ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

COVID-19 Vaccine Safety Interest Group (CVSIG) Update

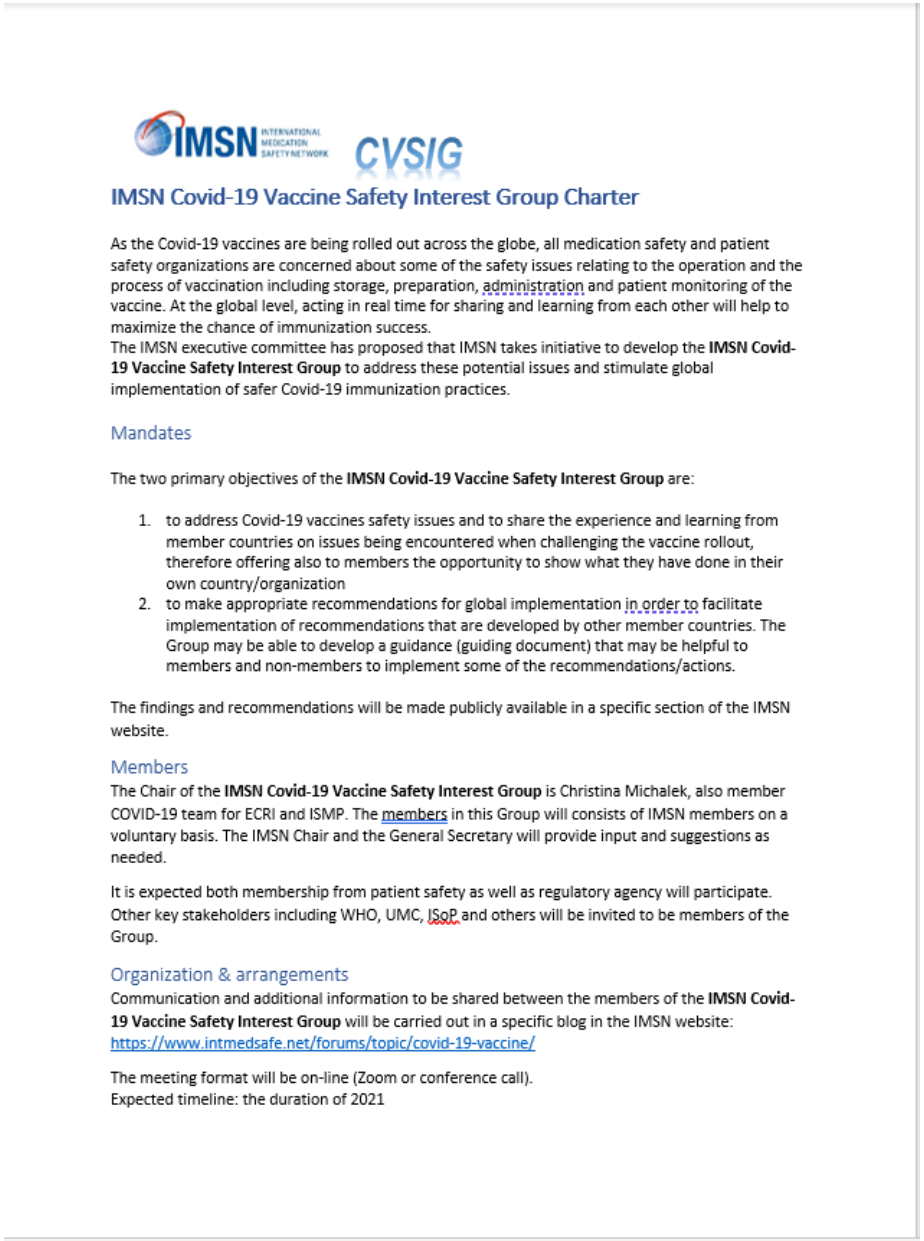
Christina Michalek

Inception

- *How do PV centers prepare for the authorization of a future COVID-19 vaccine…….* 30 October 2020
- *Does anyone have detailed information with recommendations for preparing the Pfizer vaccine……..* 18 December 2020
- *Important question - preparation of individual doses of Pfizer vaccine……..* 31 December 2020
- 21 January 2021 IMSN Executive Committee proposal

Charter

- Two objectives:
  - Address Covid-19 vaccine safety issues by sharing experience and learning from member countries
  - Make appropriate recommendations for global implementation
  - Timeline: duration of 2021



IMSN INTERNATIONAL MEDICATION SAFETY NETWORK CVSIG

IMSN Covid-19 Vaccine Safety Interest Group Charter

As the Covid-19 vaccines are being rolled out across the globe, all medication safety and patient safety organizations are concerned about some of the safety issues relating to the operation and the process of vaccination including storage, preparation, administration and patient monitoring of the vaccine. At the global level, acting in real time for sharing and learning from each other will help to maximize the chance of immunization success.
The IMSN executive committee has proposed that IMSN takes initiative to develop the **IMSN Covid-19 Vaccine Safety Interest Group** to address these potential issues and stimulate global implementation of safer Covid-19 immunization practices.

Mandates

The two primary objectives of the **IMSN Covid-19 Vaccine Safety Interest Group** are:

1. to address Covid-19 vaccines safety issues and to share the experience and learning from member countries on issues being encountered when challenging the vaccine rollout, therefore offering also to members the opportunity to show what they have done in their own country/organization
2. to make appropriate recommendations for global implementation in order to facilitate implementation of recommendations that are developed by other member countries. The Group may be able to develop a guidance (guiding document) that may be helpful to members and non-members to implement some of the recommendations/actions.

The findings and recommendations will be made publicly available in a specific section of the IMSN website.

Members

The Chair of the **IMSN Covid-19 Vaccine Safety Interest Group** is Christina Michalek, also member COVID-19 team for ECRI and ISMP. The members in this Group will consists of IMSN members on a voluntary basis. The IMSN Chair and the General Secretary will provide input and suggestions as needed.

It is expected both membership from patient safety as well as regulatory agency will participate. Other key stakeholders including WHO, UMC, ISoP and others will be invited to be members of the Group.

Organization & arrangements

Communication and additional information to be shared between the members of the **IMSN Covid-19 Vaccine Safety Interest Group** will be carried out in a specific blog in the IMSN website: https://www.intmedsafe.net/forums/topic/covid-19-vaccine/

The meeting format will be on-line (Zoom or conference call).
Expected timeline: the duration of 2021

Participants

- Brazil- Mario Rosa Borges
- Canada- David U, Dorothy Tscheng, Gary Lee, Sarah Finlayson
- Health Canada- Sally Pepper, Jhona Rose
- Columbia- Ismael Basto, Juan Pablo Osorio
- EMA- Alexios Skarlatos
- France- Marie-Blanche Rabier, Etienne Schmitt
- Germany- Torsten Hoppe-Tichy, Birgit Vogt
- Hong Kong- Benjamin Lee
- Ireland- Muriel Pate, Niamh O'Hanlon
- ISoP- Brian Edwards, Angela Cora
- Morocco- Ghita Benabdallah, Houda Sefiani
- Netherlands- Jaap Dik, Rob Essink
- New Zealand- Michael Tatley
- Norway – Sigurd Hortemo
- Saudi Arabia- Hind Almodaimegh
- Singapore- Augustine Tee, Alvin Lee, Adelina Young (MOH)
- Spain- Maria Jose Otero
- UAE- Sohail Fitieh
- UK- Mitul Jadeja (MHRA), Jennie Hall (NHS)
- UMC – Alem Zekarias
- US- Mike Cohen, Rita Jew, Jill Paslier, Merissa Andersen
- US FDA – Lubna Merchant, Karen Farizo, Craig Zinderman
- US Vaccine Dynamics – John Grabenstein
- WHO – Ayako Fukishima, Raffaella Balocco
- Novartis- Matt Fried, David Yoon

ISMP
An ECRI Affiliate

Global Sharing and Learning

Virtual meetings, blog post communication and resource page

Initial country survey

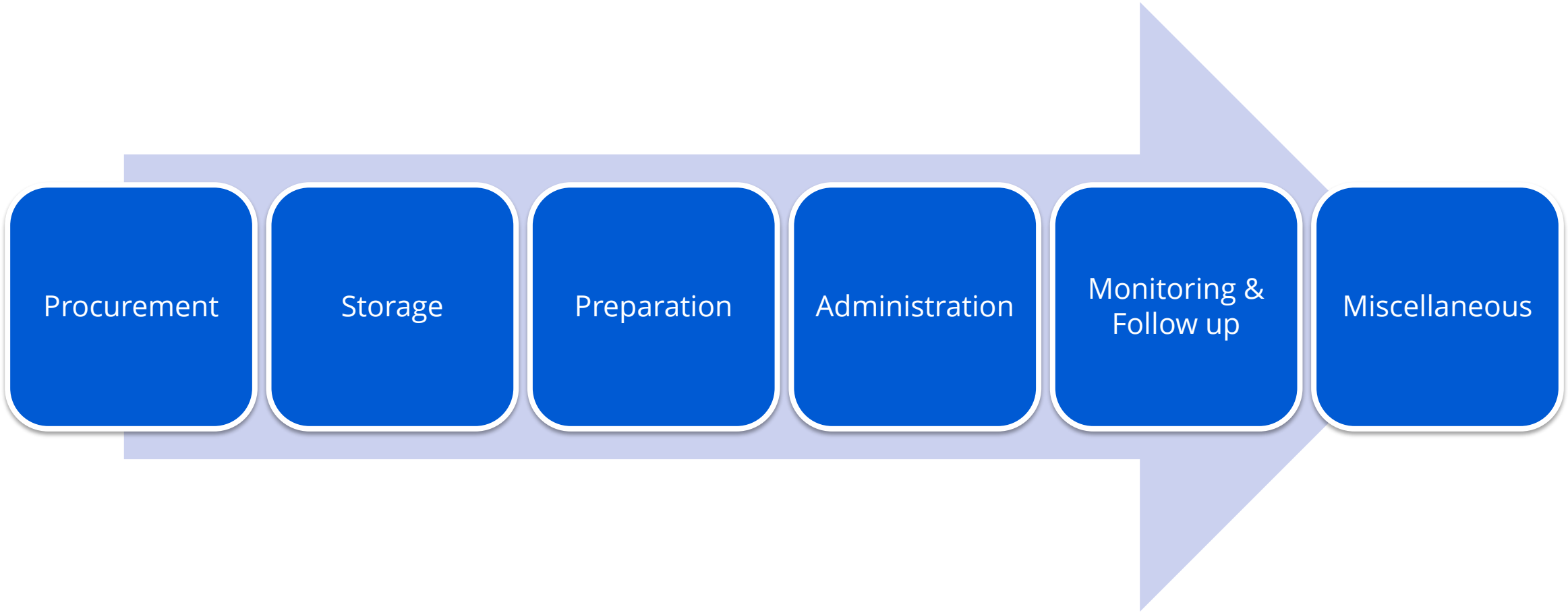
- Available vaccines
- Vaccine roll out process
- Top concerns

Approach to COVID-19 vaccinations –six monthly meetings

- France
- Ireland
- United States
- Canada
- Norway
- Singapore
- New Zealand
- Morocco
- Saudi Arabia
- Uppsala Monitoring Centre
- World Health Organization

Risks and Recommendations

Goal: identify risks, actual errors and address priority recommendations



Recommendations

- Procurement
  - Ensure adequate vaccine doses and supplies are available based on the number of people to be vaccinated
  - Communicate vaccine delivery timing
  - Ensure proper storage conditions for vaccines during transportation and distribution
- Storage
  - Plan for appropriate storage of vaccines considering inventory volume, required storage temperature, and transportation needs
  - Ensure consistent maintenance of cold chain storage including temperature monitoring of refrigerators and freezers
  - Store vaccines in a manner to avoid confusion with other medications or other vaccines
  - Segregate vials in use from those that have not been used in storage locations

Recommendations

- Preparation
  - Establish a clean, organized area for vaccine preparation
  - During preparation follow a workflow that avoids known risks of error and supports early identification of potential errors
  - Have a process in place that allows for easy identification of patients who may have received a wrong dose/vaccine/diluent
  - When a vaccine requires dilution, apply a label to the vial to indicate that the diluent has been added
  - Consider usability studies when distributing multi-dose vials to identify potential issues for leakage during preparation
  - Consider usability studies when vaccines are provided in a prefilled syringe that requires assembly prior to administration to identify potential issues with connecting components
  - When possible, manufacturers should provide vaccines in a ready-to-administer form
  - Apply a label to each dose of vaccine drawn from a multi-dose vial
  - When multiple brands of vaccines are in use, restrict to one brand/vaccine type available at a vaccination site
  - When training supplies are available at the vaccination sites, restrict them to areas away from where vaccine preparation occurs (e.g., pharmacy areas) to avoid potential confusion with actual vaccines and diluents
  - Plan for end of clinic doses to avoid vaccine waste

Recommendations

- Administration
  - During appointment booking screen patients for vaccine appropriateness
  - When patients arrive to be vaccinated, review vaccine eligibility based on vaccine type/brand, patient age, time/interval between doses, and prior vaccinations
  - Ensure the patient flow is clearly marked and communicated, and patients understand how to follow the process from intake/waiting area through vaccination administration and monitoring area
  - Educate vaccinators on vaccines to be administered including the approved route of administration, dose(s), risk for SIRVA and how to prevent it, and how to prepare (as required) each dose, including how to use vials, prefilled syringes, and/or syringes and safety needles
  - When possible, have different staff prepare and label vaccines from those who will administer vaccines
  - Document vaccine administration at the time of administration

Recommendations

- Monitoring and Follow up (short and long term)
  - Have medications available in vaccine clinic locations to treat medical emergencies such as an anaphylactic reaction
  - When multiple doses are required to achieve immunity, ensure patients are appropriately scheduled to receive subsequent doses
  - Educate patients on vaccines, potential adverse effects, and when to seek medical advice
  - Communicate with patients to encourage them to complete the vaccination schedule
  - Monitor patients for adverse effects beyond the initial monitoring period
  - Report adverse events and vaccine errors

Recommendations

- Miscellaneous
  - Mis-alignment of regulatory decision making – issues with countries (or within countries) not accepting certain vaccines
  - Mixing and matching vaccine brands
  - Delays in administration of second dose to promote first doses for more people
  - Addressing vaccine hesitancy
  - Giving booster doses

Future Efforts

- Pediatric expansion to children 5 – 11 years
  - **Vaccine mix-ups predictable**
  - **Two dose regimen: 10 mcg/0.2 mL (after dilution)**
  - **Age-dependent formulations**
  - **Packaging similarities**
- Flu season causing an increase in vaccine mix-ups
  - **Influenza, COVID boosters, Shingles**
  - **Possible causes: syringes near each other; unlabeled syringes; distractions; staff shortages; demand to co-administer**

ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

Questions?