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Using the Classical Model for source attribution of pathogen caused illnesses

Lessons from conducting an ample structured expert judgment study

Elizabeth Beshearse, Gabriela F. Nane, Arie H Havelaar

A recent ample Structured Expert Judgment (SEJ) study [2] quantified the source attribution of 33 distinct pathogens in the United States. The source attribution for five transmission pathways: food, water, animal contact, person-to-person and environment has been considered. This chapter will detail how SEJ has been applied to answer questions of interest by discussing the process used, strengths identified, and lessons learned from designing a large SEJ study. The focus will be on the undertaken steps that have prepared the expert elicitation.

1. Introduction

Source attribution is the process by which illnesses caused by specific pathogens are attributed to sources of infections. Illnesses transmitted by food and water result in a major disease burden worldwide. The World Health Organization (WHO) estimated that in 2010, 31 known hazards resulted in 600 million foodborne illnesses and 420,000 deaths globally [1]. A separate study in the United States estimated that approximately 9.4 million illnesses, 56,000 hospitalizations, and 1,351 deaths are caused by 31 known pathogens transmitted through food each year [2]. Despite recognition of the high disease burden caused by food-and waterborne illnesses, gaps in data remain a barrier to producing fully data-based source attribution and burden estimates. Methods to produce such estimates have historically used outbreak analysis, epidemiologic studies, and other surveillance-based data.

However, these methods are limited due to scarce and incomplete data. Structured expert judgment (SEJ) methods have been increasingly applied to address the lack of data. Structured expert judgment has been applied to estimate the source attribution globally and at the national level in many countries, including Australia, Canada, the Netherlands. To aid with addressing the ongoing efforts for the prevention and control of foodborne and waterborne diseases in the United States, a national SEJ study using Cooke's Classical Model [3] was undertaken to attribute domestically acquired illnesses to a comprehensive set of transmission pathways representing 100% of transmission for the 33 selected pathogens. These pathways included foodborne, waterborne, person-to-person, animal contact, and environmental transmission.

This chapter will explore how SEJ has be applied to answer the questions of interest, by discussing the process used, strengths identified, and lessons learned from designing a large SEJ study. A procedures guide was followed to ensure completeness and comprehensiveness [3]. The guide divides the study into three primary stages: preparation, elicitation, and post-elicitation. This chapter focuses primarily on the preparation and elicitation stages, as the data-analysis for an SEJ done during the post-elicitation is covered in greater detail in Chapter 10 of this book, for example. Furthermore, the expert data analysis and results from this SEJ study are reported in a separate manuscript [2].

The first steps in following the procedures guide are the preparation for the study. The importance of adequate time and review for this step of an SEJ study cannot be overstated. Without proper preparation, it is difficult to execute the subsequent elicitation. We will further discuss each of the steps in the order and how they were addressed for this study. Nonetheless, these steps do not necessarily have to be followed in the exact stepwise order, as some may need to occur simultaneously.

2. Definition of the case structure and questions of interest

Firstly, exactly what will be elicited must be determined, that is identifying the questions of interest, also referred to as target variables. The questions of interest or target variables should include uncertain quantities for which there are no (easily) available data. For the US SEJ study discussed in this chapter, this means the identification of pathogens that are transmitted via the five main pathways, but for which the proportion of illnesses that occur through each transmission pathway is uncertain. Pathogens that were known to have greater than 95% transmission through a single pathway were not elicited (e.g., *Staphylococcus aureus* toxin was considered primarily foodborne transmission). Input from both the problem owner and the research team has been used to guide and make decisions about the variables to include. Consideration has been given to the number of target questions that will be elicited, as expert fatigue can occur if too many are assigned to each individual. Some studies address this issue by focusing their questions on target variables that cause the highest burden as opposed to eliciting a more comprehensive selection of causes[10]. Initially, 33 distinct pathogens were considered for this study; After extensive discussions with the problem owner, it was considered relevant to elicit separate estimations of transmission pathways for multiple clinical manifestations or subtypes for certain pathogens. Hence, the final total number of target questions included in the elicitation was 47.

Next, clear definitions for the items being elicited needed to be established. There are several challenges that can exist when attempting to write clear definitions. Established definitions that are used broadly may not exist. This may mean that different institutions, and even individual expert participants, might have disparate views on the elicited quantities. For the estimates elicited from the experts to be meaningful, they must all apply the same definitions in the same way for all target questions. Without this, experts will be providing estimates with differing understandings and the combined assessments will produce inaccurate uncertainty quantifications for the variables of interest. To highlight an example of some of these challenges, consider how an individual can become ill from *Salmonella*.

EXAMPLE: Suppose an individual owns chickens, goes out to feed them, and his hands become contaminated with *Salmonella*. He subsequently comes inside and washes his hands, but the sink has now been contaminated. He prepares his lunch by rinsing lettuce and placing it in the sink. Water droplets containing *Salmonella* bacteria from when he washed his hands contaminate the lettuce. He then eats this lettuce and becomes ill. What would you say is the transmission route for this? Is it animal contact because the bacteria originated from his chickens, or is it foodborne because it is ultimately the lettuce he ate was the vehicle that led to ingestion of the bacteria?

Without clear definitions on exactly what constitutes animal contact transmission and foodborne transmission, expert participants might answer this question differently. Numerous other examples can be given, in which there might not be a clear definition of the pathway transmission. Thinking through challenging examples to test the study definitions can help strengthen the study design and to identify gaps that may not have been considered beforehand.

As surprisingly as it may seem, there are no existing, broadly agreed upon, definitions for attribution of foodborne and waterborne illness transmission. Based on our experience, even within a single institution, different groups use different definitions for the pathway transmissions. Consequently, several months of iteration were needed to achieve clear transmission pathway definitions, that were comprehensive and mutually exclusive for this study. To accomplish this, multiple meetings, discussions, and testing of definitions against difficult scenarios that could cause infection were necessary.

In addition, expert participants received, approximately two months before the elicitation, both a training webinar on pathway definitions followed a quiz with 20 challenging exposure scenarios to verify there was common understanding of the definitions used in the study. Documents with the definitions were provided to the experts in advance of the webinar. This provides the experts the opportunity to ask questions and clarify any concerns with the definitions. In addition, the questionnaire responses allow study designers to ensure that a common understanding was met, and if not, address this prior to the elicitation. It can also be helpful to think through and prepare responses as to why definitions were formatted and designed in the way they were. For this study, the definitions were aligned with how they would be applied and used by the stakeholders and this was explained to the expert participants. So, while they might use slightly different definitions in their work, they would be applying the study definitions when providing estimates.

An example of a problem given during the webinar is presented below.

EXAMPLE: Please choose the transmission pathway that best fits each scenario described

1. Norovirus illness among attendees of a banquet linked to carpet and indoor environment that had been contaminated with vomit the day before the banquet and subsequently cleaned
    a. Foodborne transmission
    b. Waterborne transmission
    c. Person-to-person transmission
    d. Animal contact transmission
    e. Environmental transmission

Finally, for some target variables, transmission pathways have been blocked by the research team. The decision has been based on the well-known microbiology and ecology of certain pathogens. If the blocked pathways were not in line with experts' beliefs, they had the opportunity to provide estimates for transmission by one or more blocked pathways, along with providing a motivation for their assessments. During the elicitation, some experts used this opportunity.

All in all, careful attention has been given to this step in preparing for the expert elicitation and this focus was a strength of the US SEJ study.

3. Identification of calibration questions

The next step in the study was the selection of calibration questions, also known as seed variables. Calibration questions are designed to assess an expert's ability to provide valid estimates under uncertainty and are used to weight the responses to the target questions. In order to accomplish this, answers to these questions should be known to the study design team, but not to the expert participants. The 14 calibration questions have been selected within the domain of the target variables, and they can be classified as retrodictions. For an overview of the types of seed variables by domain, see Chapter 10 of this book. Since the US SEJ study had target questions addressing proportions of transmission by food, water, and other pathways, the 14 calibration questions focused on public health surveillance data for food- and waterborne diseases, frequency of exposure to hazards, and food consumption patterns within the United States. All topics are within the domain of food- and waterborne illness, and which have an impact on disease transmission.

As with target questions, clearly defining the calibration questions, as well as an explicit reference to the data on which the answers are based are critical in designing the calibration questions. As can be seen in the example below, it is important to first provide background about where the data are derived from, so experts provide their responses based on this. Multiple questions can be based on a single data source, so this background could apply to more than one question. Including clearly defined formats for how experts should provide their answers is important as well. If needed, giving an example of the format may be warranted, as seen in the example below. There should be some consideration for how much detail to be included, as these questions should still probe the expert's ability to provide estimates under uncertainty. In the included example, the previous year's incidence was provided to show how to calculate the requested estimate. This still requires experts to consider in their response whether the previous year's data were typical or unusual, if there have been changes to the trend seen, and predict what might have been seen in the unpublished data. Testing of the calibration questions to ensure clarity should be included in the dry-run exercise prior to the elicitation.

EXAMPLE:

Background: The U.S. Foodborne Diseases Active Surveillance Network, or FoodNet, has been tracking trends for infections commonly transmitted through food. This is done through active surveillance in the following 10 states: Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, and parts of California, Colorado, and New York. Preliminary data from the previous year are released annually, usually in the spring. The most recently available data are for 2015. Data for 2016 are expected to be published in spring of 2017.

Question: Based on active surveillance data from FoodNet, what was the incidence (per 100,000 population) of laboratory-confirmed human *Cyclospora cayetanensis* infections for the year 2016?

For example, in the year 2015, a total of 65 cases of *Cyclospora cayetanensis* were reported in the FoodNet database. This represents an incidence of 0.13 per 100,000 population.

When experts provide answers to these questions, they should rely only on their own knowledge. Therefore, they should not have access to additional resources while answering the calibration questions. This can be challenging when performing the elicitation remotely as opposed to doing an in-person workshop. After the calibration questions are completed, the experts should not be able to return to them to revise answers.

It is often the case that experts will want feedback on how “well” they performed on the calibration questions. The standard approach is that experts should not be told how much weighting they received for the target questions, based on their answers to the calibration questions. Nevertheless, if the experts insist to know their scores, then they will be informed about the performance of their assessments. The experts agree with the method that is being used to evaluate their assessments and aggregate them based on the objective scores. This is referred to as rational consensus. It is up to the study administrators, if they have the proper approvals and wish to provide the answers to the calibration questions.

4. Identification and selection of experts

No formal definition for what constitutes an expert exists, but appropriate identification and recruitment of expert participants is an important factor in the success of an SEJ study. A sufficient pool of potential experts is needed, as response rates can sometimes be low. The number of experts needed will depend, in part, on the number of target questions being elicited. For the US SEJ study, the initial list of experts was compiled by both the problem owner and research team together. One method to identify additional experts not previously identified that was used in this study was snowball recruitment. This was done by asking experts to provide the names of other experts they know of in their field that may be qualified to participate, then inviting those experts if they have not been previously identified. In the US SEJ study, a total of 182 potential experts were identified based on previous work experience, topical expertise in food- and waterborne illnesses, or previous participation in SEJ studies.

Experts were invited to apply for participation via a formal email that included details about the study and application process. The application included questions on area of expertise (e.g., microbiology, epidemiology, public health, virology, etc.), job history, education history, conflicts of interest, and self-ranking questions for individual pathogens. This self-ranking for specific pathogens was an area that introduced challenges in assigning experts to target questions. Individuals often struggle to accurately measure their own expertise, so the question was framed as “professional interest”, “knowledge” and “experience” for individual pathogens using a Likert scale of high, medium, low, or none. However, this did not overcome the inherent problems with the use of self-ranking. Nonetheless, the categories of ‘high, medium, low, or none” were not adequately defined and consequently, the applicants interpreted their meaning differently. For example, some applicants provided a 'high' ranking due to their extensive work with certain pathogens in the past, but lacked however any recent experience. This therefore led to some experts declining to provide estimates for assigned pathogens during the elicitation because they did not feel sufficiently knowledgeable. Nonetheless, the number of these cases was extremely low.

Fifty-eight experts replied to the invitation and sent their CV, along with information about their professional interests, knowledge and experience for each of the 33 pathogens, which has been quantified using a 4-point Likert-type scale (high, medium, low or none). The applications of experts have then been evaluated with respect to area expertise, education, work history, professional interest and experience. Furthermore, publication record has not been used to determine eligibility, since domain experts who might have not published frequently might have been excluded. After the selection process and some drop-outs due to, e.g., unavailability on the date of the physical meeting, 48 experts participated in the elicitation. Around 44% were female experts and 56% were male experts.

No established, uniform way to assign experts to target questions exists, to the best of our knowledge. Examination for how this can be accomplished in the most scientific way should be considered early in the study design phase. The number and breadth of the target questions, as well as the number of experts, and range of expert backgrounds should be taken into account.

Due to the large number of target questions in the US SEJ study, 15 panels consisting of related pathogens were created and experts were assigned to these panels instead of to individual pathogens. For example, one panel consisted of three different protozoa that are thought to be transmitted primarily through water, while another covered multiple serotypes of the same pathogen. Maximum bipartite matching [1] using the *igraph* package in R [11] has been used to assign experts to the panels in the study. The parameters used ensured experts were not assigned to panels with pathogens for which they reported 'none' or 'low' experience and were assigned to provide estimates for no more than 15 pathogens. While this method is an useful tool for ensuring the highest expertise ranking to all panels, it heavily relies on the high quality of the input data. The self-ratings have been quantified by using 0=none, 1=low, 2=medium and 3=high. The study team had to add additional points based on the review of expert's curriculum vitae, which was a lengthy and time-intensive process. This emphasizes, once more, the importance of careful preparation for an SEJ study.

The minimum number of experts assigned to a panel was 9, whereas the maximum number of experts assigned to a panel was 21.

5. Dry-run exercise

The dry-run exercise is an important step in determining that all documents, instructions, and questions are clear and easy to use. Documents can be provided to the dry-run participants in advance in order to ensure adequate time to review and formulate comments. Depending on the selected participants, this can be done in-person or remotely. In order to gain insight from multiple perspectives, the US SEJ study had six individuals with expertise in food- and waterborne pathogens who were not participating in the elicitation to provide feedback during the dry-run exercise. While all participant's primary work focused on food and waterborne illness, they had a variety of backgrounds including public health, government, and academia. The dry-run was conducted in a webinar format that included review of the expert training materials, calibration questions, target questions, and fillable answer forms to be used for providing estimates. During our study, we were aware of how important it is to ensure adequate time between the dry-run exercise and the elicitation, in order to incorporate feedback and make recommended changes. We believe this was another strength of our study.

6. Elicitation

The formal elicitation session can be conducted in a variety of ways and this will impact some of the study design decisions. For the US SEJ study, a 2-day, in-person workshop design was chosen to standardize the process for the large number of expert participants. Individual phone calls and discussions that have been utilized in other studies would not have been feasible.

The agenda included a project introduction, a tutorial on the Classical Model for structured expert judgment along with a probabilistic training of the experts. It should be expected that most experts will be unfamiliar with providing estimates under uncertainty and specific training on probabilistic methodology is highly recommended. For this, three domain questions have been used to train experts in reasoning with uncertainty.

A following session has been devoted to responding the calibration questions, which was followed by one which introduced, and plenary discussed the target variables and the elicitation protocol. The remaining time was dedicated to responding the target questions. During the second day, preliminary results from analyzing the calibration questions were presented and the experts were given an opportunity to revise their answers for the target questions.

Experts received a number of documents necessary for the elicitation, including the definitions of pathways and a background document with detailed epidemiological information about all pathogens, along with an extensive list of references. It has been emphasized that the background document was not meant to be exhaustive, but to provide guidance and points for consideration. The document of 122 pages included a standardized table for each pathogen, with clinical and elicitation specific information, surveillance and outbreak data in the period 2009-2015, as well as data from case-control studies and other epidemiologic information. Available literature has been gathered in an extensive reference list. Finally, the document also included statistics on the U.S. population.

Moreover, each expert has received an Excel file containing the elicitation instrument, along with information about panel and pathogen assignment. An example of one sheet from the elicitation instrument is provided in Appendix A. Another document provided detailed instructions on completing the elicitation instrument (the Excel file), and is included in Appendix B. The instructions covered specific steps and timelines, along with guidelines for providing estimates. These included specific requirements, such as the requirement that the elicited quantiles should be distinct values in ascending order, that values outside the assessed 90% confidence intervals would still be possible, but the expert would be surprised to see them and guidelines on how experts should provide estimates for very unlikely and very likely events, etc. These requirements have been detailed and exemplified in Chapter 10 of this book. Measures to reduce entry errors were included, such as error flags if the 5th, 50th, and 95th percentile estimates were not in ascending order.

As mentioned beforehand, for some pathogens, the research team in consultation with the problem owner has concluded that one or more pathways were very unlikely. Consequently, very low values have been assigned a priori and the pathway has been regarded as “blocked”. The experts have been asked to indicate if they did not agree with these assumptions.

Strict timelines have been used for answering the calibration questions, that is, experts needed to complete the calibration questions at the end of the dedicated session during the first day of the workshop. Answers to the calibration questions were recorded and stored electronically for all the experts by the end of the first day and experts could not make changes to these. Experts were provided time on both the first and second day of the workshop to complete their target questions. While the experts were not allowed to access any resources for answering the calibration questions, they were encouraged to access resources provided in the background document and other available materials, or to engage in discussions with colleagues. This ensured that the experts had access to as much information as possible when answering the target questions. While this might raise a question on differences between the elicitation of the calibration and target questions, we will not address this matter in this chapter.

A number of experts were able to finish answering all the target questions during the workshop. Others requested more time and they sent, via email, their assessments within a week after the workshop.

7. Discussion and Conclusion

The US SEJ study has been an ample study, which involved an impressive number of experts and elicited variables. Consequently, considerable amount of time , of roughly 14 months, was required from the research team to carry out all necessary steps for a careful preparation of the expert elicitation. The substantial allocated time rendered a smooth elicitation process and high expert data quality.

Despite the extensive preparation that went into the US SEJ study, re-elicitation for some variables after the in-person meeting was required. The problem owner requested further division and inclusion of other clinical manifestations for several pathogens. These re-elicitations were conducted through video webinars but finding time for all experts to participate was extremely challenging. This highlighted the importance of verifying all final materials with all involved stakeholders, especially if multiple teams are involved.

Furthermore, during the elicitation, some experts expressed their desire to discuss their estimates of the target questions together with other participants. Unfortunately, there was no time during the two-day workshop to have discussions over the 517 total of target questions which were distributed over the 15 panels. It is worthwhile mentioning that the IDEA protocol [6] allows for the discussion of experts' estimates in between the two rounds of individual assessments. The discussion is meant to clarify ambiguities and to allow motivation of individual assessments, and it is not mean to influence one's opinion.

A challenging aspect of the study has been the expert assignment to panels. We encountered situations when expert's self-assessment differed from the evaluated experience from the CV or publication list. Subjective evaluations of experience can thus lead to different interpretation of what defines a "non-relevant" experience, for example.

Overall, the US study is an example of a robust, well executed structured expert judgment study. Attention to detail in the preparation and study design ensured the results would be high-quality and meaningful. Hopefully this chapter provides some insight into the practical application and decisions that can occur when designing a structured expert judgment study.

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Appendix A

Pathogen **Brucella spp.**
Acronym **BRUCL**
Participant number: **XXX**

	Percent of All Domestic Human Cases in a Typical Year			
	lower credible value (5th percentile)	**central value** (50th percentile)	**upper credible value** (95th percentile)	**Validation**
Major pathways				
Foodborne				****
Waterborne				****
Person to person	0%	0%	0%	
Animal Contact				****
Environmental				****
Foodborne subpathways				
Foodhandler related	0%	0%	0%	
Waterborne subpathways				
Recreational Water				****
Drinking Water				****
Non-recreational/Non-drinking				****
Environmental subpathways				
Presumed Person to Person	0%	0%	0%	
Presumed Animal Contact				****

Elicitation instrument for Brucella bacteria and the 11 major pathways and sub-pathways. The black shaded boxes indicate the blocked (sub)pathways. Note that the corresponding percentages are not, in fact, 0%, but actually 0.000001% (for the 5% quantile), 0.0001% (for the 50% quantile) and 0.01% (for the 95% quantile). The validation flag ensured that experts would provide strictly increasing quantiles.

Appendix B

Completing the elicitation instrument

- Save the Excel file as "DATE Expert name completed.xlsx". The original file can be used as a backup.
- Check your name in the sheet "ID".
- You have been assigned a random participant number that will be used for data analysis and anonymous presentation. The key to link your name and the random number is known only to the elicitation team and will not be revealed to any other individual or organization.
- The sheet "CALIBRATION" will be completed in the morning session.
- For each calibration question, please provide your 5-percentile, median (50-percentile) and 95-percentile values in the grey shaded cells. Refer to the document “Calibration questions.docx” for full details. You will also receive a hard copy.
- Remember that values outside your 90% interval are still possible but you would be surprised to see them. We are not asking for a full range of possible values. By definition, a value outside your 90% interval might be observed 1 out of ten times.
- The cells have been preformatted for the appropriate number of significant digits or as a percentage, where applicable.
- Your percentiles should be distinct values in ascending order, with 5-percentile < 50-percentile < 95-percentile. If values have been entered correctly, the **** flag to the right of the entries should disappear.
- The sheet "Pathogens" contains a complete list of pathogens included in the elicitation session and the codes used in the data analysis. For each pathogen, you will find a standardized set of epidemiological data and other information in the file "Expert background document.docx". Supplemental information can be found in pdf files that have been organized by pathogen.
- Your personalized instrument includes target questions for only those pathogens that have been assigned to you. Please complete estimates for each and every pathogen in the afternoon session.
- For some pathogens, the elicitation team in consultation with problem owner, has concluded that one or more pathways are very unlikely. These are indicated by white font against a black background and have been assigned very low probabilities a priori. Please do not overwrite these cells.
- If you consider additional pathways very unlikely, you can also assign very low probabilities to these pathways. The data analysis program does not accept "0" probability. In such cases please enter 0.000001%, 0.0001% and 0.01% for your 5-, 50-, and 95-percentiles, respectively.
- If you consider one particular pathway very likely (virtually 100%), you can assign very high probabilities to this pathway. The data analysis program requires ascending values for the percentiles, and does not accept 100%. Therefore, enter 99%, 99.9% and 99.99% for your 5-, 50-, and 95-percentiles, respectively.
- All pathways and subpathways are mutually exclusive. Please refer to the pathway definitions when needed. The major pathways and the subpathways for the waterborne route are also comprehensive, i.e. they cover all possible transmission pathways. The medians of these pathways should sum up to approximately but not necessarily exactly 100%. To assist you in evaluating this, the sum of the medians is calculated directly below the cells where you enter your estimates.

- The worksheets have not been protected against accidental overwriting. Please enter your data carefully. In case of accidental overwriting, we will use the original file for reconstruction. Please consult the elicitation team if necessary.
- Please complete all sheets, indicated by disappearance of the **** flag and return your completed worksheet to the elicitation team. Also, store a copy on your computer for backup.

Thank you!