

**Vaccines and Related Biological Products
Advisory Committee October 14-15, 2021 Meeting
Presentation Meeting**

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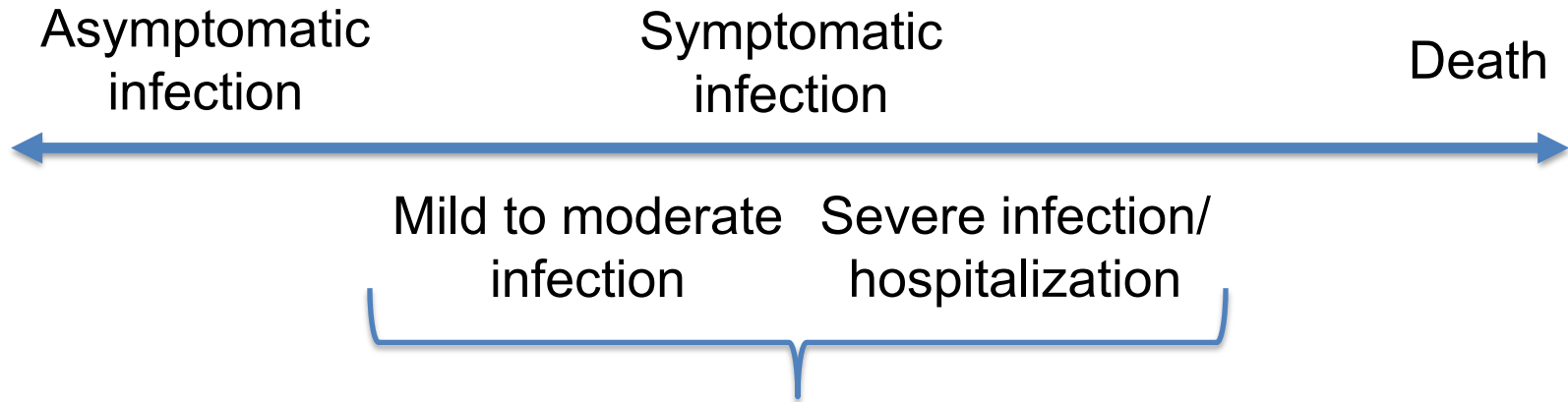
Welcome Remarks

Peter Marks, MD, PhD

169th Meeting of the Vaccines and Related Biologic Products Advisory Committee

October 14, 2021

The Spectrum of SARS-CoV-2 Infection

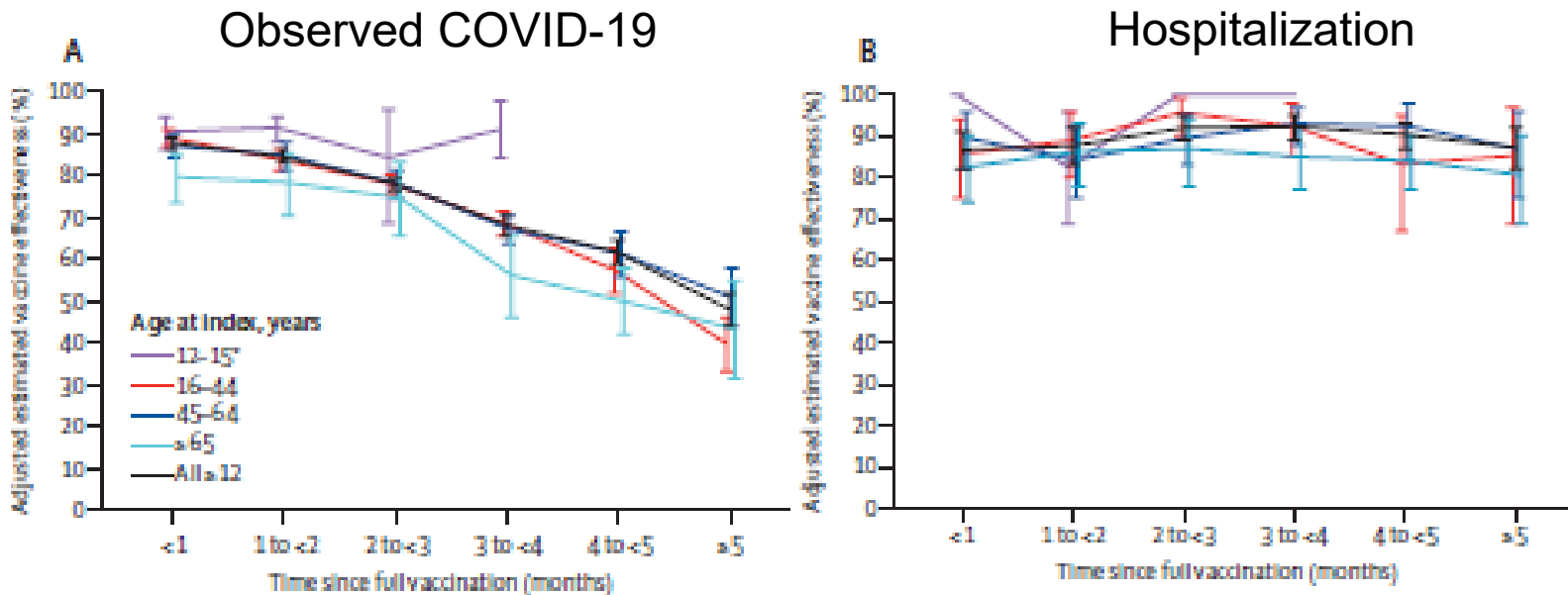


Potentially associated with Long COVID-19:
Cardiac, pulmonary, neurologic and other symptoms

Vaccine Effectiveness Over Time

- Pfizer-BioNTech, Moderna, and Janssen have all submitted data suggesting some waning of effectiveness over time
- Most evidence is based on neutralizing antibody titers or real-world evidence (RWE) on symptomatic infection
- Separating waning effectiveness from reduced effectiveness against variants, such as Delta, can be challenging
- Vaccines are still very effective against serious outcomes

RWE on Effectiveness of Pfizer-BioNTech

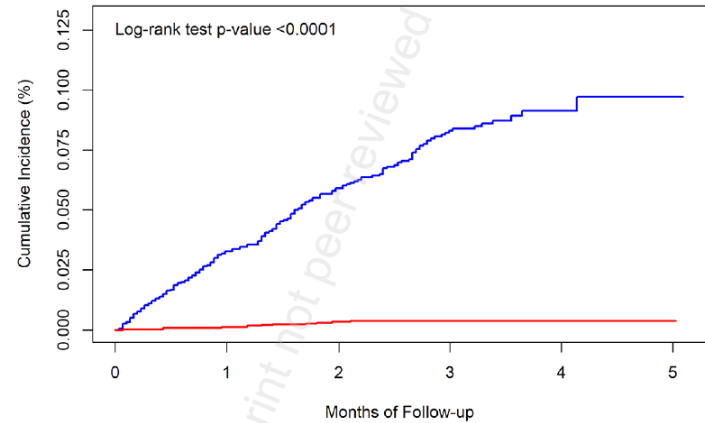
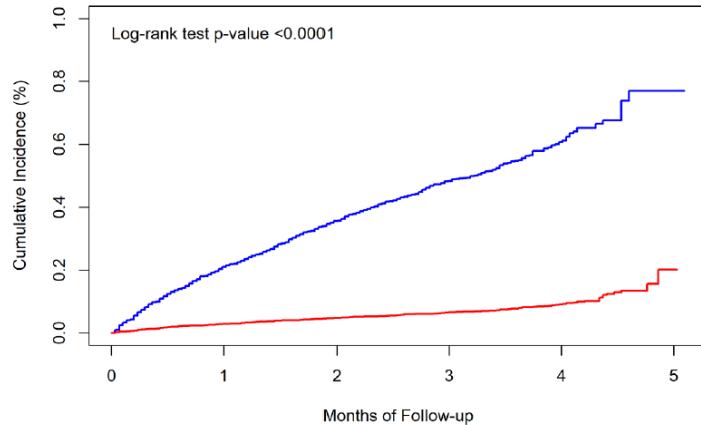


Source: Tartof SY et al., Lancet, published online October 4, 2021

RWE on Effectiveness of Moderna

Observed COVID-19

Hospitalization

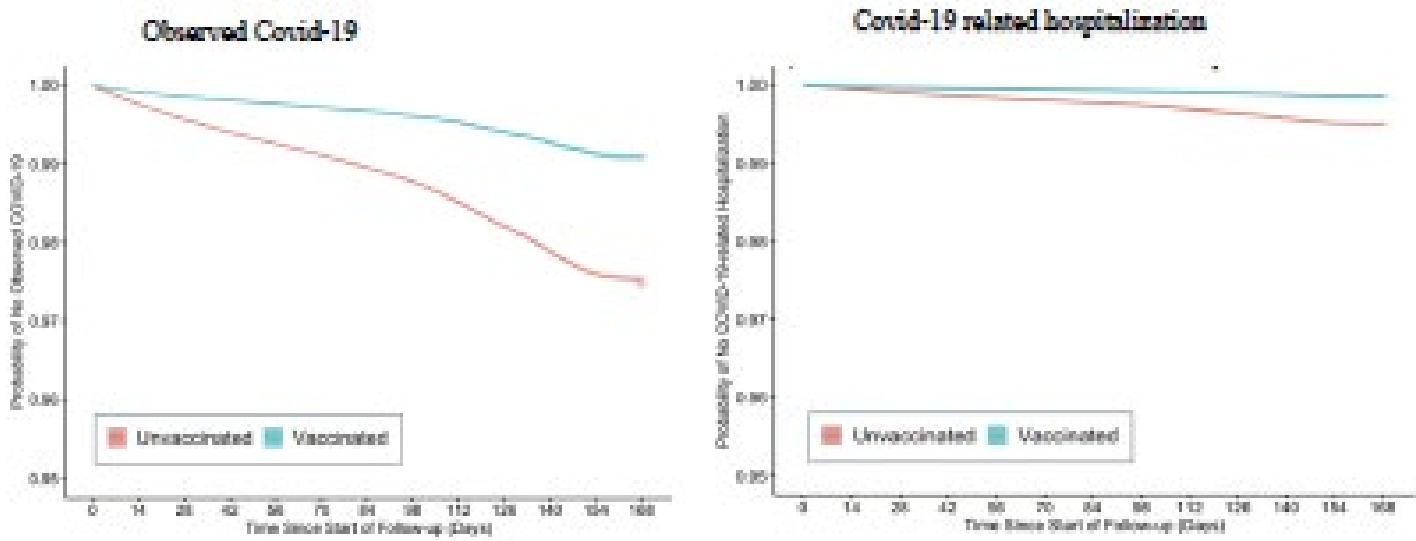


	Months of Follow-up					
	0	1	2	3	4	5
Vaccinated						
Number at Risk	352878	351289	350048	286530	81540	20
Cumulative Events	0	98	165	225	269	289
Cumulative Incidence	0	0.03	0.05	0.06	0.09	0.2
Unvaccinated						
Number at Risk	352878	215961	171652	120592	17267	1
Cumulative Events	0	582	861	1055	1131	1144
Cumulative Incidence	0	0.21	0.36	0.48	0.61	0.77

	Months of Follow-up					
	0	1	2	3	4	5
Vaccinated						
Number at Risk	352878	351383	350201	286701	81619	20
Cumulative Events	0	4	12	13	13	13
Cumulative Incidence	0.000	0.001	0.003	0.004	0.004	0.004
Unvaccinated						
Number at Risk	352878	216375	172161	121076	17418	1
Cumulative Events	0	89	139	175	181	182
Cumulative Incidence	0.000	0.033	0.059	0.083	0.091	0.097

Source: Bruxvoort KJ et al., Lancet, preprint posted Sept 4, 2021

RWE on Effectiveness of Janssen



Source: Janssen Briefing Document

Vaccine Effectiveness Over Time

- Vaccines still provide strong protection against serious outcomes, especially for younger age groups
- Vaccine effectiveness against mild and moderate disease appears to wane over time for the different vaccines
- Mild to moderate COVID-19 can be associated with adverse outcomes such as blood clots and long COVID-19
- Facilitating higher primary coverage of the entire vaccine-eligible population should still be a key priority



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