

COVID-19 Vaccine Safety Interest Group (CVSIG) Meeting Minutes

Date and Time:

Thursday, May 6th, 2021

7 am – 8 am EST

Attendees

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

| Topic | Presenter | Discussion | Action Items |
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| Welcome | Chris Michalek | Introduction Recap from last time: heard from Norway, Canada, Sweden and ISMP fellows | None |
| Member Presentations- New Zealand | Dr. Michael Tatley Director New Zealand Pharmacovigilance Centre, University of Otago | NZ Vaccine Safety Surveillance Strategy <ul style="list-style-type: none"> - Passive monitoring <ul style="list-style-type: none"> o CIR monitoring o CARM o Reports are triaged (review for serious reports) o Independent safety monitoring board - Active monitoring - Adverse events - Hospital surveillance - Mortality review group <p>300k doses. 3,300 adverse events. 0.8% reporting rate.</p> <p>CARM to receive reports resulting in HARM.</p> | None |
| Member Presentations- Singapore | Dr. Alvin Lee Deputy Director of Professional Training and Assessment Standards at the Ministry of Health | #iGotMyShot hashtag Scheduling and screening Challenges: <ul style="list-style-type: none"> - Administer vaccine to contraindicated group (e.g., pregnant women, immunocompromised patients) - Booking second dose too early/late Interventions <ul style="list-style-type: none"> - Registration app screens people who are not eligible - Book both doses at the same time - On day of vaccination- another screening for eligibility Vaccine preparation Challenges <ul style="list-style-type: none"> - Compromised cold chain - Incorrect volume of diluent, or undiluted vaccine - Expired vaccines - Mix-ups of similar vials (Moderna COVID-19 vial and Regeneron monoclonal antibody) Interventions <ul style="list-style-type: none"> - 1 venue only holds 1 vaccine (staff only needs to know one, decrease prep errors). Visual guides to help distinguish between two vaccines - SMS alert alerts 3 people if vaccine refrigerator deviates from range. Backup power supply plan required - Prefilled syringes must be stored with corresponding vials - First in/first out system for retrieving vials from refrigerator - Vials labeled with date and time of dilution and expiration date. - Handover checklist when handing over duties (date/time of dilution, dilution status, pre-admin verification of patient and vaccine) - Physically separate are for dilution and administration - Limit distractions for vaccine preparation and administration. No multitasking, staff has adequate rest time. - Staff to check vial and syringe for discoloration or particulates. - Staff to check 5 rights. Vaccinator training Challenges <ul style="list-style-type: none"> - Need to have competent, trained, qualified vaccinators | None |

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| | | <ul style="list-style-type: none"> - Significant manpower needed- training new vaccinators <p>Interventions</p> <ul style="list-style-type: none"> - Training toolkit, and competency assessment - End-to-end guidance for vaccination providers - Ground communication and feedback (site inspections, incident reports, ops instructions) <p>SAE and incident management</p> <p>Challenges:</p> <ul style="list-style-type: none"> - Licensing requirements for handling medical emergencies. <p>Interventions</p> <ul style="list-style-type: none"> - All patients must stay 30 minutes after vaccination for observation - MOH's guidance on management of anaphylaxis and severe allergic reactions - If patient experiences symptoms after leaving vaccination site- protocol for if/when they visit any clinic or hospital - Must submit incident report to MOH within 3 hours (no need to establish causality) - Serious AE: 0.004% <p>Vaccination record</p> <ul style="list-style-type: none"> - Vaccination card - Trace together app - Health hub (personal record) | |
| Member Presentations- Morocco | Dr. Ghita Benabdallah Poison Control and Pharmacovigilance Centre | <p>AEFI surveillance system</p> <ul style="list-style-type: none"> - Collecting data, validation and data analysis, database alimentation, signal detection and validation, risk quantification alert generation, RCA and risk minimization actions <p>Vaccination strategy involving PV</p> <ul style="list-style-type: none"> - Obligatory AE reporting. Organizing monitoring of AEFI at regional and national level. <p>Reporting</p> <ul style="list-style-type: none"> - Phone call, use app, visit doctor → reported to national pharmacovigilance center <p>Vaccination plan</p> <ul style="list-style-type: none"> - AZ and Sinopharm - Primary group 75+, healthcare providers 40+, teachers 45+, police/firemen 40+ - Contraindications: pregnancy/breastfeeding, previous anaphylaxis or angioedema, active ongoing disease <p>Serious adverse events 1.18%</p> <ul style="list-style-type: none"> - Immune system disorders, nervous system disorders, cardiovascular disorders, respiratory disorders, skin disorders | None |
| Member Presentations- Saudi Arabia | Dr. Hind Almodaimagh Chairperson Saudi Medication Safety Center | Plan to cover next time | |
| Next Steps | Chris Michalek | Next Meeting | |

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| | | <ul style="list-style-type: none">- Two more country presentations- Presentation about INN names- Working meeting to identify top concerns and recommendations- Considering booster vaccinations | |
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Respectfully submitted, Jill Paslier, PharmD, CSP, ISMP International Medication Safety Management Fellow