFs). Total 24 injections will be observed (see Table 2c).

Table 2c: Total number of procedures to be observed in HCFs, Uzbekistan.

HCFs	# of HCFs	# of departments	# of procedures per department	Total # of procedures
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Hospitals	65	7	8	3640
City outpatient clinics	4	2	8	64
Lower level HCFs	6	1	4	24
Total	75			3728

Tajikistan

A sampling of injections observed will be devised in the following manner:

- **Hospitals: 8 injections per service area (department)**, that is, 8 in medicine, 8 in pediatrics, 8 in gynecology-obstetrics, 8 in surgical, 8 in the laboratory, 8 in ICU and 8 in the outpatient department (8 injections per service area x 7 service areas x 28 hospitals). Total 1624 injections will be observed.
- **City outpatient clinics: 8 injections per service area (department)**, that is, 8 in laboratory and 8 in s where patients receive treatment (8 injections per service area x 8 service areas x 25HCFs). Total 400 injections will be observed.
- **Lower-level health facilities: 4 injections per facility** of which 2 should be a vaccination, 2 curative. Note that the goal is to observe 4 injections. Data collectors should observe ***no more than*** 2 immunizations and 2 curative injections. (4 injections per facility x 53 HCFs). Total 212 injections will be observed (see Table 2d).

Table 2d: Total number of procedures to be observed in HCFs, Tajikistan.

HCFs	# of HCFs	# of departments	# of procedures per department	Total # of procedures
Hospitals	29	7	8	1624
City outpatient clinics	25	2	8	400
Lower level HCFs	53	1	4	212
Total	106			2236

4.5.4 Injection Administrators

A single person (“injection administrator”) performing injections within each department will be chosen for the injection provider interview. This is a quota/convenience sample of one. The injection administrator to be interviewed will be the health worker who administers the largest number

of injections being observed on the day of data collection in each facility (or, in the case of the laboratories, the one who uses the largest numbers of devices to draw blood). Usually, this will be the treatment room nurse in each department or the laboratory technician responsible for blood drawing.

Kazakhstan:

Injection providers will be sampled according to the following breakdown:

- **Hospitals: 1 participant per service area:** 1 in the medical department, 1 in pediatrics, 1 in gynecology-obstetrics, 1 in surgical , 1 in ICU , 1 in the laboratory, and 1 in the outpatient department. (7 participants x 39hospitals). Total 273 participants.
- **City outpatient clinics: 1 participant per service area:** 1 in the laboratory and 1 in for treatment. (2 participants x 16 HCFs). Total 32 participants.
- **Lower-level facilities⁴: 1 participant per facility** (1 participant x 25 facilities). Total 25 participants.

Kyrgyzstan:

Injection providers will be sampled according to the following breakdown:

- **Hospitals: 1 participant per service area:** 1 in the medical department, 1 in pediatrics, 1 in gynecology-obstetrics, 1 in surgical , 1 in ICU , 1 in the laboratory, and 1 in the outpatient department. (7 participants x 36 hospitals). Total 252 participants.
- **City outpatient clinics: 1 participant per service area:** 1 in the laboratory and 1 in department for treatment. (2 participants x 18 HCFs). Total 36 participants.
- **Lower-level facilities: 1 participant per facility** (1 participant x 26 facilities). Total 26 participants.

⁴ If the configuration of a lower-level facility is such that there are essentially two separate departments, each with its own staff, then it may be possible to take 1 participant from each department. For example, if there are urban health centers, each of which has an outpatient area and a maternity area with its own staff, it would be possible to select 1 participant in the outpatient area and 1 in the maternity department. This approach would double the number of participants in the facility, as currently only one participant per facility is planned.

Uzbekistan

Injection providers will be sampled according to the following breakdown:

- **Hospitals: 1 participant per service area:** 1 in the medical department, 1 in pediatrics, 1 in gynecology-obstetrics, 1 in surgical department, 1 in ICU , 1 in the laboratory, and 1 in the outpatient department. (7 participants x 65 hospitals). Total 455 participants.
- **City outpatient clinics: 1 participant per service area:** 1 in the laboratory and 1 in department for treatment. (2 participants x 4 HCFs). Total 8 participants.
- **Lower-level facilities: 1 participant per facility** (1 participant x 6 facilities). Total 6 participants.

Tajikistan

Injection providers will be sampled according to the following breakdown:

- **Hospitals: 1 participant per service area:** 1 in the medical department, 1 in pediatrics, 1 in gynecology-obstetrics, 1 in surgical department, 1 in ICU , 1 in the laboratory, and 1 in the outpatient department. (7 participants x 28 hospitals). Total 196 participants.
- **City outpatient clinics: 1 participant per service area:** 1 in the laboratory and 1 in department for treatment. (2 participants x 25 HCFs). Total 50 participants.
- **Lower-level facilities: 1 participant per facility** (1 participant x 53 facilities). Total 53 participants.

4.5.5 Supervisors of injection providers

Kazakhstan

Supervisors of the staff responsible for administering injections or blood draws will be selected according to the following breakdown:

- **Hospitals: 1 participant per service area:** 1 supervisor in the medical department, 1 in pediatrics, 1 gynecology-obstetrics, 1 in surgical department, 1 in ICU, 1 in the laboratory, and 1 in the outpatient department (7 participants x 39 hospitals). Total 273 participants.
- **City outpatient clinics: 1 participant per service area:** 1 supervisor in the laboratory and 1 in department where treatment is provided. (2 participants x 16 HCFs). Total 32 participants
- **Lower-level facilities: 1 participant per facility** (1 participant x 25 facilities). Total 25 participants.

Kyrgyzstan

Supervisors of the staff responsible for administering injections or blood draws will be selected according to the following breakdown:

- **Hospitals: 1 participant per service area:** 1 supervisor in the medical department, 1 in pediatrics, 1 gynecology-obstetrics, 1 in surgical , 1 in ICU, 1 in the laboratory, and 1 in the outpatient department (7 participants x 36 hospitals). Total 252participants.
- **City outpatient clinics: 1 participant per service area:** 1 supervisor in the laboratory and 1 in department where treatment is provided. (2 participants x 18 HCFs). Total 36 participants
- **Lower-level facilities: 1 participant per facility** (1 participant x 26 facilities). Total 26 participants.

Uzbekistan

Supervisors of the staff responsible for administering injections or blood draws will be selected according to the following breakdown:

- **Hospitals: 1 participant per service area:** 1 supervisor in the medical department, 1 in pediatrics, 1 gynecology-obstetrics, 1 in surgical department, 1 in ICU, 1 in the laboratory, and 1 in the outpatient department (7 participants x 65 hospitals). Total 455 participants.
- **City outpatient clinics: 1 participant per service area:** 1 supervisor in the laboratory and 1 in department, where treatment is provided. (2 participants x 4 HCFs). Total 8 participants
- **Lower-level facilities: 1 participant per facility** (1 participant x 6 facilities). Total 6 participants.

Tajikistan

Supervisors of the staff responsible for administering injections or blood draws will be selected according to the following breakdown:

- **Hospitals: 1 participant per service area:** 1 supervisor in the medical department, 1 in pediatrics, 1 gynecology-obstetrics, 1 in surgical department, 1 in ICU, 1 in the laboratory, and 1 in the outpatient department (7 participants x 28 hospitals). Total 196 participants.
- **City outpatient clinics: 1 participant per service area:** 1 supervisor in the laboratory and 1 in department, where treatment is provided. (2 participants x 25 HCFs). Total 50 participants
- **Lower-level facilities: 1 participant per facility** (1 participant x 53 facilities). Total 53 participants.

4.5.6 Staff in charge of waste management

Kazakhstan and Kyrgyzstan

Among staff responsible for waste management, only the main person responsible for waste management will be interviewed. So, **1 participant per hospital and 1 participant per lower-level facility** will be selected for interview. Total: 80 participants per country will be selected for interview.

Uzbekistan and Tajikistan

Among staff responsible for waste management, only main person responsible for waste management will be interviewed. So, **1 participant per hospital and 1 participant per lower-level facility** will be selected for interview. Total: 75 participants in Uzbekistan and 106 participants in Tajikistan will be interviewed.

4.5.7 Patients, hospitalized in the observed departments

Kazakhstan

Patients receiving medical care in these healthcare facilities will be selected for interview according following breakdown.

- **Hospitals: 4 participants per service area:** 4 patients in the medical department, 4 patients in pediatrics, 4 patients in gynecology-obstetrics, 4 patients in surgical, 4 patients in outpatient department, 4

patients in laboratory, excluding ICU (4 participants x 6 departments x 36 hospitals). Total 864 participants.

- **City outpatient clinics: 4 participants per service area:** 4 patients in the laboratory and 4 in department, where treatment is provided. (8 participants x 16 HCFs). Total 128 participants
- **Lower-level facilities: 2 participants per facility** (2 participant x 25 facilities). Total 50 participants.

Kyrgyzstan

Patients receiving medical care in these healthcare facilities will be selected for interview according following breakdown.

- **Hospitals: 4 participants per service area:** 4 patients in the medical department, 4 parents in pediatrics, 4 patients in gynecology-obstetrics, 4 patients in surgical department, 4 patients in outpatient department and 4 patients in laboratory, excluding ICU (4 participants x 6 departments x 36 hospitals). Total 864 participants.
- **City outpatient clinics: 4 participants per service area:** 4 patients in the laboratory and 4 in department, where treatment is provided. (8 participants x 18 HCFs). Total 144 participants
- **Lower-level facilities: 2 participants per facility** (2 participant x 25 facilities). Total 52 participants.

Uzbekistan

Patients receiving medical care in these healthcare facilities will be selected for interview according following breakdown.

- **Hospitals: 4 participants per service area:** 4 patients in the medical department, 4 parents in pediatrics, 4 gynecology-obstetrics, 4 in surgical department, 4 patients in outpatient department and 4 patients in laboratory, excluding ICU (4 participants x 6departments x 65 hospitals). Total 1560 participants.
- **City outpatient clinics: 4 participants per service area:** 4 patients in the laboratory and 4 in department, where treatment is provided. (8 participants x 4 HCFs). Total 32 participants
- **Lower-level facilities: 2 participants per facility** (2 participant x 6 facilities). Total 12 participants.

Tajikistan

Patients receiving medical care in these healthcare facilities will be selected for interview according following breakdown.

- **Hospitals: 4 participants per service area:** 4 patients in the medical department, 4 patients in pediatrics, 4 patients in gynecology-obstetrics, 4 patients in surgical department, 4 patients in outpatient department and 4 patients in laboratory, excluding ICU (4 participants x 6 departments x 28 hospitals). Total 672 participants.
- **City outpatient clinics: 4 participants per service area:** 4 patients in the laboratory and 4 in department, where treatment is provided. (8 participants x 25 HCFs). Total 200 participants
- **Lower-level facilities: 2 participants per facility** (2 participant x 53 facilities). Total 106 participants.

Table 3a: Target Population Sample for Kazakhstan

# Target Population		Sample size			
		Hospitals	City outpatient	LL HCFs	Total
1	Stock room inventory	273	32	25	329
2	HCF observations	39	16	25	80
3	Observations of injections or phlebotomy	2184	256	100	2540
4	Injection administrator interviews	273	32	25	330
5	Interviews with supervisors of injection administrators	273	32	25	330
6	Waste management interviews	39	16	25	80
7	Patients	864	128	50	1042

Table 3b: Target Population Sample for Kyrgyzstan

# Target Population		Sample size			
		Hospitals	City outpatient	LL HCFs	Total
1	Stock room inventory	252	36	26	314
2	HCF observations	36	18	26	80
3	Observations of injections or phlebotomy	2016	288	104	2408
4	Injection administrator interviews	252	36	26	314
5	Interviews with supervisors of injection administrators	252	36	26	80
6	Waste management interviews	36	18	26	80
7	Patients	864	144	52	1060

Table 3c: Target Population Sample for Uzbekistan

# Target Population		Sample size			
		Hospitals	City outpatient	LL HCFs	Total
1	Stock room inventory	455	8	6	469
2	HCF observations	65	4	6	75
3	Observations of injections or phlebotomy	3640	64	24	3728
4	Injection administrator interviews	455	8	6	469
5	Interviews with supervisors of injection administrators	455	8	6	75
6	Waste management interviews	65	4	6	75
7	Patients	1560	32	12	1604

Table 3d: Target Population Sample for Tajikistan

# Target Population		Sample size			
		Hospitals	City outpatient	LL HCFs	Total
1	Stock room inventory	196	50	53	299
2	HCF observations	28	25	53	106
3	Observations of injections or phlebotomy	1624	400	212	2236
4	Injection administrator interviews	196	50	53	299
5	Interviews with supervisors of injection administrators	196	50	53	299
6	Waste management interviews	28	25	53	106
7	Patients	672	200	106	978

4.6. Data Collection

Teams will visit an average of 1 hospital or 2 lower-level facilities per day. The estimated number of days for data collection in the field for each country is as follows:

This activity will be carried out using the assessment tools adapted to the context of the health system. The assessment tools are questionnaires with 6 components or “Sections” that relate to specific intervention areas of injection safety. (See Appendices 3 under separate cover.) These sections are:

- Inventory/stock rooms: Section 1
- Observations of health facilities and waste management: Section 2
- Observations of injection practices: Section 3
- Interviews of injection providers: Section 4
- Interviews with supervisors of injection providers: Section 5
- Interviews with waste management staff: Section 6

- Interviews of patients: Section 7

Data will be collected by 12 people. There will be 4 teams consisting of, on average, 3 people consisting of 2 data collectors and 1 team leader. Generally, there will be one data collection team per 2 districts.

4.6.1 Respondent selection

Respondents will be selected according to the specific criteria detailed below:

- In each department, if more than one HCW provides procedures the provider who gives the most injections will be selected for interview (“injection administrator”). The data collector will ask the individual health care workers for their permission to be observed prior to the interview.
- If the injection provider who was interviewed has a supervisor in the department at the time of the survey, this person is to be selected for the supervisor interview. Head nurse of observed department would be preferable as supervisor for interview. In case the head nurse is not available, the head doctor could be interviewed as a supervisor. If the provider does not have a supervisor, another injection provider will be interviewed; or if none is available at the time of the survey, the questions are asked of the injection provider.
- Only one waste handler is to be interviewed in each facility .The surveyor should select the waste handler who is the primary person in charge of managing health care waste.
- Patients in departments in hospital will be selected randomly from the list of patients hospitalized into observing department, excluding ICU patients. In city outpatient clinics and LL HCF any patient in turn will be selected for interview. In case if only children are receiving vaccinations at time of observation, their relatives who are accompanying them will be selected for interview.

4.6.2 Confidentiality protections

To ensure confidentiality protection prior to conducting interviews, an informed consent will be read to the respondent and signed by the interviewer with no health care worker or patient identifying information. There is potential risk to the participant from signing a consent form. Potentially risky practices will be observed and the consent form will be the only objective link of participants to having participated in the assessment. Thus, we believe a waiver of signed consent is justified. If the person refuses to participate, the data collector will accept the refusal and record that a potential participant has declined. Also participants will have a clear choice to leave the interview at any time. Data collectors will ensure that HCW’s or patient’s interviews are conducted in a private setting where they will not be overheard by facility health care staff or anyone else. Data collection will involve adults only and data collected will not be

identifiable. To minimize risk to the participant, data collected will not include any identifying information and will only be handled by the study team. Data will be presented publicly in aggregate form (by district, by type of facility, and by department in hospitals.) Results presented in the report are not linked to individual facilities where data are collected, so they are not traceable to individual respondents. (See Appendix 4 for Sample Informed Consent Forms).

4.6.3 Other ethical concerns/issues

We will take ensure risks to participants are minimized and information is kept confidential such as holding interviews in a private setting where they will not be overheard by other facility health care staff, supervisors, or anyone else. Specific risks and protections are detailed below:

Health care workers that are observed giving injections or conducting phlebotomy will also be interviewed to find out if they have ever had a needle stick injury, what diseases they are aware of that can be transmitted by needle stick injuries, and their HBV vaccination status. This activity is similar to supervisory visits and the risk to the employment position of the respondent is minimal. Data collectors will not collect the names or other information to identify the health care worker being interviewed or observed and will ask individual HCWs for their permission to observe procedures. If HCWs experience a needle stick injury during the observation or disclose during the interview that one was suffered within the preceding seven days (arbitrarily determined by the likelihood of successful interventions, e.g., HBV vaccination, ART prophylaxis, patient being accessible) the study team will be able to provide participants information and correct referrals for post-exposure prophylaxis (PEP) within the facility where the health worker is currently employed. This is to ensure that if a HCW reports a needle stick or other occupational exposure to BBP, they can be quickly referred to the appropriate person or service. This arrangement will be made before research activities take place in collaboration with the health facility infection prevention and control specialist. .

- Surveyors will be trained to tactfully interrupt any health care workers who may be about to re-use syringes and needles prior to them endangering patients; training will be provided on when to intervene. In case of such intervention no more injections will be observed for this healthcare worker. In this case, observation of another HCW will begin to complete observation of the required number of procedures.
- Patients receiving injections may need to remove clothing to expose injection sites. The possible risks of embarrassment or worry are not expected to outweigh the potential benefits of the study. Before beginning the observation, data collectors will inform the patient that a survey is being conducted during which the health care worker will be observed giving an injection and ask for their permission.

- Supervisors are interviewed about documentation and logistical issues related to injection equipment. These questions are not sensitive or potentially stigmatizing, and the risk to their position is minimal. Data collectors will not collect the names or other information to identify the supervisor being interviewed.
- Waste handlers are asked about waste handling practices, training, protective equipment, etc. This activity is similar to supervisory visits and the risk to their positions is minimal. Data collectors will not collect the names or other information to identify the waste handler being interviewed.
- Feedback will be given to facility administrators about hazards needing improvement and strengths without providing information that would allow individuals to be identified. Hospital administrators will be informed prior to data collection activities that feedback will not include any information that could identify an individual (including department name).

Table 4: Tentative Schedule for Data Collection

Day	Date	Activities	Comments
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			
Day 8			
Day 9			
Day 10			
Day 11			
Day 12			
Day 13			
Day 14			
Day 15			

4.7. Organization and Coordination of the Data Entry and Analysis

All collected data will belong to the MoH and MoH will share these data with the CDC. Supervisors of the survey teams will check forms prior to leaving a facility to make sure entries are legible and forms are complete. Nobody except assessors, CAAP and CDC /CAR staff will have access to collected data.

Data will be captured on the assessment tools and entered into a data entry program in Epi Info. The data collected will be codified prior to data entry, especially in regards to open-ended questions. The data will be analyzed by comparing facility-level indicators over time and when possible between districts using Epi Info.

The survey questionnaires will be returned to the CDC office for data entry. The data entry staff will be hired by the CDC/CAR. Access to the dataset will be limited to the data entry staff and CDC epidemiologist who will oversee all aspects of data coding, entry, cleaning and reporting. The data entry staff will consist of 2 people, independently creating two databases which will be merged to identify discrepancies. The data entry program will also have control checks to ensure proper skips and logical values. Database will be protected by password. This password will be available for data entry staff as well as CDC staff responsible for data analysis. As disaster recovery measure data entered in the computer will be backed up daily.

Hard copies of the observations and interviews will be stored in a locked cabinet. The original data collection forms will be retained for three years following completion of data entry, and then shredded. Electronic database will be kept

during three year period till analysis and report is prepared and presented to the MoH.

Once that process is finished, the CDC specialist will send the data files and draft report to CDC/Atlanta staff for review.

4.8. Analysis Plan

The analysis will be used to provide the types of expected results as described in Section 3 of this protocol. The general analysis plan will be provided to the person responsible for data analysis (See Appendix 5 under separate cover.) This plan may be expanded as needed to accommodate additional questions which are added to the questionnaires or areas of interest to partners in country. The data will be analyzed to the extent possible:

- By type of facility (hospital vs. lower level)
- By hospital service department (medicine, pediatrics, ob-gyn, etc.)
- By type of injection (vaccination, curative, diagnostic)
- Per type of injection (IM, IV injection, IV infusion, phlebotomy)

For the evaluation component of the study in which we compare the likelihood of observing unsafe injections pre- and post- intervention, we will use a frailty model (a proportional hazards model with random effects terms). In this model individuals are considered to have been observed over time, with time being the injection number and a “death” is delivering the first unsafe injection⁵. In this model sites are handled as the random effects term and the indicator for pre- or post- intervention is consider a fixed effect. These models will be fit looking at each type of injection separately.

4.9. Preparation of the Assessment Report

The report will be written based on the results of the database analysis. It will be prepared by the CDC/CAR specialists, and will undergo technical review to ensure the overall quality of the report. The report will follow the general outline provided to the analyst and will cover the different topics mentioned in the analysis plan. [See Appendix 5 for sample table of contents and Appendix 6 (under separate cover) for analysis plan.]

4.10. Dissemination of the Results of the Assessment

The results and the assessment will be presented as a report combined with information from other countries at a regional workshop for all countries of CAR. This workshop will include national decision makers, the survey team, directors of large facilities where assessments were conducted and other national or

⁵ Injections are considered as deaths in this model in that once an unsafe injection is observed, the observer may intervene and the health care worker referred for training. In this situation no further injections will be observed.

international agencies with an interest in the results. Results to be presented will be shown as aggregated results by CAR region, district or by type of facility (such as grouping all hospitals together, for example). Data from individual countries will be presented only if there is preceding approval from the Ministry of Health of each country to do so and countries will not be announced; each country will be given a number -1, 2, 3 and 4. If one country objects, then all data will be aggregated.

The final country-specific survey report will be shared with MOH. MOH will decide the sharing mechanism with other counterparts. Results may also be presented at conferences as lessons learned in the following areas (1) need for changing the behavior of health care workers to ensure safe injection practices through capacity building, behavior change and communications, and policy interventions; (2) ensuring the availability of safe injection equipment and supplies through procurement and logistics interventions; and (3) managing health care waste safely and appropriately; (4) reduction/elimination of unnecessary injections

4.11. Human Resources

The protocol was written by CDC/CAR and CDC/Atlanta staff, CV's can be found in Appendix 7.

Local consultants will be hired as a General Coordinator of the study, supervisors for teams, data collectors for teams, and data entry clerks. The General Coordinator, supervisors, and data collectors are usually doctors or nurses. Consultant CVs will be made available and will be provided to the CAAP and CDC/CAR offices and, through a collegial process guided by consensus, individuals will be selected.

Data collectors will be trained in a classroom setting with an introduction to Injection safety and waste management concepts. This training will include a detailed review of the entire questionnaire including all instructions and skips. Practice sessions will be held at a local hospital and lower level facility which are not included in the sample. This visit provides an opportunity to standardize the approach to data collection, to provide feedback on the performance of data collectors, and to field test the questionnaires in the local context. In the first few days of the actual data collection, data collectors will receive close support from technical advisors and hired supervisors to ensure good quality data and to help address any issues that arise. Data collectors are to be supervised throughout data collection by supervisors; they should be provided with contact information to have immediate access to a supervisor as needed during data collection.

Table 4: Tentative Composition of the Data Collection Teams per country

AREA	Team Composition	# People	# Teams	Total
Coordination	General Coordinator (consultant)	1	—	1
Supervision	Supervisors	4	4	4
Data Collection - Inventory Management - Observations of Waste Management - Observations of Injection Administration - Interviews of providers, supervisors, waste handlers and patients	Data collectors	12	4-6	12
Support Activities	Field Guide (local)	1	TBD	1
Data Entry	Data entry consultants	2	—	2
Analysis of the Data	Epidemiologist CDC/CAR	1	—	1
TOTAL				15

4.12. Material Resources

- **Vehicles**

It will be necessary to mobilize a vehicle to transport each team of data collectors and its supervisor to the districts and within each district. CAAP is responsible for teams' transportation.

- **Data Collection Tools** - See under separate cover (Appendix 3).

- **Office Supplies**

The data collectors will be given the following materials:

- Pencil, pen, eraser
- Folders for carrying completed forms and blank forms
- Memo pad for notes on problems to discuss with their supervisors
- Copies of the questionnaires
- Copies of consent forms

- **Fuel**
The fuel allocation necessary for travel of the assessment and coordination teams from the capital to the districts and within the districts will be reimbursed by CAAP.
- **Telecommunications Equipment**
Always mobile telephone cards for communication between teams of data collectors and supervisors and between the coordination team and the supervisors. Telephone cards will be reimbursed by CAAP.

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