

Assisting Research in COVID Vaccine Safety and Effectiveness Studies



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Background

Acumen, LLC and its affiliated firm, The SPHERE Institute, conduct policy research by leveraging vast data resources on health and social policy topics. Specifically, the Safety Team monitors and evaluates the safety and effectiveness of drugs and biologics that support the regulatory activities of their federal partners. Current COVID-19 mRNA vaccine investigations include safety surveillance in the general United States population and effectiveness investigations in the elderly Medicare nursing home population.

Learning Objectives

1. Cultivate professional communication and coordination skills by scheduling meetings and reviewing deliverables with team members.
2. Demonstrate an understanding of key analytical findings in literature review summaries and client-facing meeting notes.
3. Develop quantitative analytical skills by identifying COVID-19 risk covariates in the literature and producing descriptive summaries to support future inferential analyses.

Activities

- Attend videoconferences and take internal and external meeting notes
- Conduct literature reviews and organize findings into an excel matrix to assist manuscript drafting
- Develop programming code lists for statistical analyses
- Create dynamic excel workbook tables to assist current research projects
- Compose Safety Team research guides to support future research protocol development
- Design and conduct preliminary descriptive analyses to guide future inferential analyses

Deliverables

- COVID-19 Vaccine Effectiveness Literature Review
- Code List Development Memo
- Common Study Considerations Memo
- Nursing Home Dataset Memo
- Safety Team Nursing Home Resource Library
- Minimum Data Set (MDS) Covariate Descriptive Summary

Lessons Learned

1. Management and coordination of multidisciplinary teams are vital for project productivity.
2. Communication of key analytic findings should be based on the audience and the purpose of the presentation.
3. Medicare reimbursement policy affects data availability and accuracy of observed diagnosis and procedure codes in claims datasets.
4. There are important epidemiologic study design considerations based on research questions and data collection methodology.

Public Health Implications

COVID-19 continues to spread throughout the United States as the emergence of variants pose a risk to long-term vaccine effectiveness. Current investigations can help federal regulators determine the safety and effectiveness of mRNA vaccines as a novel preventative intervention against COVID-19. Study findings may also influence the uptake of COVID-19 vaccines in the most vulnerable populations, such as elderly nursing home residents.

Acknowledgements

I would like to thank my manager, Katie Matuska, for committing her time towards developing my professional research skills and providing invaluable feedback on my work. I would also like to thank Acumen, LLC and the Safety Team for granting me the opportunity to support research projects shaping national public health policy. Lastly, I would like to thank Andrew Morris for advising me throughout the practicum process.

