

CVSIG April 8, 2021

Date and Time:

Thursday, April 8th, 2021

10 am – 11 am EST

Attendees

Present	Country/ Organization	Name		Present	Country/ Organization	Name
	Brazil	Mario Borges		x	Netherlands	Jacob Dik
x	Canada	David U (temporary)			Netherlands	Rob Essink
x	Canada	Dorothy Tscheng			New Zealand	Michael Tatley
x	Canada	Gary Lee		x	Norway	Sigurd Hortemo
x	Canada	Gloria Giraldo			Saudi Arabia	Hind Modaimagh
x	Colombia	Ismael Basto		x	Singapore	Augustine Tee
	Colombia	Juan Pablo Osorio		x	Spain	Maria Jose Otero
x	European Medicines Agency (EMA)	Alexios Skarlatos		x	Uppsala Monitoring Centre (UMC)	Alem Zekarias
x	France	Etienne Schmitt		x	USA	Christina Michalek
x	France	Marie-Blanche Rabier		x	USA	Jill Paslier
x	Germany	Birgit Vogt		x	USA	Merissa Andersen
x	Germany	Torsten Hoppe-Tichy		x	USA	Mike Cohen
x	Health Canada	Jhona Rose		x	USA	Rita Jew
x	Health Canada	Sally Pepper		x	ECRI	Andrew Furman (guest)
	Hong Kong	Benjamin Lee		x	USA	Donald Singh (resident at ISMP)
x	International Society of Pharmacovigilance (ISoP)	Angela Caro		x	USA	Matthew Fried
x	International Society of Pharmacovigilance (ISoP)	Brian Edwards		x	US Food and Drug Administration (FDA)	Lubna Merchant
	Ireland	Muriel Pate			US Food and Drug Administration (FDA)	Karen Farizo
x	Ireland	Niamh O'Hanlon		x	US Food and Drug Administration (FDA)	Craig Zinderman
	Medicines and Healthcare products Regulatory Agency (MHRA) UK	Mitul Jadeja			United Arab Emirates (UAE)	Sohail Fitieh
x	Morocco	Ghita Benabdallah			Vaccine Dynamics USA	John Grabenstein
x	Morocco	Houda Sefiani		x	World Health Organization (WHO)	Ayako Fukushima
	National Health Service (NHS) UK	Jennie Hall				

Topic	Presenter	Discussion	Action Items
Welcome	Chris Michalek	Introduction	none
Member Presentations- The Canadian Experience	Sally Pepper, Jhona Rose, Dorothy Tscheng, Gloria Giraldo- ISMP Canada and Health Canada	<p>Vaccine approval process</p> <ul style="list-style-type: none"> Interim order- temporary regulatory pathway for flexible and agile review process <p>Vaccine activities in Canada</p> <ul style="list-style-type: none"> BRDD (Biologic and Radiopharmaceutical Drugs Directorate) MHPD (Marketed Health Products Directorate) PHAC (Public Health Agency of Canada) <p>Available vaccines</p> <ul style="list-style-type: none"> Pfizer-BioNTech, Moderna, AstraZeneca, Janssen <p>Terms and conditions for risk management plan of vaccines</p> <ul style="list-style-type: none"> Adverse reactions Immunization reminder and information card Monthly safety reports Risk management plan <p>Medication and Vaccine Errors</p> <ul style="list-style-type: none"> Canada Vigilance database Monthly summary safety reports <p>Reporting pathways for adverse events</p> <ul style="list-style-type: none"> Public health- vaccine recipient reports to healthcare practitioner to public health units Report to Health Canada <p>Health Canada Advisories</p> <ul style="list-style-type: none"> Advising on vaccine communications <p>Safety concerns</p> <ul style="list-style-type: none"> Patients directed to wrong clinic address Transitions of care (given different manufacturer for second dose)- vaccination records may not be transferred upon admission to hospital Wasted doses Delayed vaccination of LTC residents due to inoculation with other vaccines SIRVA Non-approved age group Dilution/preparation errors Wrong documentation provided to patients Confusing portals to book appointments Long waits outside clinics for older patients with appointments 	none
Member Presentations- The Norwegian Experience	Sigurd Hortemo	<p>Denmark and Austria suspended batch or general use of AstraZeneca vaccine due to two reports of blood clots- patients admitted to hospital</p> <p>Rare cases of unusual blood clots and low blood platelets after AZ vaccine</p> <ul style="list-style-type: none"> Possible mechanism: immune response, similar to heparin induced thrombocytopenia Symptoms: Blood clots in brain or abdomen, low platelets, sometimes bleeding Treatment is difficult: corticosteroids <p>Now listed as rare side effect for AZ vaccine</p> <ul style="list-style-type: none"> Approx. 1:100 000 cases 	none

		<p>Still consider benefit to outweigh risk</p> <ul style="list-style-type: none"> • 3 deaths following AZ vaccine in Norway • 10 deaths from COVID-19 for people under 50 years old in Norway 	
Update from Uppsala Monitoring Centre	Alem Zekarias	<p>COVID-19 vaccine surveillance</p> <ul style="list-style-type: none"> • Timely detection and reporting of adverse events following immunization <p>WHO programme for international drug monitoring</p> <ul style="list-style-type: none"> • 143 members and 28 associate members <p>VigiBase</p> <ul style="list-style-type: none"> • Database for adverse event reports • 440 000 reports for COVID-19 vaccines <p>Signal detection</p> <ul style="list-style-type: none"> • Can identify potential safety concerns for further investigation • Syndrome detection- find patterns <p>Error reports: 1697 COVID-19 vaccine reports currently.</p> <ul style="list-style-type: none"> • US, UK, Germany, France, Poland top reporters • 34 cases life threatening, but no deaths to date • Top errors <ul style="list-style-type: none"> ○ Inappropriate schedule of product administered ○ Inappropriate age ○ Wrong dose ○ Wrong product 	none
Review of CVSIG survey	ISMP Fellows; Merissa Andersen and Jill Paslier	<p>Summary table provided of vaccines available in different countries (as of March 2021)</p> <ul style="list-style-type: none"> • Most widely used vaccines: Pfizer-BioNTech, Moderna, AstraZeneca <p>Roll out plan generally starts with older adults, healthcare professionals and residents in care homes</p> <p>Most common safety concerns:</p> <ul style="list-style-type: none"> • Dilution errors • Vaccine waste • Errors with second dose • Adverse events including allergic reactions and flu like symptoms (resulting in low staffing at healthcare facilities the day after vaccine administration) 	none
Next Steps	Chris Michalek	<p>Will accept a few more countries to share their experience with the next CVSIG group in May</p> <p>Next meeting we will start discussing best practices and recommendations around COVID-19 Vaccines</p>	Identify a couple more countries to share their experiences in the next CVSIG meeting
Respectfully submitted, Jill Paslier, PharmD, CSP, ISMP International Medication Safety Management Fellow			