World Health Organization
COUNTRY OFFICE FOR India

INDIA INJECTION SAFETY IMPLEMENTATION PROJECT

2016-2018

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This implementation project document has been prepared by the World Health Organization. The draft document had been shared with the members of Government of India's Technical Expert Group on Injection Safety. The draft document was presented and discussed during the first meeting of Technical Expert Group on injection safety, held on 13 July 2016, at Nirman Bhawan, Ministry of Health and Family Welfare, New Delhi. A few sections of the document have been updated based upon the discussions during the meeting. This document provides a broad blueprint for the 'implementation project' and the specifics of the project would be developed in consultation with MoHFW and the state Government of Punjab, where TEG has proposed to initially implement the project.

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World Health Organization Country Office for India

EXECUTIVE SUMMARY

An estimated 16 billion injections are given worldwide each year and up to 40% of those injections are not safe. An unsafe injection can transmit serious diseases to patients instead of delivering the treatments that they need. The global burden of disease from unsafe injection is serious, noting that unsafe injections account for 5% of HIV, 32% of Hepatitis B and 40% of Hepatitis C infections annually, while the burden of transmission of other blood borne diseases yet to be measured.

A national study from India published in 2012 found that frequency of injections was 2.9 (95% CI: 2.8-3.2) per person per year. It also found that 62.9% (95% CI: 60.7-65.0) injections were unsafe. Injections administered for curative purpose constituted 82.5% and a large majority of these were prescribed for common symptoms like fever/cough/diarrhoea. Significant differences were observed in the injection prescription pattern in public and private facilities, and in rural and urban areas. The study also estimated that about three billion injections are administered annually in India and out of those 1.89 billion were unsafe[a]. Unsafe injections have also been responsible for outbreak of viral hepatitis. In 2009 in Gujarat an outbreak of hepatitis B was investigated and 40% of all positive cases (n=856) gave history of receiving therapeutic injections in the past 1.5 to 6 months[b].

This document outlines a plan to develop and roll out an injection safety implementation project in India based on the recognition that introduction of reuse prevention injection devices and reducing over use and reuse of injections in the curative sector is a priority. This project is proposed to be implemented at union level and one state of India. The project duration would be July 2016 till Dec 2018.

The WHO has launched a global campaign on injection safety to reduce the overall burden of diseases caused by unsafe injection practices. WHO will be supporting the Ministry of Health and Family Welfare, Government of India to develop and implement a national initiative to improve injection safety. This will be done together with other partners, including other ministries, universities, the private sector and development agencies. In addition to the reinforcement of infection prevention measures, the approach will include transition to exclusive use of safety syringes, fostering new training approaches for health care workers to achieve changes in practice as well as measures to educate and engage the community in the promotion of safe injection practices. These areas of prevention are critical to reduce the transmission of viral hepatitis and other serious blood borne diseases.

[a]IPEN Study Group. Injection practices in India. WHO South-East Asia Journal of Public Health 2012;1: 189-200.
[b]Patel et al. An investigation of an outbreak of viral hepatitis B in Modasa town, Gujarat, India. J Glob Infect Dis. 2012 Jan; 4:55-9.

WHO Global Injection Safety Campaign

Unsafe injection practices such as reuse of syringes and needles can lead to the transmission of blood-borne pathogens including human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV). The magnitude of the problem of unsafe injections, including reuse and other unsafe practices has been estimated by WHO in 2000, as follows:

- Approximately 16.7 billion injections are administered worldwide, with estimates indicating that up to 40% were given with reused equipment and citing reuse rates as high as 75% in some countries.[1]
- In some regions of the world, over 70% of injections are considered unnecessary.[2]
- Unsafe injection practices cause 260,000 HIV infections per year (5% of global burden), 21 million HBV infections per year (32% of global burden) and 2 million HCV infections per year (40% of global burden).[3] The burden of other infections and problems, such as abscess, muscle necrosis and transmission of other blood borne pathogens were not measured.

The same study published by WHO in 2003 estimated that unsafe injections cause 1.3 million early deaths annually, a loss of 26 million years of life, and direct medical costs of 535 million US dollars. [3]

Safety engineered injection devices known as "Auto Disable" (AD) and “Reuse Prevention” (RUP) syringes are specifically designed to block syringes from being reused. They have been identified as a key component of an overall strategy to improve injection safety and avoid reuse of injection equipment. These syringes also exist with Sharp Injury Protection mechanisms (RUP/SIP syringes) to prevent needle-stick injury to health-care workers (HCW) and the community. According to preliminary findings of a WHO cost-effectiveness analysis, for each one international dollar invested in the implementation of injection safety programs, including a transition to exclusive use of RUP or RUP-SIP syringes, an estimated 14.57 international dollars could be saved in treatment and other costs.

Considering that about 90% of all injections are given for therapeutic purposes, ensuring safety of all therapeutic injections needs to be urgently addressed. Together with stakeholders, WHO and the Safe Injection Global Network (SIGN) have facilitated the transfer of technology in immunization syringes (AD syringes) in several countries and as a strategy to reduce unsafe injection practices in the immunization sector. Safety syringes for therapeutic purpose called RUPs are increasingly available for manufacturers to transition to production of similar devices.

The WHO Director General, with the support of the Assistant Director General, Health Systems and Innovation and the Director of the WHO Service Delivery and Safety department, launched the initiative promoting injection safety, especially for therapeutic injections. The launch of the World Health Organization (WHO) injection safety policy and global campaign was held at WHO headquarters in Geneva, on 23-24 February 2015. Based on evidence and the problem of injection safety, three countries have been selected to implement a pilot intervention - Egypt, India and Uganda.

The Situation of Unsafe Injections in India

Unsafe injection practices have been an issue in India since the 1980s. Like many parts of the world injections were widely used in different disease eradication campaigns and possibly became popular among masses in low and middle income countries.[4,5] The problem started gaining attention when problems associated with unsafe injection practices were repeatedly published in scientific literature and the public health community started becoming concerned about transmission of bloodborne infections associated with unsafe injections in late 90s and early 2000.[6-8]

Multiple studies from India have reported on the issue of injection use from different parts of the country. These studies have researched injection practices in the therapeutic and immunization sectors. They have explored areas such as determinants of injections, perception of the community and safety issues. Contamination of injection paraphernalia and prevalence of hepatitis B infection linked with injection practices were also addressed. In 2004 a study in urban slum areas of New Delhi found that only 22.5% of injections were administered with a sterile syringe and needle. The level of knowledge about HIV and HBV transmission by unsafe injections was satisfactory amongst prescribers and community, but inadequate amongst providers. HCV was known to a very few in all the groups. The annual incidence of needle stick injuries among providers was also quite high (8-96 per provider per year).[9]

In another study in Tamil Nadu, injection practices of 40 randomly selected registered medical practitioners were examined. These providers did not have an MBBS or MD degree. Widespread contamination of injection paraphernalia as well as common reuse of disposable syringe was observed.[10] A study conducted among primitive tribes of Andaman and Nicobar Islands, Union Territory of India found high prevalence (26.3%) of hepatitis B virus infection. Unsafe injections were identified as an independent risk factor for acquiring HBV infection in this population.[11] A different study in Tamil Nadu used Rapid Assessment Guide of WHO to assess injection practices. Thirty nine prescribers, 62 providers and 175 members of the community were interviewed using convenient sampling technique. Key findings of the study included excessive and unwarranted usage of injections.[12] A national study mentioned earlier in the executive summary had found that of the three billion injections administered in India 1.89 (62.9%) are unsafe.[13] In Gujrat, unsafe injections have been identified as the main risk factor responsible for outbreak of hepatitis B in the community.[14] According to the IPEN study, the proportion of unsafe injections was highest at the immunization clinics (74.0%) followed by government (68.7%) and private (59.9%) health facilities. Rural areas have marginally higher likelihood of unsafe injection than urban areas[9], [15]. The risk of unsafe injection when administered at non-allopathic health facilities (Indigenous Systems of Medicine and non-formal prescribers) was over one and a half times as compared to that with allopathic prescribers.[16]

Healthcare waste disposal

The INCLEN report stated that written guidelines for sterilization were available at only 10.1% (95% CI: 8.8-11.4) of all health facilities across the country. Sterilization equipment was available at 84.2% (95%CI: 81.4-87.1) of the government health facilities, 76.9% (95%CI: 73.9-80.0) of the immunization clinics and 57.7% (95%CI: 54.1-61.3) of private health facilities. Satisfactory terminal disposal was observed in less than half of the health facilities (44.8%; 95%CI: 41.9-47.7); 41.55% in private health facilities.[17] A follow up of IPEN study conducted highlighted the urgent need for better policy and program for capacity building and resource investments in BMWM.

Why injections are prescribed unnecessarily

The qualitative component of the national study[13] found that most private practitioners provide injections for their own ulterior motive which is to make extra money and develop credibility among patients by providing quick relief. This is not a new phenomenon and has been documented from other parts of the world.[15] Practitioners blame patients for excessive use of injections where as in reality not all patients demand injections.[13,16] This phenomenon has been called as “cognitive dissonance” and reported from other part of Asia as well.[18]

Response of the Government of India

The Government of India has been cognizant of the fact that unsafe injections are a serious threat to patients and community and a potent source of transmitting hepatitis B and C infections in particular in the country. It is very much willing to address this problem. WHO country office for India has done advocacy and sensitized the government with the 2015 WHO guideline on safety engineered syringes in therapeutic care. MOHFW, Government of India constituted a Technical Expert Group (TEG) on Injection safety to advise the MoHFW on various aspects of injection safety including healthcare waste management in India.

The National Program on Prevention and Control of Viral Hepatitis in India under the 12th Five Year Plan (2012-2017) aimed to establish laboratory network for laboratory based surveillance of viral hepatitis in different geographical locations of India and to develop technical material for generating awareness among healthcare providers and in the community about waterborne and blood borne hepatitis. The Ministry of Environment & Forests (MoEF) brought out the first set of Bio medical waste (management and handling) rules in 1998, which were amended a number of times, most recently in 2016.

In 2015, Kayakalp an initiative for awards to public health facilities was launched by the Ministry of Health and Family Welfare. Apart from encouraging public health facilities to keep clean and hygienic environment, they are encouraged to develop systems for proper bio waste disposal under this mission.

The injection safety implementation project outlined in the following pages was shared with and discussed in the first meeting of the TEG on Injection safety in New Delhi, on 13 July 2016 and was supported by the TEG and the Government of India. This implementation project is aims to reduce the reuse of injection equipment by introducing safety engineered devices and also addressing the issue of overuse injections using behaviour change communication strategy. The TEG and MoHFW, Government of supported the project and also approved specific request from the representative of the Government of Punjab for the implementation of the project in Punjab state of India, in addition to the support and implementation at union government level. This project will be aligned with the recommendations made by TEG on Injection safety and related policy decision made by the MoHFW, Govt. of India in the area of injection safety. The injection safety implementation project is slated to be launched on 28th of July 2016 on the occasion of World Hepatitis Day 2016.

India Injection Safety implementation Project
(2016-2018)

The WHO aims to support the Union Ministry of Health and Family Welfare, Government of India in adaptation of WHO guidelines on safety engineered devices in therapeutic setting. In addition to technical assistance at National level, WHO as part of global project/campaign in three countries, namely India, Egypt and Uganda aims to implement the project in atleast one state. The project activities have been proposed to be done jointly with the Ministry of Health and Family Welfare, Government of India.

The overall objective is to reduce the risk of transmission of bloodborne infections due to unsafe injections and pave the way for introduction of safety engineered devices in the country.

Role of WHO

WHO will implement the injection safety implementation project in the country and provide international expertise as well as some financial support. WHO will mobilize international experts on injection safety assessments, strategies, policy and implementation to support the project in India (and in Punjab state of India). Financial support from WHO will be extended in part from its core budget from the WHO India offices and also through a grant received from the IKEA Foundation to support injection safety as a global need. The funds will be used as seed funding to stimulate additional resources. In addition to existing responsible staff, The WHO Country Office for India will hire a dedicated expert staff to the initiative to ensure consistent support.

Working Partners

An effective partnership is the key to success and is recognized as a critical component of the WHO global campaign on injection safety. Recognizing the value of expert collaborations, WHO Country Office for India (in collaboration with WHO HQ in Geneva) in partnership with MoHFW will collaborate with key partners including the National AIDS Control Organization, National Centre for Disease Control, academic institutions, NGOs and the private sector comprising of syringe manufacturers.

WHO will be working closely with MOHFW and the state government of Punjab, where this project is proposed to be implemented as well as with other partners in India. The project will mainly focus on injection safety with attention on improvement in healthcare waste management practices as well. Collaboration and leadership of MoHFW will be essential to help scale up the injection safety initiative in the country. Other ministries, NGOs, academic institutions and manufacturers will be important stakeholders in this project.

Duration of the project:
July 2016- Dec 2018

Level of involvement:

The project aim to support Union MoHFW, Government of India in strengthening safe injection practices. At union level, technical support could be provided to one large healthcare facility in introduction of safety engineered syringes.

In addition, project aims to work with Govt of Punjab, India. The state of Punjab has been selected, following a request from Govt of Punjab for implementation of this project in the state, submitted during the meeting of TEG on Injection safety on 13 July 2016. The request, based upon evidence on based upon burden of unsafe injections, was supported by TEG members and approved by Secretary (Health & Family Welfare), Government of India, who happens to be the chair of the TEG as well.

Overarching objectives

- To prevent unsafe therapeutic injections through the use of safety engineered injection devices and training of HCWs;
- To reduce demand for unnecessary injections by encouraging appropriate use of injectable medicines, and raising community awareness on injection safety;
- To eliminate the inappropriate disposal of healthcare waste with special attention on sharps waste.

The key components of the project:

Nationwide Independent Assessment

At the start of the project, an independent assessment has been proposed, to quantify the injection safety situation in sites finalized by MOHFW, TWG and WHO. The assessment will rely on globally established WHO Injection Safety Assessment Tool C Revised (Tool C). This Tool uses indicators for injection safety to identify the main risks as well as the most urgent areas for action. The key indicators focus on three major areas:

1. the safety of the patient (injection recipient),
2. the safety of the HCW (injection provider) and
3. the safety of the community at large vis a vis sharps waste management.

Tool C is flexible and allows the inclusion of other indicators based on the country needs, for example adaptations to add a focus on hospital-based injections. The baseline assessment will focus on tertiary and other health-care facilities in selected districts in states identified by MOHFW and TWG. Private health-care providers, pharmacies and ayurvedic medicine practitioners will also be the focus of assessment.

The independent assessment using Tool C is proposed to be carried with the full support and participation of the MOHFW to ensure that information is made available in an objective and rapid manner.

Specific activities under the project (and identified state)

1. Rapid review of available information

The injection safety work would begin with an analysis of existing information, including:

- Where available, information on reuse rates, needle stick injury, and other related statistics
- Review of existing policies related to injection practices, such as immunization policies
- Where available, review of prescription audits or other suitable sources to identify the injectable medicines most often misused in unnecessary injections

- Availability of RUP and SIPs already in use in the country
- Review policies or practices on sharps waste management
- Identify existing training materials that may require updates or revision
- Identify any other existing information gaps

2. Political commitment and stakeholder engagement

High level commitment is key to the success of the project. This can be leveraged and extended through activities to develop and implement a national policy as follows:

- High level commitment through an event to promote safe injection practices, the use of safety engineered syringes as well as advocating against unnecessary use of injections.
- Independent, expert injection safety baseline assessment using Tool C as a critical component to developing a comprehensive strategy and an objective means of prioritizing a plan of implementation. Tool C includes all aspects of injection safety, including sharps waste management
- Development of an implementation plan addressing the policy and the specific gaps identified in the independent assessment
- Adaptation of the WHO injection safety policy to national context including a transition to safety devices (RUP or a combination of RUP and SIP devices) and a target date for full implementation in India
- Development of key monitoring and evaluation indicators to follow up on progress

3. Baseline assessment in injection practices

WHO's Tool C is an international standard of assessment designed to objectively assess injection safety practices on a national basis. To implement Tool C, experts will be deployed to manage the assessment. The steps would include:

- Engagement for supporting the implementation of the study at the selected health care facilities
- Development of a sampling plan and list of facilities to be assessed
- Orientation and training of teams of surveyors
- Conducting the survey
- Analysis and reporting for discussion with the MOH and for use in the development and implementation of the strategies below

4. Procurement and continuous availability of products

Once RUPs/SIPs are part of the policies even with the availability of technology and manufacturers already producing these products, there will be a transition to cover all the country needs in terms of syringes. Therefore, it will be prudent to have a transition plan. The key procurement agencies and stakeholders should be engaged in the procurement transition towards RUP and SIP products:

- Review and analyze national forecast information with national procurement agencies to identify patterns of facilities with different capacity levels, noting that injection practices and equipment needs will be different according to the service capacity of the facility
- Perform national, state and/or facility based quantifications as needed using tools from WHO or other partners as appropriate
- Establish a technical specifications committee which includes end users to develop specifications for procurement based on standards for quality and performance and user needs.
- Estimate costs and procurement budgets required based on currently available products.
- Synchronize distribution schedules with the training programme schedule to make sure all HCWs will receive training on the devices before they are distributed for use in their respective health care facilities
- Depending on the availability of funds, a phased introduction of the safety devices can be envisaged either by geographical area or by level of care depending on where most injections are given

5. Device introduction, industry engagement

When new products are introduced to markets, it requires an understanding of the market landscape as well as an approach to phase in new technology. It is important to undertake a mapping exercise of the following when planning the introduction of safety engineered syringes especially if their local production through technology transfer is envisaged:

- Identify existing importers, distributors and manufacturers of injection equipment, noting those that comply with Bureau of Indian Standards (BIS), Good Manufacturing Practice (GMP) of WHO.
- Convene local pharmaceutical associations to provide information on the injection safety initiative, and provide information to facilitate changing product lines whether imported or locally manufactured.

6. Health care waste management

Health care waste management includes sharps waste, such as used syringes and needles. A used syringe can transmit disease and other types of infection from accidental needle sticks in handling the waste. Safe disposal includes the use of safety boxes at the point of care and also a plan for final disposal. When sharps are not contained at final disposal, such as the use of open pits, community members may also be accidentally exposed to sharps waste injuries.

The Bio Medical Waste Management Rules (2016) should be used as a reference and followed carefully for sharps management. The relevant references is reproduced here. For detail review please see the actual rules:

SCHEDULE I

[See rules 3(e), 4(b), 7(1), 7(2), 7(5),7(6) and 8(2)]

Part-1

Biomedical wastes categories and their segregation, collection, treatment, processing and disposal options

Category	**Type of Waste**	**Type of Bar of Container to be used**	**Treatment and Disposal Options**
1	**2**	**3**	**4**
White (Translucent)	Waste sharps including metal: Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, tamper proof containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.
Blue	(a) Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.	Cardboard boxes with blue colored marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.

7.Communication campaign, public awareness- raising and patient education and involvement

A strong determinant of frequent recourse to injectable medicines worldwide is high patient demand, based on the belief that injectable drugs are more effective and work faster and those injection devices represent more advanced technology. This attitude goes in parallel with very poor awareness of the infection transmission risk through injections. To combat this problem:

- Analyze and capitalize on data from Knowledge, Attitude and Practice (KAP) studies many are published from India and other parts of the world (see references: 13, 15 and 17)
- Identify target audiences from the assessment and existing data to develop key messages
- Develop a communication strategy, including media, newspapers, community leaders and other channels as appropriate to disseminate key messages
- Raise community awareness about injection safety and the need to reduce unnecessary patient demand through communication campaigns. These should be tailored according to available data and integrated within the national communication strategy for viral hepatitis where possible
- Promote community involvement by developing patient advocacy champions for safe injections.

2. Training

Health-care workers are a key target of the injection safety training. They may resort to the reuse of needles and syringes because of insufficient supply, but in other cases, reuse is deliberately chosen to reduce costs and increase financial income from injection practices.

The level of HCW education on infection risks from unsafe injection practices is poor in many settings, including public, private and especially with “informal” injection providers. In addition, when HCWs receive new products without training, they may reject them if they are not sensitized to minor functional differences. A strong training component is therefore essential and would include:

- Review available training tools developed and available
- Adapt and augment global tools as needed to local audiences, noting that training for nurses, physicians and community workers may have different needs
- Ensure that staff who manage sharps waste are also trained, including those who initially collect sharps waste through to those who manage final disposal
- Develop a training strategy to ensure that all health facilities have access to the training through self-training or other forms of in-service or cascade training
- Develop a training schedule so that product introduction i.e., RUPs and SIPs are distributed to facilities according to a schedule of training and sensitization on new products.
- Ensure that ALL trainings include hands-on experience with new devices so that HCWs are not penalized for “wasting” devices received in facility inventories.

3. Monitoring and evaluation

For stakeholders to remain engaged, to build confidence with community and industry partners, and to make informed changes, it is critical to have an objective and agreement monitoring and evaluation plan. Model plans exist from WHO and Centre for Disease Control that can be used as a base to develop and agree on a plan. The activities would include

- Evaluation of monitoring and planning options
- Identification of any other national indicators of importance
- Identification of existing data sources e.g., surveys that would have data available on a regular basis to support the monitoring and evaluation plan
- Agreement on a list of indicators, frequency of collection, and means of collecting information including any negotiation to include injection safety indicators into existing monitoring and evaluation activities

Conclusion

Injection safety measures are an important component of reducing and controlling the medical transmission of hepatitis B and C. WHO will be providing dedicated efforts to ensure that unsafe injections are reduced, that demand for unnecessary injections is eliminated and that communities are protected from unsafe sharps waste.

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