

IMSN COVID-19 Vaccine Safety Interest Group (CVSIG)

Date and Time: Thursday, March 11th, 2021

10 am – 11 am EST

Attendees

Present	Country	Name		Present	Country	Name
x	Brazil	Mario Borges (Rosa?)		x	Saudi Arabia	Hind Modaimagh
x	Canada	David U (temporary)		x	Singapore	Augustine Tse (Tee)
x	Canada	Dorothy Tscheng		x	Spain	Maria Jose Otero
x	Health Canada	Sally Pepper		x	UAE	Sohail Fitieh
	Health Canada	Jhona Rose		x	UMC	Alem Zekarias
x	Colombia	Ismael Basto		x	USA	Christina Michalek
	Colombia	Juan Pablo Osorio		x	USA	Mike Cohen
x	EMA	Alexios Skarlatos		x	FDA	Lubna Merchant
x	France	Marie-Blanche Rabier		x	USA	Jill Paslier
x	France	Etienne Schmitt		x	USA	Merissa Andersen
x	Germany	Torsten Hoppe-Tichy			USA	Bennet Ninan
x	Germany	Birgit Vogt		x	USA	Rita Jew
	Hong Kong	Benjamin Lee		x	Vaccine Dynamics USA	John Grabenstein
x	Ireland	Muriel Pate		x	WHO	Ayako Fukushima
x	Ireland	Niamh O'Hanlon			UK (NHS)	Pauline Lockey
x	ISoP	Brian Edwards			Netherlands	Joost de Metz IVM
	ISoP	Angela Cora		x	Health Canada	Gloria Giraldo
x	Morocco	Ghita Benabdallah			Saudi Arabia	Norah BinSabbar
x	Morocco	Houda Sefiani		x	US FDA CBER	Craig Zinderman
x	Netherlands	Rob Essink		x	US FDA CBER	Karen Farzio
x	Netherlands	Jacob Dik		x	UK (NHS)	Jennie Hall
	New Zealand	Michael Tatley				
	Norway	Sigurd Hortemo				
x	Novartis- USA	Matt Fried				

Topic	Presenter	Discussion	Action Items
Welcome	Chris Michalek	<p>New additions since last meeting: Karen Farizo and Craig Zinderman from FDA (US) Center for Biologics Evaluation and Research (CBER)- regulates biological products (for human use) Matt Fried- Novartis Pharmaceuticals Corporation, IMSN associate member</p>	none
Approval of Charter	Chris Michalek	<p>The two primary objectives of IMSN's CVSIG group and our plan to achieve them:</p> <ol style="list-style-type: none"> 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. <p>We will achieve objective #1 through meetings, discussions and blog posts. Several countries will present their vaccine experience to group members during our March (France, Ireland, and US) and April meetings.</p> <p>We will achieve objective #2 through data analysis, consolidation and previously reported and discussed best practices for vaccine preparation and administration. This will be done with input from CVSIG members.</p> <p>The findings and recommendations will be made publicly available in a specific section of the IMSN website.</p> <p>Charter approved in meeting 3/11/2021 10:05 am EST</p>	
IMSN Reporting Portal	David U	<p>IMSN created an international error reporting portal for the international healthcare community to learn from events and be in a better position to prevent future events and possible patient harm. The information provided will always be confidential and may be used in collaboration with international regulators and other patient safety organizations to improve patient safety.</p> <p>Portal is only available in English currently.</p>	<p>Please report errors (including vaccine related errors) on this portal</p> <p>Per Brian Edwards: we will share reporting portal within the International Society of Pharmacovigilance</p>
The approach to COVID-19 vaccinations	Chris Michalek	<p>We asked each presenter to discuss: roll out plan, strategies to ensure second doses (where required) are given as directed, how vaccines are being prepared (who is drawing up the doses, how are they being labeled, any special preparation steps), who is vaccinating (practitioner type and vaccine locations), and errors they are seeing)</p>	none
France COVID-19 Vaccine Update	Marie-Blanche Valnet-Rabier	<p>Available vaccines: Moderna, Pfizer/BioNTech (Comirnaty), AstraZeneca</p> <p>Roll out: mRNA vaccines for persons 75+/50+ with comorbidities, AstraZeneca first for HealthCare workers & starting in March general population. Health ministry portal provides resources online.</p>	none

		<p>Ansm drug agency has drug information/technical sheets (e.g., what to do in the event of an adverse event).</p> <p>Strategies to ensure second dose: Web tool provides traceability and allows patients to schedule first and second doses</p> <p>Safety concerns/errors: -Administration either too diluted vaccine or just administration of the diluent. -Some wrong site administrations have been reported too. -Reports of severe flu like syndrome with the AZ vaccine with a lot of health professionals in work stopping because of high fever (40°C). - Expired product -Wrong injection technique (not in deltoid, incorrect needle size) -product preparation error (with 10% sodium chloride instead of 0.9%) - second dose is still indicated if patient only had a mild reaction to the first dose (e.g., urticaria)</p> <p>Strengths: -reactivity -interprofessional collaboration -pharmacological expertise with enhanced surveillance -real time communication -Developed expertise for each vaccine with a weekly analysis of all adverse events and you can find each report on the ANSM website.</p>	
Ireland COVID-19 Vaccine Update	Niamh O’Hanlon	<p>Available vaccines: Moderna, Pfizer/BioNTech (Comirnaty), AstraZeneca</p> <p>Roll out: Provisional sequencing for groups to be vaccinated based on clinical priorities and an ethical framework to minimise harm, and maintain fairness, moral equality and reciprocity. Started with Phase 1 & 2: Long stay residential care residents >65 yrs old, and front line healthcare workers Phase 3 & 4: People over 70 (starting with >85yr olds) and other healthcare workers Over 500,000 total vaccine doses given to date.</p> <p>How vaccines are being prepared: Pharmacy involvement for dilution, process flow, medication information, vial reconciliation</p> <p>Who is vaccinating: -nursing and medical staff -community pharmacists in the future</p> <p>Safety concerns/errors: – availability of vaccines – availability of consumables – specifically low dead space/volume syringes to optimize doses obtained – vaccine stewardship (from receipt to admin to post dose monitoring) – as we scale up to mass vaccination programs, risk mitigation to optimize national COVID19 vaccination program -issues around transport, storage, standards, cold chain management -communication around vaccine delivery and timing -variability in vial yield -insufficient consumables -risk of blood borne disease transmission with multidose vials</p>	none

		<ul style="list-style-type: none"> -planning for end of clinic doses/standby list -adverse drug reactions/side effects <p>Learning opportunities</p> <ul style="list-style-type: none"> -ensure new staff aware of process in place and why -plan for end of clinic to ensure zero waste (standby lists) -logistics- locations, sequencing, vaccine choice -consumables and low dead space syringe availability -time out between clinic change of vaccines -resources: Covid-19 vaccine bulletin, FAQ document, clinical guidance 	
USA COVID-19 Vaccine Update	Michael Cohen	<p>Available vaccines: Moderna, Pfizer/BioNTech, Janssen (single dose)</p> <p>Roll out: The roll out plan is state dependent. The vaccine is generally available to the following groups in this order: 1a- healthcare personnel, long-term care facility residents 1b- frontline essential workers, people aged 75 years and older 1c- people aged 65-74 years and people aged 16-64 years with underlying medical conditions, other essential workers 2- all other individuals</p> <p>Safety concerns/errors:</p> <ul style="list-style-type: none"> -Dilution errors with the Pfizer/BioNTech COVID-19 vaccine. -Moderna COVID-19 vaccine and casirivimab COVID-19 monoclonal antibody mix up to do look alike packaging and basic label on the monoclonal antibody. -Waste of vaccine doses. -Administration to the wrong age group. -Error with scheduling the second dose or giving a different manufacturer for the second dose. -Allergic reactions. -Eligibility criteria is state specific and may lead to confusion. -shoulder injuries related to vaccine administration (SIRVA) due to incorrect injection technique <p>Tools and resources:</p> <ul style="list-style-type: none"> -USP COVID-19 vaccine handling toolkit -ISMP COVID-19 Resources -ASHP/ISMP/USP FAQ for Optimizing COVID-19 Vaccine Preparation and Safety 	none
Questions		<p>Q: Mario Rosa: Is there any recommendation from a patient who received the 1st dose and has to undergo surgery?</p> <p>A: John Grabenstein: CDC's Clinical Considerations documents do not discuss surgery. We can take analogy from post-splenectomy vaccination, which is that not much wait is needed. Let the patient recover from the surgery acutely, then vaccination should be fine.</p>	none
Next Steps		<p>Meeting in April that will include a couple more presentations.</p> <p>Presentation of the compiled country data (Jill and Merissa)</p>	none
Respectfully submitted, Jill Paslier, PharmD, CSP, ISMP International Medication Safety Management Fellow			