International Alliance for
Biological Standardization

The Role of Real-World Evidence for Regulatory and Public Health Decision Making for Accelerated Vaccine Deployment

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Title: Improving quality of evidence for decision making through innovative design and collaborative studies leveraging RWE platforms: sharing experiences from Influenza vaccine effectiveness evaluation

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**Global Medical Evidence Generation, Influenza, Sanofi*

Background OR Introduction: *(5 lines)*
The digital expansion in healthcare offers the possibility to generate real-world evidence (RWE) on the use and performance of vaccines in a real-world setting, complementing evidence from randomized controlled trials (RCTs). While the use of RWE for informed decision making is not new, as it has been largely used for safety signal evaluation, potential for bias and confounding pose additional challenges for vaccine effectiveness (VE) evaluation.
Challenges OR Issues: *(6 lines)*
Influenza vaccine performance varies across seasons, populations, settings, and outcomes. RCTs, while the gold-standard, are often highly selective in terms of subjects, may not be representative of the general population with various medical conditions, and limit the assessment of broader clinical outcomes and number of seasons. Assessing influenza VE in counties or region with scattered vaccine type utilization, heterogeneous policies and uptakes further underscores the need for wide RWE platforms to produce robust vaccine performance estimates.
Proposed Approach, Approach Being Taken, Proposed Solutions, OR Relevant Guidance: *(10 lines)*
We tested two proofs-of-concept aiming to improve the quality of RWE for VEE. The DANFLU-1 study aimed to assess the feasibility and scalability of an individually randomized pragmatic framework to demonstrate the relative VE of a high-dose influenza vaccination against broader, clinically meaningful endpoints. This platform utilized scalable, innovative methods (electronic consent, digital invitations, randomization integrated into routine clinical practice, and follow-up via national registries) to create a minimally invasive experience for participants and simultaneously generate robust RWE. DRIVE was an Innovative Medicines Initiative project aiming to set up a multi-stakeholder, collaborative pan-European RWE platform for robust influenza VE monitoring. Over 5 years, this project has shown the value of a large and experienced surveillance network, implementation of a master/generic protocol, pre-defined pooled analyses, and multi-stakeholder dialogue to deliver timely RWE for informed decision making.
Conclusions *(3 lines):*
These two proofs-of-concept offer promising solutions to change the use and perception of RWE to support influenza vaccination programs and vaccine coverage. Implementation and acceptance warrant further steps and multi-stakeholder discussions to move to actionable decision-making.