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Activity: Symposium/Workshop
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Challenges and potential of vaccine post-licensure benefit-risk assessments in resource limited countries

Author Block: Daniel Weibel[1], Patrick Zuber[2], Alena Khromava[3], Abraham Oduro[4], Andy Stergachis[5], James Stark[6], Harry Seifert[7], Miriam Sturkenboom[8], Steve Black[9], Andrea Sutherland[7]. [1]Erasmus Medical Center, Rotterdam, Netherlands; [2]WHO, Geneva, Switzerland; [3]Sanofi Pasteur, Toronto, ON, Canada; [4]Navrongo Health Research Centre, Navrongo, Ghana; [5]University of Washington, Washigton, DC; [6]Pfizer, New York, NY; [7]GSK, Brentford, United Kingdom; [8]VaccineGRID Foundation, Basel, Switzerland; [9]Vaccine GRID, Basel, Switzerland

Proposal / Abstract:

Background: Vaccines are cost-effective health interventions and are especially valuable in resource limited countries (RLCs), where infectious disease morbidity and mortality is high. Some vaccines are exclusively introduced in RLCs (e.g. dengue, malaria), while safety profiles are still evolving. For example, recent safety concerns regarding the first vaccine against dengue virus has limited its introduction and use globally. The introduction of novel, new vaccines into RLCs is likely to continue over the next decade. Effective benefit-risk assessments of vaccines, particularly post-licensure, are pivotal to maintaining confidence and uptake of vaccines. In RLCs monitoring and assessment of vaccine benefit-risk issues are still challenging, even though they are pivotal to ensure the safe and effective use and maintain confidence of vaccines.
Objectives: 1) Present findings from assessments of available capacity and infrastructure for vaccine benefit-risk monitoring and evaluation in RLCs. 2) Learn from vaccine benefit-risk monitoring conducted in RLCs. 3) Define opportunities and propose a roadmap to support building sustainable capacity and infrastructure to generate real world evidence on safety and effectiveness of vaccines within an integrated health system
Description: The symposium will be devoted to sharing experiences, gaps and successes using real-world examples. Manufacturers, regulators, public health specialists, and academics discuss the various scenarios, adaptations, and opportunities they have assessed, experienced or envision to meet the desired objectives related to strengthening monitoring and assessing the benefit-risk vaccine profiles in RLCs. International institutions will share their perspectives. Lessons learned will inform monitoring of available vaccines and the introduction of new vaccines or drugs in RLCs.
Symposium format (90 mins, moderators VAXSIG representatives)

1. Introduction (5 min., VAXSIG representatives)
2. WHO perspective on needs, gaps and capacity in RLCs (15 min P. Zuber, WHO, Geneva, Switzerland)
3. Manufacturer perspective on needs, gaps and capacity in RLCs (15 min, Alena Khromava, Sanofi Pasteur, Toronto, Canada)
4. Examples of distributed network studies in RLCs (10 min, Daniel Weibel, Erasmus University Medical Center)Ongoing activities to build capacity in RLCs (15 min. Abraham Oduro, INDEPTH Navrongo, Ghana)
5. The Way forward (15 min Andy Stergachis, University of Washington, USA)
6. Panel discussion and Q & As (15 min.)

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Author Disclosure Information:

D. Weibel: None. **P. Zuber:** None. **A. Khromava:** None. **A. Oduro:** None. **A. Stergachis:** None. **J. Stark:** None. **H. Seifert:** None. **M. Sturkenboom:** None. **S. Black:** None. **A. Sutherland:** None.
Topic (Complete): Benefit-Risk Assessment, Communication, and Evaluation ; Vaccines
Keyword (Complete): post-licensure benefit-risk assessments ; Vaccines ; resource limited countries
Questionnaire (Complete):
Presentation Preference: Symposium only
Workshop Participation : The symposium will be devoted to sharing experiences, gaps and successes using real-world examples. Manufacturers, regulators, public health specialists, and academics will discuss the various scenarios, adaptations, and opportunities they have assessed, experienced or envision to meet the desired objectives related to strengthening monitoring and assessing the benefit-risk vaccine profiles in RLCs. International institutions will share their perspectives. Lessons learned will inform monitoring of available vaccines and the introduction of new vaccines or drugs in RLCs. 7) Panel discussion and Q & As (15 min.)
Presentation Release: Yes
SIG-Endorsed: Yes
If "YES" please select appropriate SIG: Vaccines

Status: Complete