WHO PQS Prequalification Scheme
for Injection Equipment &
Safe sharps disposal

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WHO/HIS/EMP/PQT
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Outline

Main issues for the safety of injections

Prequalification of devices for IM, ID, SC

WHO new policy

ISO ADs, RUPs, SIPs and SBs

Other technologies

Conclusions
Use of injections worldwide

16.7+ billion/year

Immunization injections
5% to 10%

Therapeutic injections
90 to 95%

World Health Organization
Risks for immunization

- Injection safety issues are similar therapeutic/immunization
- People's confidence is critical for the success of immunization and can be easily jeopardized
  - Medical intervention on healthy children
  - Fear of AEFI and increased demand for safety
- Large number of injections during immunization campaigns require special attention
Manipulation of Sharps for Disinfection

Soaking

Improvised sharp container

Autoclaving
## Solutions proposed

- **Improper use of equipment**
  - Reuse
  - Recapping needles
  - Needle sticks

- **Unsafe collection of used equipment**
  - Use of inadequate containers

- **Unsafe disposal (improper procedures)**
  - Treatment of waste (disinfection)
  - Incineration or burying
  - Recycling of plastic

<table>
<thead>
<tr>
<th>Use of AD/SIP and RUP/SIP syringe</th>
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<th>Use of single use safety box</th>
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<tr>
<td>In accordance with national policy</td>
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<td>Proper incineration preferred</td>
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World Health Organization
WHO PQS prequalification

http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/index.aspx/
Immunization related equipment: prequalification for UN agencies

8 categories of equipment
- Transport and storage of vaccines
- Temperature monitoring
- Injection devices
- Waste collection

Regulation of equipment and devices for immunization
WHO prequalification
Performance Quality and Safety project (PQS)
Prequalification scheme – E008 & E013

PQS Dossier requirements

1. Information on the manufacture
2. Information on the product
3. QM certificate (up to date; ISO13845)
4. CE marking or alike
5. Samples
6. Laboratory test results (no pass / fail) to assert compliance with ISO 7886 part 3 or 4
7. Needle ISO compliance:
   ISO 7864:1993, Sterile hypodermic needles for single use
   ISO 9626, Stainless steel needle tubing for the manufacture of medical devices
Auto-Disable Syringes

Fixed needle

- Reduced dead space
- Scale with two marks only

ISO definition of AD feature

- Automatically activated at start, middle or end of injection
- No additional action required
- No possibility to reuse syringe and needle after injection

AD does not stand for Auto Destructible or Auto Disposable syringe

28 AD syringes prequalified
Average of 5 cts per unit
"A syringe which has: a reuse prevention feature that is passively engaged at the start of vaccine administration; a needle-stick prevention feature that is passively or actively triggered at the end of vaccine administration; requires no manipulations posing a risk to the health worker; and results in a well encapsulated needle."

Revision 7886-3
ISO RUP definition
1. Automatic during or upon completion (Type 1)
2. Elective activation (Type 2)
3. Single aspiration (Type A)
4. Multiple aspiration (Type B)
"A syringe and needle combination which has: a reuse prevention feature that is engaged at the commencement of injection administration; and a sharps injury prevention feature that is triggered at the end of injection administration; requires no manipulations posing a risk to the health worker; and results in a well encapsulated needle."

Revision of ISO 7886-4
Safety box

- Defined as a single-use container intended to safely hold used sharps
- Has a sufficient penetration resistance to avoid needle piercing
- Resistance to water and shocks
- Aperture and fill line to avoid contacts with the content
- ISO 23907:2012

10 SBs PQed – price = 3 cts per unit
NO,

RUPs & ADs prevent reuse problems
But do not protect the vaccinator
nor the community if improper collection

Another solution:
Syringes with Needle Injury Protection
features

Compliance with ISO 23908:2011
Syringes with NIP (Needle Injury Protection)
Main objective:
• To promote rational and safe use of injections in therapeutic settings
  - • Reduce re-use of syringes, especially in curative injections
  - • Ensure sufficient supply availability through procurement channels and improved planning
New WHO Policy: Key Elements

- Transition to **AD/RUP/SIP devices** for both immunization and therapeutic injections
- Develop standards for rational use and supply of standard disposable syringes where they remain necessary
- Call to partners to fund procurement of safety engineered injection devices in all projects
- Call to industry to switch to "safe" syringes
- Call to countries to develop national policies and implementation strategies, with special focus on curative settings
Policy Implementation: Industry

- Support clients by transitioning to quality assured AD/RUP/SIP products.
- Leverage marketing channels to educate.
- Ensure affordability of quality devices
- Working with WHO, promote greater accessibility to safe syringes
Industry engagement

WHAT

- Strongly encouraging to switch to or increase safety engineered injection devices production and transfer technology as soon as possible, and to seek PQS prequalification

- Associating PQS prequalified or equivalent products with the WHO global IS initiative branding
Industry engagement

HOW

- Mapping all RUP and SIP technologies currently available
- Developing demand forecasts
- Building a business case for manufacturers to switch from standard disposable to RUP/SIP manufacturing
- Formal collaboration platform with umbrella organizations of injection devices manufacturers to develop or expand the production of safety engineered injection devices
- To facilitate procurement in countries
- To reduce device costs as much as possible
Other technologies

Reconstitution syringes plastic needles
Other technologies: AD jet injectors
Other technologies

Uniject/cPAD

Micro-needle

Nasal sprayer
New Technologies a great step, but...

- AD & RUP syringes is big step towards mitigation of risk of reuse for immunization – SIP syringes, another step for the protection of HCW and the community

- Injection safety is NOT only about devices as they won't provide all the answers but are important steps forward

- Few major considerations for the introduction of new technologies: access, acceptability, continuous supply and sustainability

- Training, advocacy and information, education and communication are essential and require continued attention and resources at all levels