



Government of Pakistan  
Ministry of National Health Services,  
Regulations & Coordination



World Health  
Organization



# NATIONAL ACTION PLAN

To Address Unsafe  
Injection Practices  
in Pakistan



**MARCH 2021**





## ■ ACKNOWLEDGEMENT

The National Action Plan to Address Unsafe Injections in Pakistan was developed with hard work and collective efforts under the guidance of Ministry of National Health Services, Regulation and Coordination with technical support from the World Health Organization. The National Injection Safety Task Force provided valuable inputs in its development. Extraordinary efforts put in by Drs Samara Mazar Arshad Altaf, Muhammad Safdar Pasha, Anis ur Rahman and Umair Siddiqui deserve special recognition.

## ■ MESSAGE BY WHO REPRESENTATIVE IN PAKISTAN

Prescription of unnecessary injections and injections given with reuse injection equipment is a common practice in Pakistan, especially in the private sector. Epidemiological investigations carried out for the 2019 HIV outbreak in Larkana identified a strong association between unsafe injections (reuse of syringe and intravenous drip set) and transmission of HIV infection.

Unsafe injections have also contributed significantly in increasing the burden of Hepatitis C (HCV) in the country whereby Pakistan now has the highest number of HCV prevalence in the world. Other HIV outbreaks in parts of the country have also been attributed to unsafe injection practices of health care providers. More outbreaks are expected as the underlying causes of blood borne diseases like HBV, HCV and HIV/AIDS are the same. A common denominator to these infections is the use of unsafe injections.

Improper disposal of health care waste including sharp waste is another dimension of the same problem. All sharps including syringes and needles should be safely disposed of. Vaccine injections given by the Expanded Programme on Immunization (EPI) to prevent disease are one example. Using auto-disable (AD) syringes, the EPI administers injections to around 7.8 million children every year, generating tons of health care waste including syringes, needles and vaccine vials. It is prudent that all of this immunization waste is safely disposed of.

The Ministry of National Health Services, Regulations and Coordination is committed to reduce the burden of blood borne infections by introducing strategies that can prudently address unsafe injection and ensure appropriate health care waste management.

The present National Action Plan to Address Unsafe Injection Practices requires urgent support and implementation from all national and provincial stakeholders. I urge everyone to take a serious note of this problem and support in implementing this action plan-otherwise; we will continue to have similar outbreaks of blood-borne diseases in our country.

**Dr Palitha Mahipala**  
WHO Representative in Pakistan



## ■ FOREWORD FROM MINISTER OF HEALTH

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**Dr Faisal Sultan**

Special Assistant to the Prime Minister

Ministry of National Health Services, Regulations and Coordination.

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## SALIENT FEATURES OF NATIONAL ACTION PLAN

A multi-pronged approach to reduce unnecessary and unsafe injections in Pakistan through

### ENHANCED ROLE OF REGULATIONS

- Curtail the supply of substandard syringes in the country
- Promote rational use of injectable medicines
- Address quackery and malpractice
- Promote adequate management of healthcare waste

### ENABLING ENVIRONMENT

- Introduce reuse prevention (RUP) syringes in the health care delivery system of Pakistan, as recommended by WHO injection safety guidelines
- Train health care providers on rational prescription of injections
- Improve infection prevention and control (IPC), health care and sharps waste management

### COMMUNITY EMPOWERMENT

- Enable the patients and community to question the provider regarding the need of an injection and whether the syringe is new and opened from a new packet
- Safeguard the physical as well as social environment

## ■ ABBREVIATIONS

<b>CME</b>	Continued Medical Education
<b>DRAP</b>	Drug Regulatory Authority of Pakistan
<b>EPI</b>	Expanded Programme on Immunization
<b>HBV</b>	Hepatitis B virus infection
<b>HCV</b>	Hepatitis C virus infection
<b>HIV</b>	Human immunodeficiency virus
<b>ICT</b>	Islamabad Capital Territory
<b>IV</b>	Intravenous
<b>MBBS</b>	Bachelor of Medicine; Bachelor of Surgery
<b>MNHSRC</b>	Ministry of National Health Service, Regulation and Coordination
<b>MSDS</b>	Minimum Service Delivery Standards
<b>PMA</b>	Pakistan Medical Association
<b>PPA</b>	Pakistan Pediatric Association
<b>RUP</b>	Reuse prevention syringe

## ■ STATEMENT OF PROBLEM

### Strong Association between Unsafe Injections and Blood borne Infections: hepatitis B, hepatitis C and HIV



In 1997, one of the first ever publication documented the association between unsafe therapeutic injections and transmission of hepatitis C virus (HCV) infection among patients from Hafizabad, Punjab in a case control study. Patients who received more injections were at higher risk of acquiring HCV compared to those who received less injections.<sup>1</sup> Likewise, higher rates of reusing single-use, disposable syringes on multiple patients were also documented from an observational study published in 2000, conducted in peri urban Karachi. More than 90% injections were given with syringes reused on more than one patient.<sup>2</sup> Another case control study from Karachi in 2003 among patient with hepatitis B virus (HBV) infection concluded that HBV infected patients were more likely to have received therapeutic injections in the recent past.<sup>3</sup>

***Pakistanis receive the highest number of injections per person per year in the world. That number ranges between 8.2-8.5 injections. Out of these, almost 95% are unnecessary***

Pakistanis receive the highest number of injections per person per year in the world. It ranges between 8.2-8.5 injections.<sup>4,5</sup> Exposure to poor infection control practices during prenatal care and birth and unsafe injections as the causes of HCV transmission were identified as key risk factors in a study

published in 2008.<sup>6</sup> The national hepatitis survey of 2007 reported prevalence of HBV as 2.5% and HCV as 4.8%. The national survey also documented strong association between exposure to injections and HBV and HCV infections.<sup>7</sup> A study published in 2019 collected data from private health care providers in Sindh and Punjab and explored specific factors associated with syringe reuse. Overall 38% providers in both districts (14% in Rawalpindi and 44% TandoAllahyar) reused syringes 2-3 times. The very high syringe reuse was driven by high injection demand by patients, to which providers complied. Patients were generally unaware of the harms of injections and syringe reuse or that reuse happens.<sup>8</sup>

At least three HIV outbreaks in Pakistan among rural communities have been linked with unsafe injection. The first one occurred in Jalalpur Jattan in Punjab in 2008, where 88 patients were found HIV positive and exposed to unsafe injections.<sup>9</sup> The second one in Kot Imrana in Sargodha district in 2018 where 699 patients were confirmed HIV positive.<sup>10</sup> The third one has happened in Ratodero, a small town in Larkana district where, as of 4th of November 2019 a total of 1,189 (3.2%) people out of 36,736 screened for HIV have been confirmed HIV positive. In an unprecedented way, over 80% of HIV affected population belongs to less than 18 years of age group.<sup>11</sup>

## Injections given for preventing disease among children



Government of Pakistan has introduced the National Immunization Support Project (NISP) in the country, to support Expanded Programme on Immunization (EPI). The World Bank provides assistance for this purpose. The EPI has a mandatory policy that all injections are given using the auto-disable syringes. Moreover, in line with the environmental legislation of Pakistan as well as the World Bank safeguard policies, an environmental and social management plan (ESMP) is being implemented at all EPI centers

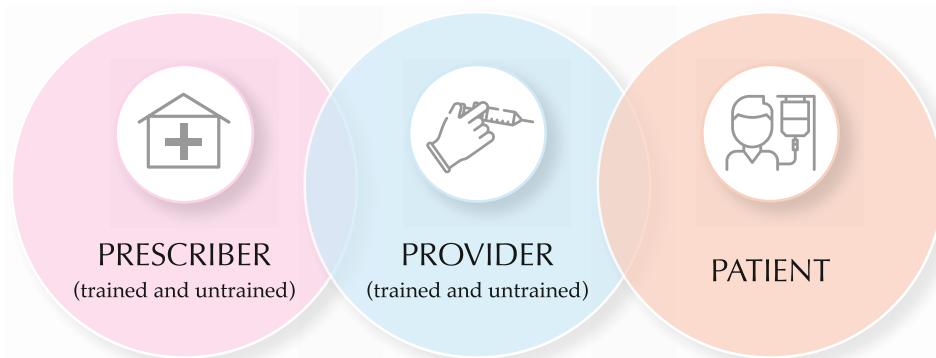
across the country to address the potentially negative environmental and social impacts associated with collection, storage, transportation and final disposal of the EPI waste (used syringes & vials). The ESMP also requires that the vaccination should be carried out in connection with the Emergency Response Project for Internally Displaced People (IDP-ERP) in the Tribal Merged Districts or any other immunization initiative that may have procurement of syringes, monitoring and evaluation of the activities.



## ■ DRIVERS OF UNSAFE INJECTIONS

Injections are overused in Pakistan. Patients accept injections as a therapeutic norm and standard practice, believing that they provide quick relief. According to the patients, the initiative of prescription of injections is in the hand of the doctor. Moreover, they are not usually aware of the risks associated with reuse of injection equipment.<sup>12</sup>

A critical analysis of injection practices reveals at least three drivers of unsafe and unnecessary injections in Pakistan. They are:



### Prescriber

Most unnecessary and unsafe injection practices happen at private health care facilities (clinics or dispensaries) across the country. These prescribers comprise of MBBS doctors or in some cases nurses and paramedics. Sometimes these medical care providers have no formal medical background or training. They prescribe unnecessary injections to provide quick relief, increase their clientele and income. IV drips are also prescribed in conditions, which can be dealt with oral medications. The charges for an IV drip literally depend on the paying capacity of the patient and can range from 250 to 1000 plus rupees. Syringes and IV drip sets at these clinics are reused because of the inability of the patient to pay extra, patients' lack of knowledge of the risks associated with reuse and prescriber's intention to save money.

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## Provider

The provider is the person at the health facilities (clinics or dispensaries) dispensing medicines and providing injections and IV drips. S/he in some cases is a nurse or paramedic but often a completely untrained person who learns skills while on the job. This person is the employee of the prescriber and only follows orders. Lack of infection control practices, reuse of injection equipment and unnecessary injections happen at this end.

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## Patients

Patients want to get well soon and while the prescribers and providers claim that it is the patient demand who insist on an injection or a drip. The reality is that patients are at the mercy of the prescriber or the provider. Our social dynamics dictate that patients do not question about the need of an injection and rarely question about safe injection practices. Majority of patients are unaware of the risks associated with reuse of injection equipment including syringes or IV drip sets.<sup>8,12</sup>

## ■ TARGETED ACTIONS TO IMPROVE INJECTION SAFETY

### Demand and Supply



Globally, an estimated 16.7 billion injections are provided every year. Out of these 90-95% are therapeutic while 5-10% belong to 'other' (e.g., immunization, family planning) category. The number of injections in Pakistan was estimated in 2006, which informed that 1.5 billion injections were being provided annually, out of which 94.2% were unnecessary.<sup>13</sup> International Medical Statistics have extrapolated that based on 2017 census, 1.76 billion injections are provided in Pakistan.

Among other factors, it is necessary to understand different types of syringes available in the country and their quality.

According to the Drug Regulatory Authority of Pakistan (DRAP), there are 14 registered syringe manufacturers and 50 importers of 166 different types of syringes. According to DRAP, imports fulfill 80% need of syringe market while local manufacturing meets only 20% of this demand. DRAP estimates that out of the 50 importers, between 30-33 are active importers, while the rest are dormant.

***In 2006 it was estimated that in Pakistan, 1.5 billion injections are provided, 94.2% of them being unnecessary. Extrapolating this number to 2017 census, it is estimated that annually, 1.76 billion***

## Enhancing Regulation to Control Supply Side

Globally, syringes for therapeutic and immunization purposes have to conform to following national and international standards mentioned in the table below:

Standard	Brief description
ISO 10993	Manufacturer to substantiate that the product (all components in case of the syringe) is made of medical grade materials fulfilling the applicable international standards for each step/ component of the product
ISO 7886-1	Hypodermic single use, sterile manual syringe
ISO 7886-2	Hypodermic single use, sterile manual syringe for use with power driven syringe pump
ISO-7886-3	Auto disable syringe for single dose immunization
ISO-7886-4	Hypodermic sterile single use syringe with reuse prevention feature
ISO-7864	Standard related to syringe needle
ISO-11135	Ethylene Oxide Sterilization Standard
ISO-11137	Radiation Sterilization Standard
GMP/ISO 13485	Commonly referred to “quality systems in manufacturing”; A “Quality System” is defined as organizational structure, responsibilities, procedures, processes and resources needed to implement quality management.

**It is unclear how many Pakistani manufacturers and importers conform to these international standards.**

A 2019 WHO UNICEF joint policy statement strongly recommended systematic and exclusive use of AD syringes for immunization and RUP syringes for therapeutic injections. It urges countries to switch to RUP for injections by 2020. The joint statement urges manufacturers to develop and improve affordability of AD and RUP syringe technologies.

WHO Prequalification Department recommends that all therapeutic syringes must conform to ISO Standards 7886-(1 and 4) and 7864 for needles used in all therapeutic and immunization syringes.

Syringes available in Pakistan must conform to these international standards.

## MOH 2010 SRO Related to Syringe Quality

It is prudent at this time to understand what is the status of the implementation of SRO 916-919-October 1, 2010 that comprehensively covers all manufacturing and other required standards. For example, it states in Clause 3-d, “the starting materials used in the manufacturing of the medical device shall be of a grade quality acceptable for manufacturing of medical devices by regulatory authority of Canada or Australia or USA, or UK or Japan or as may be specified by the Central Licensing Board.”

In “clause 6 i and ii (a) Medical Devices” it is mentioned that Medical devices shall meet the requirements for specification as set out in the most recent edition of British Pharmacopeia. If specifications for medical devices are not included in the British Pharmacopeia, the specifications in the following order of preference shall be followed-a) specifications set out by the International Standards for relevant type of medical device.”

## Reuse Prevention Syringes

WHO Injection Safety guidelines of 2015 recommend that all Member States should switch to the use of Reuse Prevention (RUP) syringes, and use conventional disposable syringes only when multiple plunger movements are required. The RUP syringes, therefore, should be introduced in Pakistan on immediate basis.

RUP syringes can play a key role in bringing the reuse down especially among private practitioners. It is equally essential to make a countrywide market of RUP syringes. Reuse of syringes will decrease when RUP syringes will come in use among private health care providers. However, it is also important to ensure their uninterrupted availability.

## Curbing Supply to Prevent Reuse

Controlling supply of reusable, substandard syringes which are flooded in the market and introducing RUP syringes has two key benefits:

- 1) Number of injections will come down; and**
- 2) RUP syringes will provide the added benefit of preventing intentional reuse at providers' level.**

## Role of District Administration

The District and Town Health Administrations in rural and urban areas are stretched thin with multiple tasks. Alone, they cannot deal with regulating unsafe health care practices. Monitoring bodies such as the Health Care Commissions in Sindh and Punjab provinces can play a pivotal role working in tandem either with the District Health Administration or alone in improving unsafe health care practices in the country. Similar bodies should be formed in ICT, Khyber Pakhtunkhwa and Balochistan. With immediate effect they should:

- Penalize reuse of injection equipment.
- Enforce the Minimum Service Delivery Standards (MSDS) in true spirit
- Ban quackery.
- Monitor (audit) practices of trained health care providers for unnecessary prescription of injection and IV drips.

## Regulating Prescribers

- Rational prescription of injections and IV infusions to be ensured by instituting monitoring mechanisms:
  - Auditing of prescriptions
  - Infection prevention and control (IPC) measures

- Injection safety as part of CME and a requirement for renewal of license to practice
- Penalizing reuse and irrational prescription of injections
- Engaging Pakistan Medical Association (PMA) or Pakistan Pediatric Association (PPA) and other bodies as stakeholders in accountability
- Trainings via PMA or association of family physicians
- Monitoring of practices through local PMA

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## Capacity building of Providers

- Preparing injections on clean counters
- Improving regulation and monitoring as mentioned earlier
- Penalizing reuse and irrational prescription of injections
- Trainings via PMA or association of family physicians

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## Educating Patients

- Intense injection safety campaign nationwide using popular celebrities
  - The campaign should be linked with messages highlighting unsafe injections and unsafe and poor infection control practices to infections
  - It has to be ensured that the diseases are not stigmatized as it can create more problems
- Empowering women with knowledge about risks of HIV, HBV and HCV because of unsafe injections
- Increasing knowledge to question the need of an injection and if required the patient should ask to open syringe from a new packet
- Making tests available for screening HBV, HCV and HIV at the point of care
- Linking those found positive to treatment and care

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## Infection Prevention and Control (IPC)

There is limited or no concept of infection prevention and control (IPC) at private health care providers. However, this problem is also prevalent at government health facilities including the primary, secondary and tertiary care hospitals. Sterilization for minor and major surgeries is an issue even at tertiary care hospitals. There are glaring gaps in health care and sharps waste management. Incinerators may be found in some government health facilities; however, they are often found to be non-functional.



## ■ KEY CONSIDERATIONS

Besides the financial implications of an action plan, other issues to be considered include the technical feasibility, the legal and administrative constraints and the long-term sustainability in terms of managerial and financial resources. Wider effects of an intended change on the traditional, social or power structure of communities, on employment, equity and gender as well as possible environmental effects need to be equally assessed. The below table of key process indicators helps address some of these considerations.

## ■ KEY PROCESS INDICATORS

### NATIONAL ACTION PLAN TO ADDRESS UNSAFE INJECTIONS

#### ■ Injection overuse

Objective	Core intervention	Beneficiary / Target Group	Indicators	Timeline	Responsibility
Reduce injection overuse	Promote oral medication <ul style="list-style-type: none"> <li>Media forums</li> <li>Educational material</li> <li>Community based interventions</li> </ul>	Patient and communities	<ul style="list-style-type: none"> <li>proportion of population reporting preference for injection in case of fever</li> </ul>	<ul style="list-style-type: none"> <li>2nd Quarter of 2020</li> </ul>	<ul style="list-style-type: none"> <li>MNHSRC</li> <li>Provincial Health Departments</li> <li>Health Care Commissions</li> <li>District and Town Administration</li> </ul>
	Reduce prescription of injectable medications <ul style="list-style-type: none"> <li>Standard treatment guidelines</li> <li>Policy statements from Pakistan Medical and Pakistan Pediatric Associations and similar other bodies</li> </ul>	Injection prescribers (e.g. physicians, nurses and para medics in the private sector)	<ul style="list-style-type: none"> <li>proportion of prescriptions including at least 1 injection</li> </ul>	<ul style="list-style-type: none"> <li>1st Quarter of 2020 and ongoing</li> <li>Ongoing process</li> </ul>	<ul style="list-style-type: none"> <li>MNHSRC</li> <li>Provincial Health Departments</li> </ul>

## KEY PROCESS INDICATORS

## ■ Injection reuse

Objective	Core intervention	Beneficiary / Target Group	Indicators	Timeline	Responsibility
	Reduce access to injectable medications <ul style="list-style-type: none"> <li>Remove unnecessary injectable medications from the essential drug list</li> </ul>	Health facilities, medical stores / No of injectable medications on the essential drug list	<ul style="list-style-type: none"> <li>Number of injectable medications on the essential drug list</li> </ul>	<ul style="list-style-type: none"> <li>3rd quarter 2020 and ongoing</li> <li>Ongoing process</li> </ul>	<ul style="list-style-type: none"> <li>MNHSRC</li> <li>Provincial Health Department</li> </ul>

## ■ Injection reuse

Curtail reuse of injection equipment	Introducing reuse prevention syringes (RUP) in the health care delivery system <ul style="list-style-type: none"> <li>Adapting WHO injection safety guidelines</li> <li>Switching to the use of RUP for injections</li> <li>Using conventional syringes where medical warranted</li> </ul>	Health care providers (MBBS, nurses, para medics)	<ul style="list-style-type: none"> <li>Procurement of RUP / use of RUP in health facility</li> <li>Use of RUPs in health facilities</li> </ul>	2nd quarter 2020	<ul style="list-style-type: none"> <li>MNHSRC</li> <li>Provincial Health Departments</li> </ul>
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## KEY PROCESS INDICATORS

## ■ Injection reuse

Objective	Core intervention	Beneficiary / Target Group	Indicators	Timeline	Responsibility
	Penalizing health care providers found reusing injection equipment <ul style="list-style-type: none"> <li>• Syringes</li> <li>• IV drip sets</li> <li>• Cannulas</li> </ul>	Health care providers (MBBS, nurses, para medics)	<ul style="list-style-type: none"> <li>• Monitoring reports</li> </ul>	With immediate effect and ongoing	<ul style="list-style-type: none"> <li>• MNHSRC</li> <li>• Provincial Health Departments</li> <li>• Health Care Commissions</li> <li>• District and Town Administration</li> </ul>

## ■ Equipment and supplies

Ensure access to safe injection equipment and sharps boxes	Health facilities to have adequate quantities of injection equipment and infection control	Public and private health care facilities	<ul style="list-style-type: none"> <li>• Proportion of health care facilities with sufficient stocks of RUP and conventional syringes</li> </ul>	<ul style="list-style-type: none"> <li>• 4th quarter of 2019</li> <li>• Ongoing</li> </ul>	<ul style="list-style-type: none"> <li>• MNHSRC</li> <li>• Provincial Health Departments</li> <li>• Medical Superintendents of health facilities</li> </ul>
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## KEY PROCESS INDICATORS

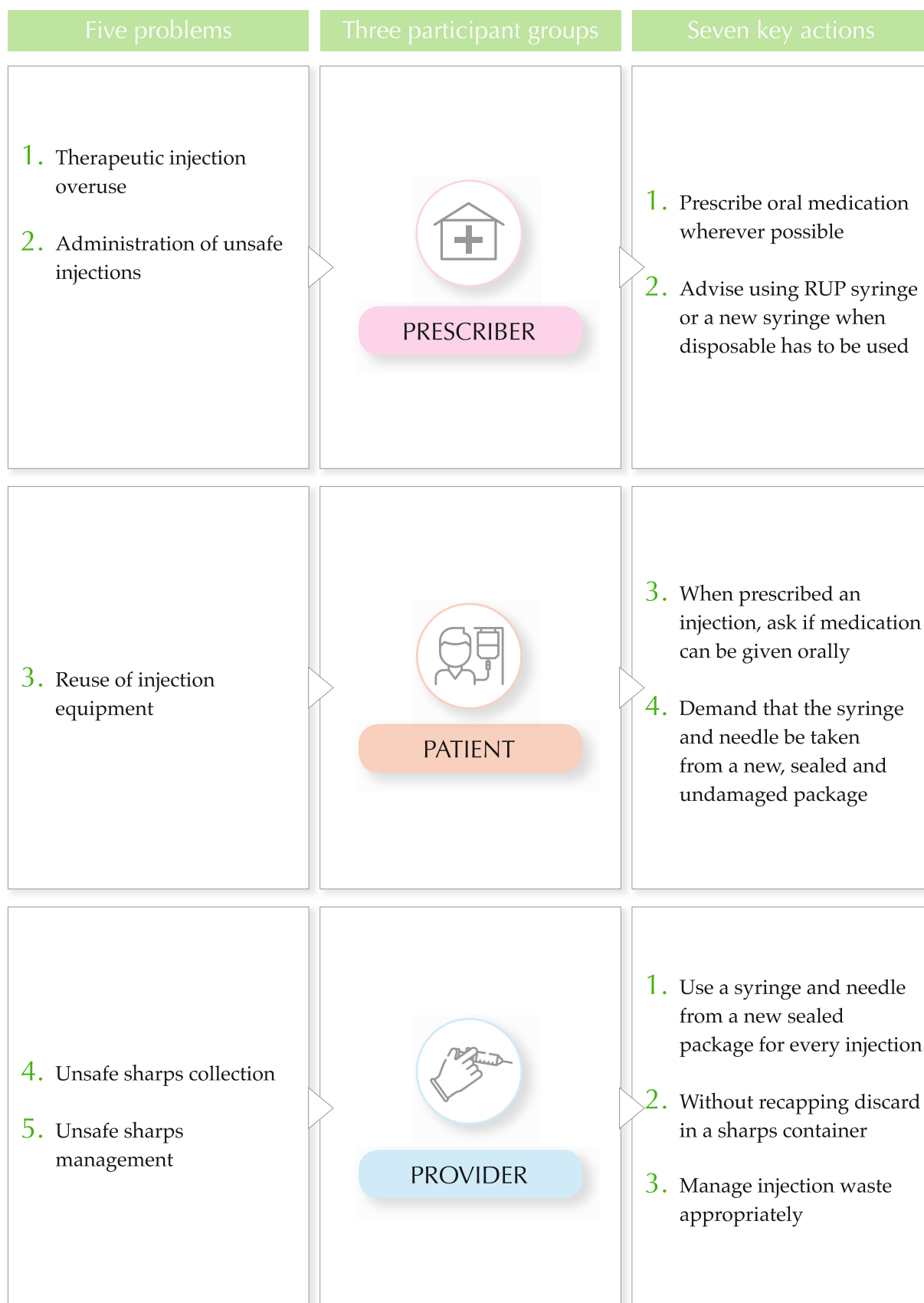
## ■ Sharps waste management

Objective	Core intervention	Beneficiary /Target Group	Indicators	Timeline	Responsibility
Integrate sharps waste management into a comprehensive health care waste management plan	<ul style="list-style-type: none"> <li>National Action Plan</li> <li>Health care waste management policy with regulatory framework</li> <li>Plan from waste production to final disposal</li> <li>Training at all levels</li> <li>Procurement of waste treatment options</li> </ul>	<ul style="list-style-type: none"> <li>Health care facilities</li> <li>Injection providers</li> </ul>	Proportion of health care facilities which surrounding environment is clear of used injection equipment	<ul style="list-style-type: none"> <li>3rd quarter 2020</li> </ul>	<ul style="list-style-type: none"> <li>MNHSRC</li> <li>National Action Plan</li> <li>Provincial Health Departments</li> <li>Health Care Commissions</li> <li>District and Town Administration</li> </ul>

## ■ Training of health care providers on injection safety and infection control

Training health care providers on injection safety and use of RUP syringes	<ul style="list-style-type: none"> <li>Focused training in collaboration with medical associations on injection safety and infection control</li> <li>Training at all levels</li> </ul>	<ul style="list-style-type: none"> <li>Health care providers</li> <li>Doctors</li> <li>Nurses</li> <li>Para medics</li> </ul>	Number of health care providers trained	<ul style="list-style-type: none"> <li>Immediate</li> <li>Ongoing</li> </ul>	<ul style="list-style-type: none"> <li>MNSRHC</li> <li>Provincial Health Departments</li> <li>Heads of health care facilities</li> </ul>
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## ■ COMMUNICATION STRATEGY FOR SAFE AND APPROPRIATE USE OF INJECTIONS





## ■ FOUR STEPS OF PROCUREMENT

Steps	Objective	Tasks
Step1	Select products	<ul style="list-style-type: none"> <li>• Select the type of injection equipment and safety boxes</li> <li>• Select ISO compliant and WHO Prequalified injection equipment</li> </ul>
Step 2	Estimate injection equipment needs	<ul style="list-style-type: none"> <li>• Estimate needs of injection equipment and sharps boxes in preventive and curative services</li> <li>• Calculate costs and funds required</li> </ul>
Step 3	Prepare for procurement	<ul style="list-style-type: none"> <li>• Define procurement or tender specifications</li> <li>• Establish injection equipment specifications</li> <li>• Prepare bidding documents</li> <li>• Select potential suppliers</li> </ul>
Step 4	Process tender	<ul style="list-style-type: none"> <li>• Choose a tender format</li> <li>• Prepare bidding documents for selective tender</li> <li>• Solicit and receive offers for selective tender</li> <li>• Select suppliers</li> <li>• Issue contract</li> <li>• Assess contract performance</li> <li>• Evaluate product performance</li> </ul>

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