Health Canada Santé Canada

Canada

Overview of COVID-19 Vaccine Regulatory Approval, Pharmacovigilance, Advisories and Patient Experiences

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Prepared by:

Sally Pepper (Patient Safety Specialist), Office of Policy, Risk Advisory and Advertising

Jhona Rose (A/Manager) and Gloria Giraldo (Senior Scientific Reviewer)

Bureau of Biologics, Radiopharmaceuticals and Self-Care Products

Marketed Health Products Directorate, Health Canada

Dorothy Tscheng (Director) Institute for Safe Medication Practices Canada (ISMP Canada)

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Agenda

- Regulatory Aspects
- Approved vaccines
- Terms and Conditions
- Adverse Events Following Immunization
- Other Pharmacovigilance Activities
- Health Canada Advisories
- Patient Experiences

COVID-19 Vaccines Approval Process

Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19

(September 16, 2020)

- Temporary regulatory pathway
- Promotes flexibility and agile review process

Rolling Submission

- Sponsors can apply before they have completed all phases of clinical trials

Health Canada Review

Pre-clinical studies

Clinical Studies

Manufacturing data

Risk Management Plan

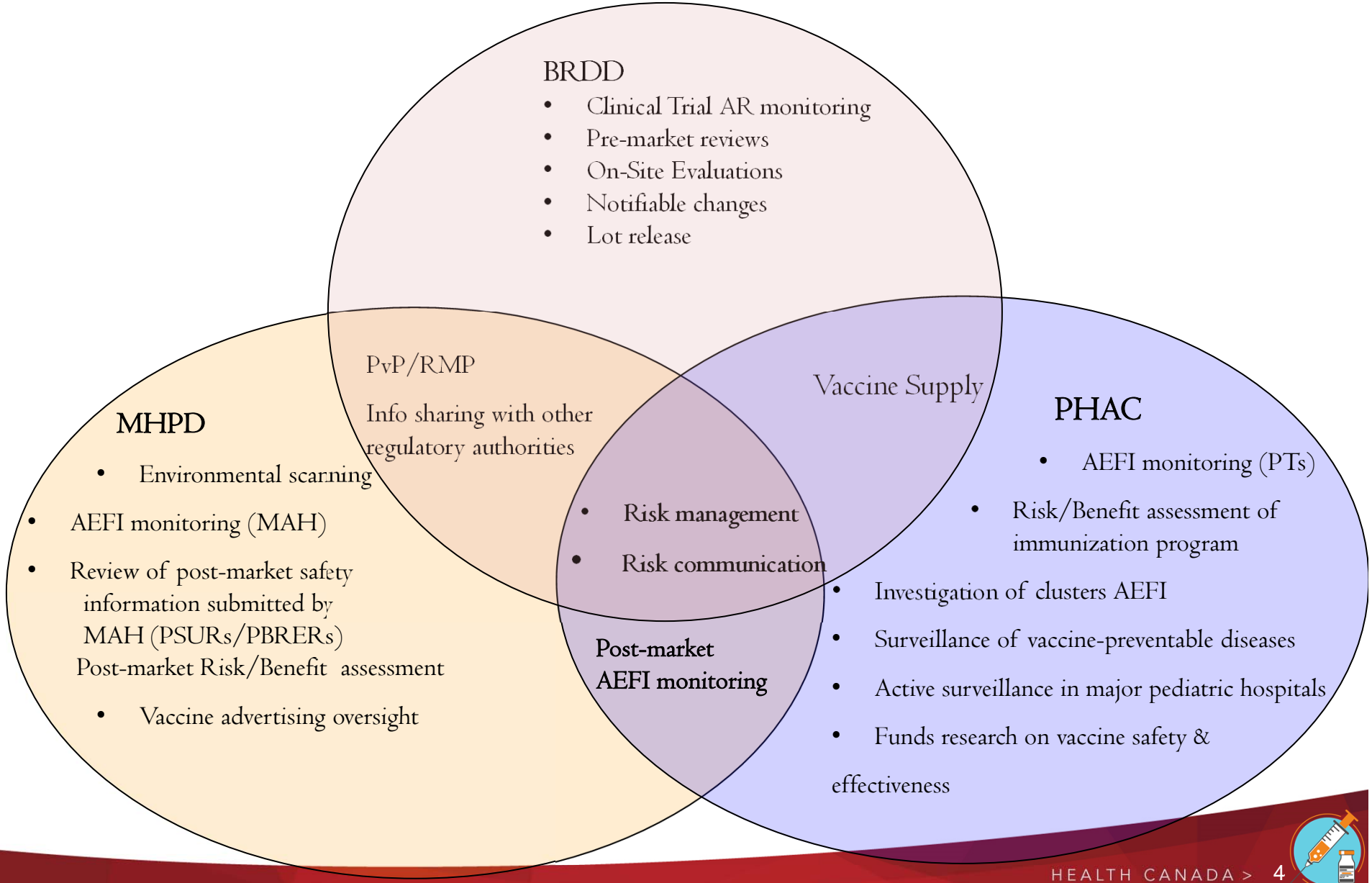
RMP Canadian Addendum

Product Monograph

Educational Materials

Post-market surveillance

Vaccine Activities in Canada



Covid-19 vaccines authorized in Canada

mRNA COVID-19 vaccines

Pfizer-BioNTech
(tozinameran)
December 9, 2020

Moderna
(mRNA-1273
SARS-CoV-2)
December 23, 2020

Viral Vector vaccines

AstraZeneca and COVISHIELD
(ChAdOx1-S
[recombinant])
February 26, 2021

Janssen
(AD26.COV2.S
[recombinant])
March 5, 2021

https://covid-vaccine.canada.ca/

Terms and Conditions: Risk Management Plan

1. **Adverse Reactions**
   - Treat as a priority
   - Identify that the Vaccine is authorized under IO

2. **Immunization Reminder Card / Immunization Information Card * Vaccination Errors Prevention**

3. **Monthly Safety Reports**
   - Interval/Cumulative Reports Global and for Canada
   - Exposure, including race, ethnicity, special populations (frail elderly, immunocompromised, indigenous and remote populations
   - Adverse Events of Special Interest
   - **Vaccination failure / lack of efficacy or effectiveness (including confirmed and suspected cases) reports and vaccination errors (categories according to preferred terms)**
   - Changes to Reference Safety Information
   - Ongoing and closed signals
   - Fatal reports, vaccination failure, interactions
   - Summary outcomes of pharmacovigilance activities
   - Overall benefit/risk assessments

4. **Risk Management Plan**
   - Canadian Addendum to the RMP – To add elements of safety specification and/or PV
   - Updated Core/EU RMP and Updated RMP Canadian Addendum when a new safety issue is identified

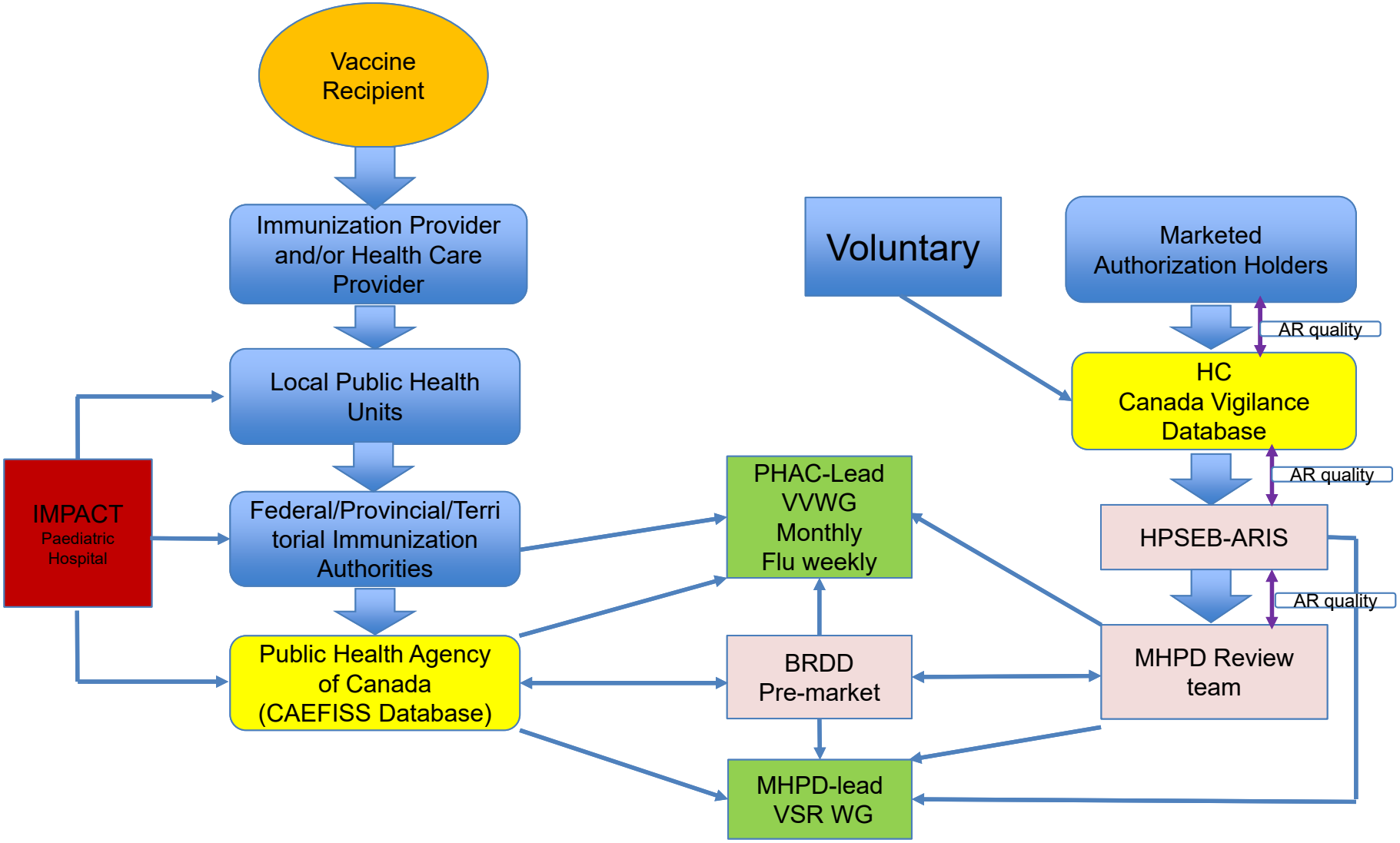
Medication Errors/Vaccination Errors

- Canada Vigilance database
  - Where manufacturers are required to report serious adverse events following immunization (AEFIs). Canada Vigilance also receives AEFI reports submitted voluntarily by healthcare professionals and the public.
  - All AEFIs including vaccination errors are assessed on a weekly basis for all COVID-19 vaccines

- Monthly Summary Safety Reports
  - Global data are collected and assessed by the MAH on a monthly basis
  - Some reports of vaccination errors are with no other adverse events other than the term of error.

- Examples of reported preferred terms include:
  - Product administered to a patient of inappropriate age
  - Incorrect dose administered
  - Underdose
  - Syringe issue
  - Expired product administered

Reporting pathway for AEFIs Reviews



Health Canada Advisories

AstraZeneca COVID-19 Vaccine and COVISHIELD: Risk of Thrombosis with Thrombocytopenia

Starting date:	March 24, 2021
Posting date:	March 24, 2021
Type of communication:	Dear Healthcare Professional Letter
Subcategory:	Biologic/vaccine
Source of recall:	Health Canada
Issue:	Important Safety Information
Audience:	Healthcare Professionals
Identification number:	RA-75211

Report a Concern

Last updated: 2021-03-24

▪ Issue ▪ Who is affected ▪ Report health or safety concerns

Audiences

Healthcare professionals including infectious disease physicians, family physicians, emergency room physicians, hematologists, neurologists, pharmacists, public health officials, nurses and nurse practitioners, and healthcare professionals at identified points of use.

Key messages

- **A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with the AstraZeneca COVID-19 Vaccine.**
- **Health Canada has assessed the available data on the reported events and has determined that the AstraZeneca COVID-19 Vaccine and COVISHIELD (the version of the AstraZeneca COVID-19 Vaccine manufactured by the Serum Institute of India that is currently being distributed in Canada) have not been associated with an increase in the overall risk of thrombosis.**

Authorization of Janssen COVID-19 Vaccine with English-only Vial and Carton Labels

Starting date:	March 5, 2021
Posting date:	March 8, 2021
Type of communication:	Dear Healthcare Professional Letter
Subcategory:	Biologic/vaccine
Source of recall:	Health Canada
Issue:	Supply, Important Safety Information, Product Safety
Audience:	Healthcare Professionals
Identification number:	RA-75077

Report a Concern

Last updated: 2021-03-08

▪ Issue ▪ Who is affected ▪ Report health or safety concerns ▪ Images

IMPORTANT: Access to Canadian-specific labelling and expiration date information during the initial distribution of the Janssen COVID-19 Vaccine.

Audience

Healthcare professionals including infectious disease physicians, pharmacists, family physicians, public health officials, nurses and nurse practitioners. Healthcare professionals at the identified points of use. Innomar Strategies Inc. (Logistics Services Provider) is distributing Janssen COVID-19 Vaccine to vaccination locations where administration of the vaccine will occur, as outlined by provincial and territorial governments and public health authorities.

COVID-19 Vaccine Moderna: Updated English-only Global Vial and Carton Labels and Post-Market Adverse Reaction Information

Starting date:	February 22, 2021
Posting date:	February 22, 2021
Type of communication:	Dear Healthcare Professional Letter
Subcategory:	Biologic/vaccine
Source of recall:	Health Canada
Issue:	Important Safety Information, Product label update, Supply
Audience:	Healthcare Professionals
Identification number:	RA-75039

Report a Concern

Last updated: 2021-02-22

▪ Issue ▪ Who is affected ▪ Report health or safety concerns ▪ Images

Audiences

Healthcare professionals including infectious disease physicians, pharmacists, family physicians, public health officials, nurses and nurse practitioners, and healthcare professionals at identified points of use. Innomar Strategies Inc. (the Canadian importer and distributor) is distributing COVID-19 Vaccine Moderna doses directly to vaccination locations where administration of the vaccine will occur, as outlined by provincial and territorial governments and public health authorities.

Key messages

- **The COVID-19 Vaccine Moderna (mRNA-1273 SARS-CoV-2 vaccine) Product Monograph (PM) has been updated with post-market adverse reaction information identified during pharmacovigilance activities. Anaphylaxis has been reported following COVID-19 Vaccine Moderna administration outside of clinical trials. This new information does not change the benefit-risk profile of this product.**

Pfizer-BioNTech COVID-19 Vaccine: Updated Dosage and Administration and Post-Market Adverse Reaction Information

Starting date:	February 8, 2021
Posting date:	February 9, 2021
Type of communication:	Dear Healthcare Professional Letter
Subcategory:	Biologic/vaccine
Source of recall:	Health Canada
Issue:	Supply, Product label update, Important Safety Information
Audience:	Healthcare Professionals
Identification number:	RA-74965

Report a Concern

Last updated: 2021-02-09

▪ Issue ▪ Who is affected ▪ Report health or safety concerns ▪ Images

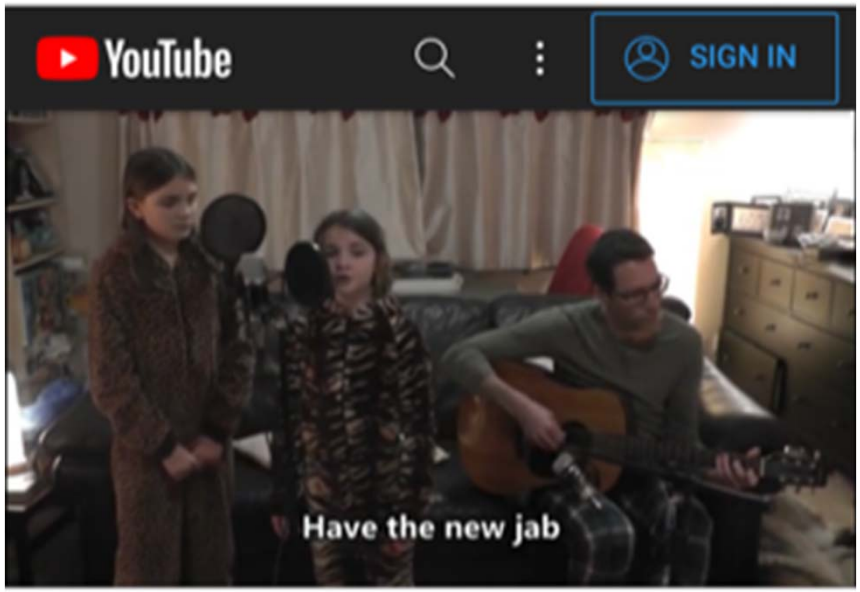
Audiences

Healthcare professionals including infectious disease physicians, pharmacists, family physicians, public health officials, nurses and nurse practitioners. Healthcare professionals at the identified Points of Use (POUs). Pfizer is distributing Pfizer-BioNTech COVID-19 Vaccine doses directly to POUs, vaccination locations where administration of the vaccine will occur, as outlined by the provincial governments and public health authorities.

Key messages

- **The Pfizer-BioNTech COVID-19 Vaccine Product Monograph (PM) and vial and carton labels are being updated to reflect an increase in the number of doses that can be extracted from each vial, from 5 doses per vial to 6 doses. This global label update to 6 doses has been implemented to minimize vaccine wastage and facilitate access to the vaccine supply during the pandemic.**
- **It is possible to extract a 6th dose of 0.3 mL of the diluted vaccine using low dead-volume syringes and/or needles. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is important to minimize volume loss during dose extractions.**

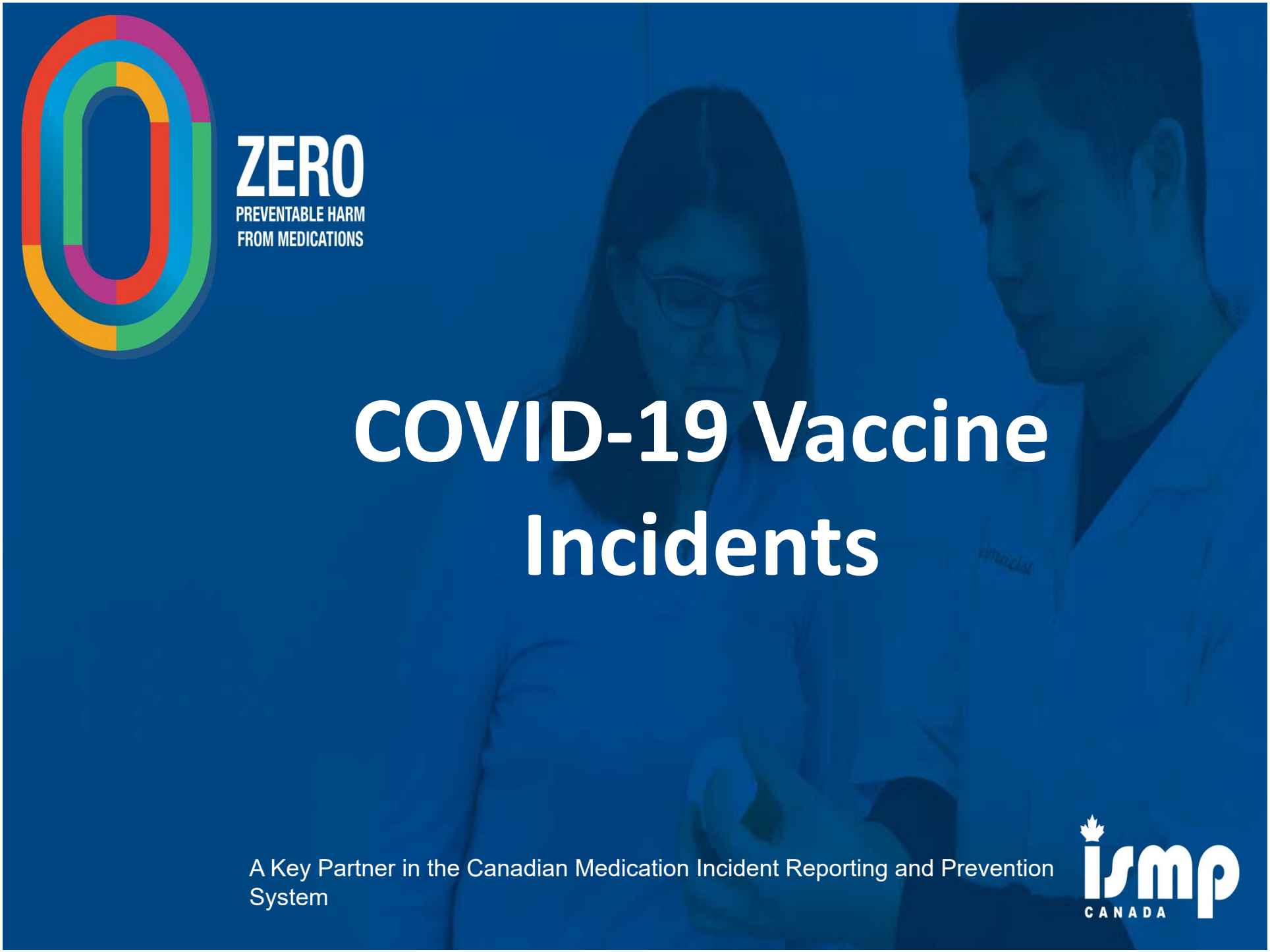
Thank you!



"Have The New Jab" - "Hallelujah" adapted by the Marsh Family

1.5M views

https://www.youtube.com/watch?v=ZnbOKH9Oe9s



COVID-19 Vaccine Incidents

A Key Partner in the Canadian Medication Incident Reporting and Prevention System

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Logistics and Planning

- Patients directed to wrong clinic address
- Wasted doses
  - Need for a prioritized wait list
- Transitions of care
  - Elderly patient accidently given 2 different COVID-19 vaccine "1st doses"
- Delayed vaccination of LTC residents due to inoculation with other vaccines

Preparation and Administration

Preparation

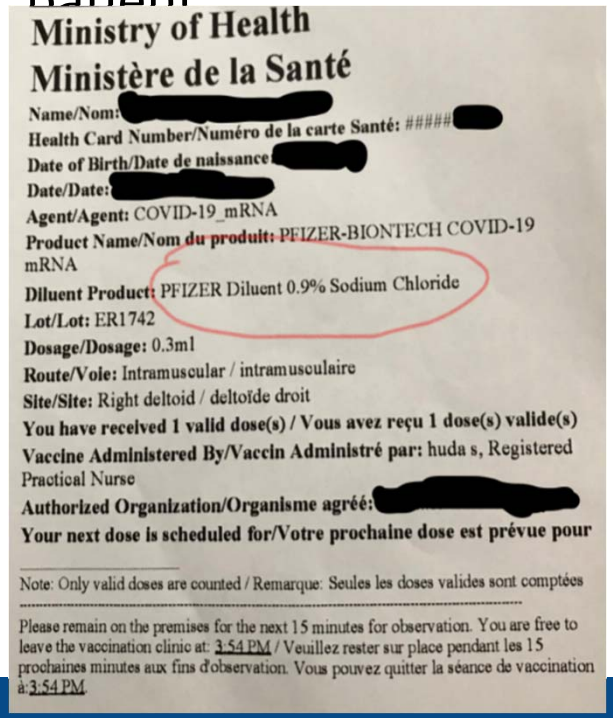
- Double dilution
- Needle-syringe misconnection

Administration

- Administration to non-approved age group
- SIRVA

Documentation

- Wrong vaccine on documentation provided to patient



Ministry of Health
Ministère de la Santé

Name/Nom: [redacted]
Health Card Number/Numéro de la carte Santé: #####[redacted]
Date of Birth/Date de naissance: [redacted]
Date/Date: [redacted]
Agent/Agent: COVID-19_mRNA
Product Name/Nom du produit: PFIZER-BIONTECH COVID-19 mRNA
Diluent Product: PFIZER Diluent 0.9% Sodium Chloride
Lot/Lot: ER1742
Dosage/Dosage: 0.3ml
Route/Voie: Intramuscular / intramusculaire
Site/Site: Right deltoid / deltoïde droit
You have received 1 valid dose(s) / Vous avez reçu 1 dose(s) valide(s)
Vaccine Administered By/Vaccin Administré par: huda s, Registered Practical Nurse
Authorized Organization/Organisme agréé: [redacted]
Your next dose is scheduled for/Votre prochaine dose est prévue pour

Note: Only valid doses are counted / Remarque: Seules les doses valides sont comptées

Please remain on the premises for the next 15 minutes for observation. You are free to leave the vaccination clinic at: 3:54 PM / Veuillez rester sur place pendant les 15 prochaines minutes aux fins d'observation. Vous pouvez quitter la séance de vaccination à: 3:54 PM.

Patient Experiences

- Confusing portals to book appointments
- Long waits outside clinics for older patients with appointments
- Plenty of gratitude and tears of joy!!