Statistical Considerations in the Development of a Consensus Statement

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Theme:

Study Design and Data Management

Abstract:

Consensus statements serve as a key method to synthesize expert opinions, particularly in areas with limited empirical evidence or when traditional research is deemed not feasible (ex: in high-risk indications). The intricacies involved in designing and analyzing consensus statement studies require distinct statistical considerations to ensure the validity and reliability of outcomes. Here, we provide a comprehensive analysis of the statistical considerations involved in developing a consensus statement. A focus was placed on the statistical thresholds for defining a 'consensus,' exploring the balance between agreement percentage and rounds conducted and

determining the appropriate and acceptable power for consensus statement studies. The importance of feedback and the challenge of participant attrition across multiple rounds (as utilized in the Delphi method) were also considered. This study emphasizes the iterative nature of consensus statement building and the necessity for clear statistical considerations in both the design and interpretation phases to ensure the validity of the consensus statement.

How Presentation Applies Across Different Industries or Application Areas:

This presentation highlights the importance and intricacies of developing consensus statements, with a focus on the statistical considerations required to ensure the validity and reliability of such statements. The relevance of consensus statements can be seen across various industries and application areas, including technology, economics, education, and importantly, healthcare.
In the tech industry, especially in the development of open standards or protocols, stakeholders come together to reach a consensus on best practices or technical specifications. The statistical measures mentioned in the abstract help ensure a broad agreement that can be adopted industry wide. For economic policies, where direct experiments are often impractical, expert opinions might be used to guide economic strategies. Proper statistical considerations guarantee that a policy recommendation has a broad agreement among experts in the field. In education, when defining curricula or teaching methodologies, especially in emergent fields, consensus among educators ensures that students are taught using the most agreed-upon and effective strategies. Statistical measures can validate the wide acceptance of these methods. Importantly, in the field of medicine, when clinical trials are not feasible due to ethical concerns (i.e., high-risk) or the rarity of a condition, consensus statements provide guidelines for diagnosis, treatment, and management based on expert opinions. The importance of consensus statements can most easily be seen within healthcare in rare diseases and case studies, as well as in the development of novel treatments and orphan drugs. Accurate statistical methods ensure that the resulting guidelines are representative of the population of interest and are reliable.
In summary, the process of building consensus statements, underpinned by rigorous statistical considerations, has applications in a myriad of fields. This presentation underscores the universality of these methods, emphasizing the importance of ensuring validity and reliability, irrespective of the industry or application area.

Relevance to Conference Goals:

Our presentation aligns with the conference theme "Study Design and Data Management" in several ways. This presentation addresses the initiation phase of research, particularly for projects aiming to create consensus statements. When empirical evidence is lacking or traditional research isn't feasible, consensus statements act as an alternative method of initiating new research projects. This approach is especially relevant in fields where direct experimentation might be risky or unethical, like in clinical trials. This presentation also touches upon the unique design considerations needed for consensus statement studies. Instead of typical experimental or clinical trial designs, these studies rely solely on expert opinions. Thus, understanding the statistical intricacies involved in this process is paramount.

The process of gathering expert opinions inherently involves sampling. The choices made about which experts to include how many rounds of input to conduct, and how to weigh each opinion are all vital sampling considerations. The balance between agreement percentage and rounds conducted, as mentioned in our presentation, is a direct reflection of the sampling strategy. This presentation delves deep into the statistical thresholds for defining a 'consensus.' This is an intricate aspect of the statistical analysis plan (SAP), ensuring that the outcomes are valid and reliable. This presentation's focus on the balance between agreement percentages and rounds conducted, as well as determining the power for consensus statement studies, contributes directly to this topic. Consensus statement studies entail collecting and managing expert opinions over multiple rounds. The challenge of participant attrition across these rounds underscores the importance of effective data management to ensure that the data remains representative and meaningful. Finally, by providing a comprehensive analysis of statistical considerations in consensus statement studies, our presentation serves as an educational resource. It enlightens statisticians about the nuances of such studies, emphasizing the iterative nature of the process and the importance of statistical considerations in both design and interpretation phases.
This is a relatively underutilized alternative to direct research studies that should be evaluated and discussed with a wider audience, which is exactly what the 2024 Conference on Statistical Practice (CSP) aims to do.

Please share the Qualifications of the Presenters:

Joshua J. Cook, M.S., ACRP-PM, CCRC is a recent graduate of Wake Forest University (WFU) where he earned his Master of Science for Clinical Research Management. He is a current graduate student at the University of West Florida (UWF) studying Data Science while working at the university as an Adjunct Professor. Joshua worked in the field of clinical research for nearly three years, starting in neurology clinical trials and then specializing in orthopedic regenerative medicine as a Research Quality Analyst. He has published his undergraduate honors thesis, entitled "Endurance exercise-mediated metabolic reshuffle attenuates high-caloric diet-induced non-alcoholic fatty liver disease" in the *Annals of Hepatology* and has recently submitted several orthopedic research papers to various journals. He has also presented his research at over ten unique conferences at the local, state, and national levels with topics spanning from the impact of blood sugar on Alzheimer's Disease to publication metric tracking with R and Microsoft Power BI®. Joshua has developed a passion for bench-to-bedside research and aims to synthesize his knowledge of the biomedical sciences, clinical research, and data science to become a physician-scientist capable of integrating clinical care with clinical research in a way that maximizes evidence-based care options for his patients.

Achraf Cohen, Ph.D. is an Associate Professor of Statistics and Data Science. Dr. Cohen teaches Statistics and Data Science courses to graduate and undergraduate students. Dr. Cohen's research focuses on statistical process monitoring (SPM). In the context of his work, SPM refers to the statistical techniques, tools, and practices that improve system monitoring, anomaly detection, and statistical control charts. One of the best ways to develop a monitoring system is to combine the three schools of thought in the literature, which are (1) statistical approach (a.k.a. SPM), which is concerned with collecting data from processes to develop statistical monitoring models, (2) knowledge-based approach that is based on experts' knowledge and their expertise, and (3) model-based approach that requires a prior physical and mathematical description of the process.

Any description (data, expert, and physical/mathematical knowledge) of the process provides new information and reinforces system understanding. In particular, my research focuses on statistical models for process monitoring. In addition to SPM, his research interests are in the intersection of statistical modeling and machine learning (inferences and predictive models), anomaly detection, wavelets analysis, and applied machine learning. His contributions span various domains, including education analytics, quality engineering, sports medicine, and IoT systems, emphasizing the versatile applications of data science.