

# CVSIG February 11, 2021

Date and Time: February 11, 2021 at 10 am ET

## Attendees

Present	Country	Name
x	Brazil	Mario Borges Rosa
x	Canada	David U (temporary)
x	Canada	Dorothy Tscheng
x	Canada	Sally Pepper
x	Canada	Jhona Rose
	Colombia	Ismael Basto
x	Colombia	Juan Pablo Osorio
x	EMA	Alexios Skarlatos
x	France	Marie-Blanche Rabier
x	France	Etienne Schmitt
	Germany	Torsten Hoppe-Tichy
x	Germany	Birgit Vogt
	Hong Kong	Benjamin Lee
x	Ireland	Muriel Pate
x	Ireland	Niamh O'Hanlon
x	ISOP	Brian Edwards
x	ISOP	Angela Cora
x	Morocco	Ghita Benabdallah
x	Morocco	Houda Sefiani
	Netherlands	Rob Essink
x	Netherlands	Jaap Dik
	New Zealand	Michael Tatley
x	Norway	Sigurd Hortemo
x	Saudi Arabia	Hind Modaimagh
x	Singapore	Augustine Tse (Tee)
x	Spain	Maria Jose Otero
	UAE	Sohail Fitieh
x	UMC	Alem Zekarias

x	USA	Christina Michalek
x	USA	Mike Cohen
x	FDA	Lubna Merchant
x	USA	Jill Paslier
x	USA	Merissa Andersen
x	USA	Bennet Ninan
x	USA	Rita Jew
x	Vaccine Dynamics USA	John Grabenstein
x	WHO	Ayako Fukushima
	UK (NHS)	Pauline Lockey
x	?	Joost de Metz IVM
x	?	Gloria Giraldo
x	?	Norah Binsabbar

Topic	Presenter	Discussion	Action Items
Welcome	David U, Chris Michalek, Mike Cohen	<p>Welcome to IMSN members and key stakeholders:</p> <p>Purpose of group:</p> <ul style="list-style-type: none"> <li>As the Covid-19 vaccines are being rolled out across the globe, we are all concerned about some of the safety issues relating to the operation and the process of vaccination including transport, storage, preparation, administration, and patient monitoring. The IMSN executive committee has proposed to develop an international interest group to address these potential issues.</li> </ul> <p>ISMP International Fellows:</p> <ul style="list-style-type: none"> <li>Merissa Andersen</li> <li>Jill Paslier</li> </ul>	
Framework for group activities	Chris Michalek	<p>Introduction to draft charter</p> <ul style="list-style-type: none"> <li>key points, sharing of experiences, focus on safety, how we can address challenges, timeline duration of 2021</li> </ul> <p>Plan</p> <ul style="list-style-type: none"> <li>Plan is to combine virtual meeting sharing with IMSN blog posts</li> <li>Virtual meetings to begin monthly; we believe there will be a lot to share initially</li> </ul>	Group can provide feedback on draft charter via email or blog

		<ul style="list-style-type: none"> <li>As time goes on, we will re-evaluate meeting frequency and extend to perhaps every 6 or 8 weeks</li> <li>Virtual meeting – to keep on time and allow everyone to speak, our goal to have a facilitated discussion; we would like to hear from everyone during the live meeting</li> </ul>	
Communication	Chris Michalek	<p>Communication in between meetings will be via IMSN blog</p> <ul style="list-style-type: none"> <li>There is a CVSIG Forum topic in the IMSN blog</li> <li>We will post questions- group can respond and share information</li> <li>CVSIG information location on IMSN site: IMSN Advocacy; Vaccine Safety; COVID-19 Vaccine Safety</li> </ul>	
Spreadsheet Data	Chris Michalek, John G.	<p>COVID 19 Summary</p> <ul style="list-style-type: none"> <li>Lists vaccine efforts around the world</li> <li>This will be available on the website as part of the CVSIG documents</li> </ul>	Please let us know if spreadsheet data is not up to date or if any changes are needed
Reporting Portal	Mike Cohen	<p>International error reporting portal on the IMSN website</p> <ul style="list-style-type: none"> <li>Reports go to ISMP International Fellows: Merissa Andersen, Jill Paslier</li> <li>Can be used for all medication errors and vaccine errors</li> <li>See “Reporting Portal” on IMSN toolbar</li> </ul>	
Questions		<p>Does this group have any gaps for areas of the world?</p> <ul style="list-style-type: none"> <li>A few areas not represented, group may reach out to individuals in these areas</li> </ul> <p>Question about pooling vaccines: is any country considering using part vials to obtain additional doses? Question arose with Pfizer BioNTech vaccine</p> <ul style="list-style-type: none"> <li>Our national guidance states not to pool vaccines from different vials (even from same batch) to obtain additional dose <ul style="list-style-type: none"> <li>Same recommendation in Norway, Ireland, USA, Canada</li> </ul> </li> </ul> <p>Any other reported deaths</p> <ul style="list-style-type: none"> <li>Norway: system for reporting adverse events. Started vaccination efforts with nursing homes, noticed changed in deaths in nursing homes, may or may not be related to vaccine side effects. Recommend evaluating risk/benefit of vaccination with very frail elderly people.</li> <li>France: system to follow adverse events. So far no deaths considered to be related to vaccine. Some deaths with elderly people with comorbidities. Some severe reactions that could potentially result in deaths.</li> </ul>	See chat transcript for more

		<p>Dr. Grabenstein mentioned, As I gathered information regarding the Oxford/AstraZeneca vaccine (AZD1222), I noticed that the MHRA and EMA have assigned different potency measurement systems (viral particles versus infectious units) within prescribing information for apparently the same physical product, but I have seen no conversion factor. How should we understand the difference between units?</p> <ul style="list-style-type: none"> <li>• With respect to John's query might I suggest that Christina writes to EMA and MHRA seeking an explanation and then she can share a response please?</li> </ul>	
Next steps		<p>Future meeting invitations Chris to post survey via blog</p>	<p>Look for survey via blog</p> <p>Follow us on Twitter and LinkedIn</p>
Respectfully submitted, Jill Paslier, PharmD, CSP, ISMP International Medication Safety Management Fellow			