

Report from the First Meeting of the WHO Private Organizations for Patient Safety Injection Safety Initiative with Syringe Manufacturers

Meeting date: 13-14 September 2016

Venue: Room M405, WHO headquarters

Geneva, Switzerland

Infection Prevention and Control Unit
Safe Injection Global Network (SIGN) Secretariat
World Health Organization
Geneva, Switzerland



Abbreviations

| | |
|------|--|
| AD | auto-disable syringe |
| ADG | Assistant Director-General |
| AMR | antimicrobial resistance |
| HIS | Health Systems and Innovation cluster |
| IPC | Infection prevention and control |
| IS | Injection safety |
| ISO | International Organization for Standardization |
| MOH | Ministry of Health |
| NGO | nongovernmental organization |
| POPS | Private Organizations for Patient Safety |
| PQS | WHO prequalification standard |
| RUP | reuse-prevention syringe |
| SDS | Service Delivery and Safety department |
| SIP | sharps injury prevention |
| SIGN | Safe Injection Global Network |
| UN | United Nations |
| WHO | World Health Organization |

1. Summary

This first meeting of the POPS IS initiative hosted by the IPC unit at WHO headquarters was attended by 18 different syringe manufacturers from 12 countries. The WHO injection safety focal persons from the three pilot countries (Egypt, India and Uganda) also attended the meeting.

Given that the 2015 WHO injection safety guidelines recommend switching to RUPs/SIPs by 2020, industry support will be vital in making this switch possible and viable. The purpose of the meeting was, therefore, to promote the POPS IS initiative to the syringe manufacturing industry, to seek their input on the initiative's sustainability and make plans for future collaboration. Manufacturers expressed their interest in the initiative and were willing to be a part of it. However, there were certain areas identified in the legal framework which will need to be addressed by the WHO headquarters team and share back with the industry representatives, who will then consult with their respective legal departments and provide feedback.

A tentative timeline of the end of October 2016 was proposed as the deadline to determine whether there will be sufficient sign-up from the industry or not. The next POPS IS meeting can be tagged on to the next SIGN meeting, due to be organized in the first quarter of 2017.

2. Background

The injection safety policy released by WHO in February 2015 recommends the exclusive use of auto-disable/reuse-prevention/sharps injury prevention (AD/RUP/SIP) syringes for most medical injections and recommends to all WHO Member States, particularly those with a problem of unsafe injection, to switch to their use by 2020. It also recommends the provision of adequate training on the use of these syringes, safe and rational injection practices and ensuring appropriate disposal of all used sharps. Part of the strategy is to engage the syringe manufacturing industry in the uptake and implementation of the key elements of the policy since the industry will have a critical role to play in ensuring the supply of RUPs and SIPs to countries and regions.

To translate the new policy into practice, the SDS department is leading the development of a global injection safety multimodal campaign. Since 2012, the Private Organizations for Patient Safety (POPS) initiative has been working successfully with the industry whose business and social responsibilities focus on supporting the global agenda of preventing harm resulting from unsafe health-care practices. The POPS initiative has provided the opportunity to align messages, enhance standards, ethically promote safe devices/products

and approve projects enabling collaboration between WHO and industry, primarily aimed at improving systems and knowledge.

POPS Injection Safety (IS) is envisioned on the same model, one which allows interaction between the private sector/industry stakeholders, such as the manufacturers and distributors of safety-engineered syringes and WHO. The purpose is to establish a coherent means of communicating and sharing information in line with WHO recommendations, and through projects to enhance injection safety by making these proposed products available and accessible across all parts of the world.

The goal of this collaboration is to benefit all recipients of injections, but particularly those in developing countries, and not the participants in the POPS collaboration.

The meeting with industry representatives was planned as the first step to gather feedback on the initiative's feasibility, continuity and sustainability.

3. Objectives of the meeting

- To promote the POPS IS initiative to stakeholders, particularly industry representatives.
- To seek industry input on long-term sustainability of the initiative.
- To make plans for future collaborations between industry and POPS IS.

4. Expected outcomes

- Receive practical feedback and solutions on how to sustain and make POPS IS successful.
- Enroll a number of industry stakeholders at the end of the meeting.

5. Meeting participants

A total of 18 manufacturers representing 14 companies were present during the two-day meeting.

6. Welcome and introductions

The Director of the Service Delivery and Safety department, Dr Edward Kelley, welcomed everyone, opened the meeting and identified a co-chair for the first session until lunchtime on Day One. Following that all, participants introduced themselves. Then Dr Marie-Paule Kieny, Assistant Director-General of the Health Systems and Innovation cluster, gave some opening remarks. She emphasized that the meeting would help to design a joint collaboration which would first and foremost assist Member States to improve injection safety issues. She opined that the goals of POPS were aligned with WHO and industry's

goals. Dr Benedetta Allegranzi then presented the agenda (Annex A) for the two-day meeting and also explained what the objectives of the meeting were.

7. Summary of key discussion points on day 1

Overall, the meeting participants expressed the view that POPS IS could provide added value in generating evidence for Member States to take concrete policy decisions towards improving injection safety. Participants also felt that the collaboration had to be a balanced one as manufacturers are also under parallel pressure and challenges which WHO should appreciate. Clarity on the legal framework was provided, namely that it would be in line with WHO's Framework for Engagement with Non-State Actors (FENSA), details of which can be obtained from <http://www.who.int/about/collaborations/non-state-actors/en/>.

Useful feedback on rephrasing some of the terms such as “preferential access” for those manufacturers who sign up to POPS IS was provided and it was suggested that it is not the usual UN style to use this type of terminology and it should be replaced with terms such as “added value”, as “preferential” has connotations of favouritism. has elitist connotations. However, it was made clear that even after paying and signing up, companies would have to comply with the code of conduct.

More clarity on the benefits of signing up to POPS IS was sought. It was explained to the participants that overall the benefit of the initiative would be for Member States but that working together in this way would provide easy access to guidance on technical matters such as correct messages related to injection safety or using the POPS IS slogan and image on a dedicated injection safety page on the participant's website. However, this could not be used for any commercial or promotional purposes.

There was some confusion regarding POPS IS, PQS and ISO, so it was clarified that the injection safety team is not in charge of either PQS or ISO. The POPS IS concept should be looked upon as a separate entity. Furthermore, the Safe Injection Global Network (SIGN) is the larger platform for all injection safety stakeholders and will carry on existing.

Participants were told that neither POPS Hand Hygiene nor POPS IS were money-making ventures for WHO and the calculated costs related solely to administrative, IT and technical support. As mentioned in the opening remarks, it was reiterated that POPS IS aims to provide benefit to WHO Member States and improve injection safety worldwide.

With reference to local manufacturing, there was some concern that local manufacturing may close the doors for others however, it was clarified that local manufacturing should be looked at positively. Local manufacturing will pave the way for many other manufacturers entering the business. It was also suggested that manufacturers should work out a mechanism of making their ‘manufacturing capacity’ known to ministries of health since lack of information in this area could negatively affect progress in decision-making. The

POPS initiative would need to work in an equitable and fair way, giving an opportunity for all manufacturers to join in if wished.

8. Participants concerns expressed on Day 1:

- Paying fees at multiple levels - many manufacturers are already paying fees for WHO PQS and paying fee for POPS IS may be an issue for some manufacturers.
- Clarification was sought on how “low” and “high” income companies was calculated.
- The criteria of needing WHO prequalification to become a POPS IS partner would likely limit the number of manufacturers able to participate.
- Restriction on collective projects was not good; there should be provision for a single company leading a project.
- Clarification on how POPS IS would harness energy, intelligence, innovation and resources.
- How the procurement of safety-engineered syringes could be sustained in countries in the long run.

9. Group work on Day 2

The participants were divided into two groups and each group was assigned a facilitator from the WHO team, with the rapporteur and presenters coming from the manufacturers.

Group 1:

Cooperation on training and advocacy to achieve the objectives of the new policy

Objectives:

- To discuss how POPS IS can support training and advocacy in the context of the WHO global campaign on injection safety.
- To propose concrete approaches and deliverables for POPS IS participants to contribute to training and advocacy.

Questions to address:

- What are the target audiences along the distribution chain for these activities?
- How the messages/training activities according to the target audience can be effectively developed?
- What are the existing activities already being led by companies in this field?
- How can these activities be adapted to fit the POPS code of conduct and approach?

- What should the key messages from industry be?
- What communication channels does the group propose to use?

Group 2:

Transition plan for the global switch to safety-engineered devices

Objectives:

- To discuss how POPS IS could significantly support the transition and improve access to safety-engineered injection devices.
- To propose concrete approaches and deliverables for POPS IS participants to achieve this transition.

Questions to address:

- What are the dynamics of switch, such as demand, volume and markets? (A proposed graph and specific questions were provided.)
- Who are the key players who will determine the switch and ensure improved access?
- Who are the stakeholders to be actively engaged to achieve the transition?
- What are the levers we can use for changing consumers' preferences?

10. Presentation by Group 1

Reinforcing positive advocacy by effective communication about injection safety by using seatbelt “buckle up” messages as a reference. An example could be “switch from single use disposable to auto-disable syringe.” The target audience for advocacy will be industry, donors, ministries of health, health care workers, patients, NGOs and others.

Target organization and communication mechanism:

| Organization | Mechanism |
|--|--|
| Donors | UN agencies need to send the messages to donors |
| Ministry of Health | Using the Press |
| MOH + national bureaucracy/technocrats | Evidence-based documents sent by UN agencies |
| Industry | Capacity-building using industry associations |
| Health care workers | Trainings, awareness-raising through interpersonal communication |
| Patients | Social media, TV, newspapers, radio, establish champions/ambassadors |

| | |
|------|--|
| NGOs | Donors should be the key communicators to NGOs |
|------|--|

Using the 6 Ps approach:

1. Policy - WHO and MOH
2. Product - Industry and PQS
3. People - Champions as well as health care workers and end users
4. Price - Industry/Donors
5. Press - POPS
6. Partnerships/Programmes - UN agencies

Simple effective communication for transition from RUP+SIP to be in a phased manner.

The group highlighted “what is being done today?”

1. Training/education
2. Partnerships
3. Media (TV, radio and social media)
4. Product range (capacity-building)
5. PQS and quantification.

How can all of the above be adapted to POPS?

1. A message developed by POPS IS which does not mention any specific company names can be developed and disseminated
2. Messages regarding POPS IS should be initiated from WHO to other UN agencies/donors/MOH
3. What is not being done today:
 - a. Outreach to agencies, donors and MOH and WHO needs to be the “door opener”
4. Messages should be followed by “dynamic action”
5. There should be a SIGN meeting every year till 2020 to keep the momentum going.

Additional recommendations by the group

1. Get a communication expert to guide the industry on messaging, including on the best channels to use

2. Messages to WHO from industry:

- a. Industry is willing and ready to build capacity but there needs to be a definitive commitment from agencies to uptake the capacity
- b. Provide timeline and demand and conversion time from conventional to RUPs
- c. Willing to invest in training and awareness-raising as well as conducting a needs assessment
- d. Existing UN procurement must move to WHO policy on injection safety
- e. Need a clearly defined road map for deliverables by 2020
- f. Need to have a timely and ongoing monitoring and evaluation programme
- g. Make this part of POPS IS and the annual SIGN meeting.

11. Presentation by Group 2

In order to define the dynamics of the switch, the group recommended to:

1. Define which regions to focus on;
2. Identify countries (referring to LMICs and the ones with a high burden of unsafe injections) which have switched to safety devices;
3. Decide who would be responsible for awareness programmes on the advantages of using RUPs/SIPs;
4. Depending on the country, involve advocacy groups such as nursing associations or other similar organizations to raise awareness among front-line health workers;
5. Impart education/training.

Key players to determine the switch and improve access:

- All levels of MOH (ministries of finance should be engaged as well)
- Directors of procurement, hospital and nursing departments important to engage
- Education departments
- Distributors of syringes referring to manufacturer sales representatives.

Levers that can be used for changing consumers' preferences:

- Most important lever is government regulation to enforce transfer from disposable syringes to a safety-engineered syringes

- There is often not enough motivation for a switch at the hospital level, which is restricted by price or hospital procurement not willing to expand product diversity e.g. RUPs cannot be used for certain medical procedures such as flushing IV lines or infusion pumps and hospital administration wants to avoid juggling with a syringe mix
- A key lever for change in this kind of situation can be government health facilities - a five-year plan is recommended:
 - Year 1: change at central government level
 - Year 2: change at state and district level health facilities
 - Year 3: targeting private hospitals and nursing homes
 - Year 4-5: focusing on smaller level health facilities
- Hospitals could be supplied with a toolkit to help them determine the syringe mix and volumes needed
- Training of front-line health care workers on different types of products.

Appropriate activities for POPS IS collaboration to undertake the demand shift:

- Removing barriers such as the issue mentioned above about the difficulty that a hospital may face in selecting the type of syringes
- Positive messages on RUPs/SIPs
- Awareness of consumers (in this case, health care workers) and the general public as well, as the community can often not differentiate between the different types of product, so they should be educated on the risks of reuse and rational use of injections.

Steps to take in markets without sufficient regulation to protect quality standards:

- PQS receives documentation from manufacturers at the time of application - it should check all facilities for quality
- Linking with labs to determine quality of syringes
- Manufacturer conforming to ISO standards.

How can the industry avoid competitive practices that disrupt long-term stability?

- By lobbying for quality and improvement
- POPS IS can provide leverage at different political levels
- By promoting the development of legislation.

12. Summary of concluding session - Day 2

It was encouraging to note that there is a will and interest within the syringe manufacturing industry to move forward with the POPS IS collaboration.

It was communicated to the participants that gaps identified in the legal framework will be addressed and shared in due course. It was also emphasized that a switch to RUPs/SIPs will be impossible without commitment from the syringe manufacturing industry, hence this industry represents a very important and key player in this global transition.

The WHO POPS IS team would like to have a clear indication by the end of October about the intentions of manufacturers in signing up to the initiative. Next POPS IS meeting can be tagged with the SIGN meeting which will be organized in the first quarter of 2017. There was feedback that two other manufacturers meetings are Medica Trade Fair in Dusseldorf, Germany, in November and Arab Health in Dubai, UAE, in February 2017, so a POPS IS update could be tied to these meetings, also.

13. Summary of presentations

POPS background

Dr Kelley provided some background on POPS and described how POPS was actually created in 2012. He explained that the idea behind POPS' creation revolved around corporate social responsibility to support the global agenda of preventing harm resulting from unsafe health care practices, which in this particular case would be about preventing harm from unsafe injection practices. The work is focused on global reach and aims to provide benefit to Member States, particularly those in low- and middle-income countries. Signing up to this POPS IS collaboration will require an agreement, including a set annual fee. It will provide a "closed web space" via an approved platform where information sharing would be bidirectional between WHO and the signed up companies. POPS has a set of rules and a code of conduct to make this work successfully.

POPS Hand Hygiene

Professor Pittet, from the University Hospital, Geneva, gave an overview on the POPS Hand Hygiene initiative which came about as part of the WHO "Clean Care is Safer Care" programme of work. The promotion of best practices in hand hygiene and infection control aimed to reduce health-care associated infection worldwide. After addressing some key hurdles on the use of hand hygiene solutions and WHO issuing an alcohol-based handrub formula for local production, the POPS hand hygiene initiative has supported increased awareness-raising in many countries and actively promoted the WHO 5 May SAVE LIVES:

Clean Your Hands campaign day. The benefits for industry of signing up have included easy access to guidance from WHO on quality and correct messages; right to use the copyrighted slogan; enhanced corporate image; easy access to relevant information on hand hygiene and other hand hygiene products and easy access to knowledge/education/research/perspective in hand hygiene.

Update on the WHO injection safety campaign in pilot countries

Dr Altaf, in his update on progress in pilot countries, provided a refresher on the key recommendations on the 2015 policy which aims to reduce the reuse of injection equipment, accidental needle-stick injuries, overuse of injections and unsafe sharps waste management. The policy also wants to ensure a more rational use of injectable drugs and sufficient supplies of injection equipment. The three pilot countries include Egypt, India and Uganda. Engagement on the part of industry is part of the key process indicators developed for the pilot intervention. After some initial delays the campaign has picked up momentum in all three countries. Egypt has recently completed a baseline assessment, across eight governorates of the country, and results will be available by the end of October. The Egyptian Government is planning to start production of AD syringes through a government-supported company. The Ministry of Health in India has made significant progress by forming a technical expert group to oversee injection safety issues in the country. The central government has also identified Punjab as the State which will conduct the pilot intervention. WHO headquarters and its Country Office are also keen to make IPC part of the pilot intervention. Finally, the Ugandan Ministry of Health has constituted an injection safety technical working group. An injection safety mission and consultations have identified multiple gaps to improve the situation in the country. WHO is also working on the development of communication tools to raise awareness on injection safety issues targeted at different populations.

Legal framework for POPS IS

Dr Allegranzi provided a detailed description of the POPS IS legal framework. She explained that the specifics of the framework include a carefully managed and evaluated model, working through a platform, defined criteria for participation, a code of conduct and the signing of a disclosure agreement between WHO and each participant company. For a company to participate it has to manufacture or distribute WHO prequalified safety-engineered syringes or be an umbrella association of such companies. The company has to prioritize production of ADs/RUPs/SIPs. It will also need to sign a code of conduct and agree to actively participate in the web-based platform. Participants in POPS IS cannot engage in any illegal or unethical marketing of the products to gain a competitive advantage. The participating organizations will be allowed to use the POPS IS image on a dedicated injection safety page of their company's website. There is a participating fee

which each company will need to pay once it agrees to sign up with WHO. For low-income companies, the fee is approximately US\$ 7000 for first year and then US\$ 4000 annually thereafter. For high-income companies, the fee is approximately US\$ 20 000 for the first year and US\$ 10 000 thereafter. Practical information about the “closed web-based platform” is available in the agreement document distributed to each participant. WHO will assess and be responsible for approving the proposed collaborative projects. Once up-and-running, all information about POPS IS will be available on the POPS IS platform, with key information being posted on the WHO web page as well.

Ideas for POPS IS projects and initiatives

Ms Hedman then provided an overview of possible POPS IS projects as part of the initiative between WHO and syringe manufacturers. She emphasized that POPS IS proposals would need to be prepared and based on the overall goals and aim of the group. “POPS participants” will be the term used for those who sign up. Everyone will be given the same and fair opportunity. The project proposal, working plan and timelines, once finalized, will be shared via the platform, to keep everyone informed. Any original material created as part of a project will be shared on the platform and will then be the property of WHO. Two examples of possible POPS IS project were given. The first example related to engaging POPS distribution channels in planning for uptake and transition to new devices. In this, WHO can develop materials with feedback from POPS members. Procurement, forecasting and transition planning materials would be tested, refined and made available to POPS members to promote uptake from within the supply chain. The second example was related to pharmacy networks which need to be engaged in training on use of the injection safety devices, to promote uptake and reduce confusion developing around the new products.

Annex A: Meeting agenda

World Health Organization Service Delivery and Safety

Meeting of Private Organizations for Patient Safety / Injection Safety (POPS IS) 13-14 September 2016 Geneva, Switzerland Room M405

Final Agenda

Day 1

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|-------------|--|----------------------------|
| 09:00-09:30 | Welcome Introduction of participants Appointment of the Chairs | E. Kelley |
| 09:30-09:45 | Objectives of the meeting | B. Allegranzi |
| 09:45-10:00 | Opening remarks by Assistant Director General | M.-P. Kieny |
| 10:00-10:20 | Overview of the POPS concept | E. Kelley |
| 10:20-11:00 | Example of POPS-Hand Hygiene | D. Pittet |
| 11:00-11:20 | <i>Coffee Break</i> | |
| 11:20-11:45 | Update on WHO injection safety campaign in pilot countries | A. Altaf |
| 11:20-12:15 | Objectives and legal framework for POPS IS | B. Allegranzi |
| 12:15-13:15 | <i>Lunch Break</i> | |
| 13:15-14:00 | Proposal for POPS IS management and work style | B. Allegranzi L. Hedman |
| 14:00-14:45 | Ideas for POPS IS projects and activities | L. Hedman |
| 14:45-15:45 | Feedback from participants | All |
| 15:45-16:00 | <i>Coffee Break</i> | |
| 16:00-16:30 | Summary of key discussion points | E. Kelley |
| 16:30-16:45 | Final discussion | All |
| 16:45-17:00 | Closing remarks | M.-P. Kieny |

Day 2

| | | |
|-------------|---|---------------|
| 08:30-09:00 | Guideline presentation on working in groups | B. Allegranzi |
| 09:00-10:30 | Working in groups | |
| 10:30-10:45 | <i>Coffee Break</i> | |
| 10:45-11:30 | Feedback from group work | |
| 11:30-12:15 | Discussion and Q&A | E. Kelley |
| 12:15-12:30 | Concluding remarks | E. Kelley |

Annex B: List of participants**WHO Private Organizations for Patient Safety Injection Safety
Geneva, Switzerland
13-14 September 2016****Provisional list of participants**

Alexander Anders
Shottli AG
Switzerland

Ibrahim Khalil
International Company for Medical
Necessities
Egypt

Federico Ceresetti
Kahle Automation
Italy

Marc Koska
Safe Point Trust
UK

Pioter Dobies
Sol-Millennium Europe

Adolph Keller
Shottli AG
Switzerland

Kathryn Duesman
Retractable Technologies
USA

Liang Lin
Sol-Millennium Group
China

Renuka Gadde
Becton Dickenson
USA

Cathy Molson
iinjec Technologies Inc
Canada

Christian Helbig
SCHOTT AG
Germany

Rajiv Nath
HMD
India

Mohamed Khalil
International Company for Medical
Necessities
Egypt

Larry Minx
Métier Médical
USA

Kurt Stolz
MPS Maschinen- & Pack-Systeme AG
Switzerland

Ester Smedhaugen
Polynor
Norway

Ikedife Uba
Integrated Medical Industries Limited
Nigeria

EXPERTS

Selma Khamassi
Tunisia

Chandrakant Lahariya
Injection Safety Focal Person
New Delhi, India

WHO COUNTRY OFFICES

Alaa Gad Hashish
WHO Country Office, Egypt

Victoria Msembe
WHO Country Office, Uganda

WHO SECRETARIAT

Marie-Paule Kieny
Assistant Director-General
Health Systems & Innovation
World Health Organization
Geneva, Switzerland

Edward Kelley
Director, Service Delivery & Safety
World Health Organization
Geneva, Switzerland

Benedetta Allegranzi
HQ/HIS/SDS
Coordinator a.i., Infection Prevention and
Control Global Unit
World Health Organization
Geneva, Switzerland

Arshad Altaf
HQ/HIS/SDS
World Health Organization
Geneva, Switzerland

Lisa Hedman
HQ/HIS/EMP/PAU
World Health Organization
Geneva, Switzerland

Jérôme Delauzin
HQ/HIS/SDS
World Health Organization
Geneva, Switzerland