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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**RWE use for COVID-19 public health decision-making in the UK: experiences, lessons learned, remaining challenges.**

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**INTRODUCTION** - COVID-19 vaccines were rolled out in the UK from Dec 8th 2020.

**CHALLENGES** - The immediate questions related to safety, in particular anaphylaxis, and to the optimal use of the vaccines in terms of the effectiveness of the first dose and whether the interval between doses could be extended. Rapid assessment of real-world data was required to complement clinical trial data.

**APPROACH** - Rapid assessment was achieved using linked data on covid testing and vaccine registry data. The fastest method used the test-negative case-control design, with later assessments of effectiveness done using cohort studies. Real world data were also used to assess population immunity and vaccine immunogenicity and to identify those at highest risk of severe COVID-19. Results by manufacturer using different severity end points and against different strains were presented regularly to JCVI who advised and continue to advice on the vaccine strategy. A UK wide working group was set up to evaluate UK and international studies on effectiveness and come to a consensus. On the safety side UKHSA worked with the MHRA and University research groups to evaluate safety signals and help with risk benefit assessment, such as the risk of VITT (Vaccine-induced thrombocytopenia and thrombosis). Results were presented to JCVI and the vaccine benefit-risk expert working group run by the MHRA.

**CONCLUSIONS** - We have learnt that having rapidly available linkable data along with appropriate statistical methods for analysis is hugely beneficial for decision making. Expertise to critique and understand limitations of methods and communicate these clearly is also needed. Challenges remain to continue to develop and improve these data sources and to retain/improve access. Also, to further understand the best ways to quantify and minimize bias. Designing vaccine roll out in ways that make evaluation less likely to be biased is attractive but often limited by practical considerations.