**International Alliance for
Biological Standardization**

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

**September 19-20, 2023
Park Inn Hotel, Leuven, Belgium**

Health information for policy & decision-making on vaccination
What information is needed and available for decision-making? Examples of success and challenges in a small European country.

Laura Cornelissen, *Scientific Expert and team leader for vaccine-preventable diseases, Department of epidemiology and public health, Sciensano*

Dieter Vercauteren, Department of epidemiology and public health, Sciensano
Joris van Loenhout, Department of epidemiology and public health, Sciensano
Koen Blot, Department of epidemiology and public health, Sciensano

Background - To inform decisions on vaccination, adequate, granular, timely and representative data is required. In Belgium, diverse types of data are currently being collected through various networks, ranging from passive surveillance, citizen and lab reporting over administrative data to wastewater surveillance.

Challenges – Unfortunately, challenges are numerous. There is a wealth of information available in administrative data, such as cause-specific death certificates or healthcare reimbursement, but this data often only becomes available after a delay of several years. Case definitions are not always respected, data input comes in heterogenous forms or data is not centralized. Also, issues with data registration sometimes relate back to rudimentary issues such as access to a computer for the vaccinator. A particularly big challenge is the lack of clear guidance on processing personal data for public health use. Especially with regards to linking data from several databases, current procedures in Belgium lack transparency, are administratively heavy and time-consuming.

Proposed solutions – Many aspects of data collection and reporting during the COVID-19 pandemic can be seen as best practice for other diseases and have created a precedent. At the same time, resource and capacity constraints means that it is neither feasible nor desirable to implement the same level of surveillance. Choices will thus have to be made. A particular advantage is that each Belgian citizen has a unique national number of social security which can be used to link databases. A clear legal framework and mandate for the Belgian public health institute could help in simplifying and speeding up approvals for linking databases whilst protecting data safety and confidentiality. To increase public acceptance, the opt-out system, as currently under discussion in the framework of the European Health Data Space, might be of value.

Conclusion – High-quality data is paramount for decision-making but many challenges remain. The COVID-19 experience and European push for more secondary use of health data provides momentum to improve current practices. Data collection, interpretation and reporting come with a cost and sufficient resources should be foreseen.