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SEE-ing the Future: Empowering Health Decisions through Structured Expert Elicitation

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Min-Hua Jen
Please provide a brief biography for the Presenting author(s)
Dr Min-Hua Jen is currently Senior Director - Real-World & Access analytics at Eli Lilly, leading the International Business team on Market Access/HEOR/Medical affairs statistical support. She has extensive experience applying statistics to clinical research, epidemiology and health economics and outcomes research in academia and industry settings. She is an active member in the PSI/EFSPI HTA Special Interest Group (SIG) and the chair-elect of the ISPOR Oncology SIG. She was trained in Epidemiology and Statistics and obtained her PhD at University of Bristol. Her research interests including indirect treatment comparisons and network meta-analysis; particularly incorporate external data for time to event outcomes, surrogacy analyses, multilevel modelling and health economic modelling.

Roel STRAETEMANS
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Roel Straetemans is currently working as as a scientific director in the statistical modeling and methodology group at Johnson & Johnson supporting both non-clinical and clinical research. Roel was trained in chemistry and statistics and started working in the pharmaceutical industry 25 years ago where he held roles as a statistician and PK/PD modeler. His professional interests are optimal design, translation non-clinical to clinical research, bayesian dynamic borrowing and pharmacometrics. Roel is member of the PSI/EFSPI SIG on historical borrowing.

Kate Ren
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Kate Ren is a Senior Research Fellow in statistics at the University of Sheffield. She works as a member of SCHARR-TAG (an external assessment group for NICE technology appraisals). She has extensive experience in critiquing statistical methods used in NICE single technology appraisal submissions. She is also a member of NICE Appraisal Committee C. Her research interests include indirect treatment comparisons, survival extrapolation and structured expert elicitation.

CHRISTOPHER JACKSON
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Christopher Jackson is a Senior Statistician at the MRC Biostatistics Unit, University of Cambridge. His research involves developing statistical methodology in applications to population health. His publications include work on Bayesian evidence synthesis, survival analysis, multi-state and longitudinal modelling, model assessment and comparison, and decision theory. He has also developed several popular R packages, and co-authored textbooks on the BUGS software and Value of Information analysis.

HUGO PEDDER
Please provide a brief biography for the Presenting author(s)
Hugo Pedder is a Research Fellow in based within the Population Health Sciences department of the University of Bristol. He is co-director of the NICE Technical Support Unit,

providing methodological expertise to support the development of NICE Clinical Guidelines, and is a member of NICE Technology Appraisal Committee A. His research has involved developing new methods for meta-analysis on developing and critiquing evidence to support NICE technology appraisal submissions and guidelines.

Single topic, multi-speaker session, Workshop or Single presentation submission

A single topic, mutli-speaker session/workshop

Single topic session or workshop abstracts

Structured Expert Elicitation (SEE) is increasingly recognized as a vital methodology for informing healthcare decision-making, especially in contexts where empirical data are scarce or unavailable—a frequent challenge in oncology. However, conducting SEE exercises that uphold the highest standards of credibility, accuracy, consistency, and transparency in expert judgments remains a persistent challenge.

This panel discussion, jointly organized by the Historical Data Special Interest Group (SIG) and the Health Technology Assessment (HTA) SIG, brings together distinguished experts in methodology, alongside representatives from industry, academia and HTA bodies. The panel will deliberate on the current state and future direction of SEE in regulatory and HTA frameworks.

Attendees will gain critical insights into best practices and emerging advancements in SEE, with a focus on its application in regulatory submissions and HTA. The session will begin with **Min-Hua Jen** providing an overview of SEE, emphasizing the importance of rigorous practices in regulatory and HTA submissions from an industry perspective. **Roel Straetemans** will follow with applied experiences in adapting formal prior elicitation techniques to support robust decision-making in drug development, sharing concrete insights and lessons learned. **Kate Ren** will present recent methodological innovations in SEE designed to address long-term survival outcomes, highlighting advancements in coherent estimation methods underpinned by meaningful expert rationale—a critical component in economic modeling for HTA. **Chris Jackson** will introduce a flexible Bayesian model and an accompanying R package that integrates expert judgments with long-term information to improve extrapolation from short-term survival data. Lastly, **Hugo Pedder** will discuss the perspectives and challenges faced by payer and regulatory authorities in reviewing expert-elicited inputs.

The session will conclude with an interactive Q&A, offering attendees the opportunity to engage directly with the panelists on practical challenges and key considerations in SEE applications.

Prior Elicitation in Clinical Development: Examples and Lessons Learned

In research and development, clinical trials and experiments must often be designed, and decisions made, in the presence of uncertainty and knowledge gaps. To guide study design and decision-making, it is crucial to understand:

1. Which factors significantly impact the outcome.
2. How likely these impacts are to occur.

SEE supports addressing these questions by combining existing data with expert knowledge to form well-informed prior distributions. Beyond generating these distributions to optimize design or inform decision-making, SEE creates a framework for in-depth scientific discussions, fostering a shared understanding of research problems, insights into available information, and identification of knowledge gaps.

The Sheffield Elicitation Framework (SHELF),[1,2,3] designed by Tony O'Hagan and Jeremy Oakley, is a well-developed process that includes pre-specified steps for eliciting probability distributions from experts. It also offers an easy-to-use R package[4] for practical implementation. This presentation will briefly introduce the SHELF framework, showcase clinical development case studies, and reflect on barriers to application, successes, and areas for improvement. The session will conclude with a discussion on the future of expert elicitation in clinical development.

A Bespoke Structured Expert Elicitation Protocol for Long-Term Survival Outcomes

Estimating long-term survival without sufficient data is a significant challenge in economic modeling for HTA and a major source of decision-making uncertainty. While NICE recommends expert elicitation to address data gaps, existing methods for long-term survival often yield speculative estimates, potentially undermining confidence in these values.

This presentation introduces a tailored SEE protocol designed specifically to generate long-term survival estimates, addressing a critical methodological gap in HTA. A case study will demonstrate the implementation of this bespoke SEE protocol and highlight its benefits in enhancing the robustness and credibility of survival extrapolation.

survextrap: Flexible and Transparent Bayesian Survival Modeling Using Data and Judgments

Health policy decisions often rely on survival data from clinical trials. However, policymakers typically need long-term survival estimates, which exceed the follow-up durations of these trials. Naively extrapolating from short-term data is widely acknowledged to be unwise. Instead, long-term estimates should incorporate both data and expert judgments within an explicit model framework.

The survextrap R package is the first user-friendly tool for survival extrapolation using Bayesian evidence synthesis. It combines shorter-term individual-level data (e.g., clinical trials) with longer-term aggregate data (e.g., registries, population studies) or expert judgments about survival probabilities. The package employs a flexible, spline-based model for hazard functions and supports proportional and non-proportional hazards models, including special features like cure models, excess hazard models, and treatment effect waning.

By using Bayesian estimation, the package automatically adapts to available data and accounts for uncertainty where data are limited. Long-term estimates become confident only when supported by robust long-term data or judgments, avoiding reliance on parametric functions extrapolated from short-term data. This presentation will demonstrate the package's capabilities and how it addresses key challenges in survival modeling.

What Do We Want to SEE? Views and Challenges in Appraising SEE

In the absence of robust clinical data, payers and regulatory agencies often rely on expert opinions. However, these opinions are frequently unstructured, prone to bias, and primarily used to confirm assumptions rather than being formally integrated into models. While reimbursement and regulatory agencies welcome methods that address these issues, they also prioritize simplicity and transparency.

This presentation will discuss the perspectives and challenges faced by payers and regulatory agencies in appraising SEE. It will highlight the balance between robustness and ease of understanding, as well as the need to prepare SEE within tight timelines. A fictitious NICE HTA case study will be used to explore whether manufacturers can meet these demands and whether simplification of the process could help achieve these goals.

References

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