Beyond Translation: An Overview of Best Practices for Evidence-Informed Decision Making for Public Health Practice

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Abstract The literature on best practices for evidence-informed decision-making has seen considerable growth from both knowledge users tasked with assessing the quality of the evidence and knowledge creators wishing to make a stronger contribution to evidence-based decisions. The knowledge translation process is highly dependent on the quality of the original research study, the completeness of the reporting, and the cross-discipline accessibility. The aim of this chapter is to introduce scientists

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interested in using their statistical, analytical, mathematical, or modelling skills to contribute evidence for evidence-informed decisions in public health to the various guideline systems used in the knowledge translation process. As these guideline systems are extensive, we have provided only an overview, highlighting recommendations of potential interest to researchers reporting statistical estimates, analytical results, or modelled output. We have also included a few references to published reporting recommendations by these analytical groups. Knowledge translation does not end with a policy decision. Public health messaging is needed to inform and often persuade the general public to take the appropriate action. We have included a discussion on public communication, as media coverage of research studies can often be traced to the abstracts of the original study.

Keywords Report writing for data translation · Best practices for evidence-informed decision-making · Evaluating the quality of evidence · Novel analytical methods · Forecasting and modelled output · Public health messaging for communication and persuasion

1 Introduction

The last decade has witnessed considerable effort aiming to improve communication and collaboration between disciplines. In the area of health research, the Canadian Institute of Health Research (CIHR) was established in 2000 with a mandate to excel in the creation of new knowledge and its translation into improved health outcomes [4]. CIHR views knowledge translation as including all steps from the creation of new knowledge, by knowledge creators, to its application by knowledge users. Disciplines associated with knowledge creation have also made efforts to promote collaboration with knowledge users. For example, the Statistical Society of Canada (SSC) established the Data Science and Analytics Section with the aim of advancing Data Science and Analytics broadly, and strengthening the role of statistical science in enabling evidence-based decisions and communicating and disseminating domain-informed results. The recent publication of "Ten simple rules for effective statistical practice" [19] has useful suggestions in line with this aim.

The aim of this chapter is to introduce scientists interested in using their statistical or mathematical skills to contribute evidence for evidence-informed decisions

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in public health to the various guideline systems contributing to the knowledge translation process. These guidelines are typically written by multi-disciplinary committees with a focus on the knowledge users' perspective. The term evidence-informed decision-making implies that the decision-makers are expected to rely on their public health expertise to integrate all relevant factors, including evidence-based research studies, into any conclusions or recommendations. As decision-makers in public health are tasked with evaluating the harms and benefits of an intervention as well as the costs, cost-effectiveness, available resources, and the community or political climate, the disciplines of statistics, mathematical-modelling, and health-economics figure prominently in creating the evidence basis. Statistical methods are used in most subject matter domains to separate signal from noise, provide reliable estimates, to quantify the uncertainty of these statistical estimates, and to make inferences. Of note, publication criteria for most medical or health-science journals require that the statistical analysis be performed appropriately and rigorously. Often direct evidence of the potential effect of an intervention is not available or the actual disease burden is unknown. Mathematical models are used to bridge this gap using estimates taken from many studies and mathematical formulas, along with assumptions where data is not available. In this way, the models can account for disease progression, or transmission in infectious diseases, in describing the disease burden. Experts in health-economics incorporate cost considerations and provide decision-makers with estimates of the cost-effectiveness of an intervention.

Once a policy decision is reached, public health officials look for persuasive explanations that support the recommended policy. These more intuitive explanations are used for consensus building among health-care officials who are tasked with implementing the new policy. They will also be used to target the general public if behavioural changes are needed on their part, thus adding behavioural-science and risk-communication to the list of helpful interdisciplinary skills. Daniel Kahneman's book "Thinking, Fast and Slow" [18] offers insight into why humans struggle to think statistically and prefer to think intuitively, providing a rich source of insight on irrational decision-making. He hypothesizes that there are two modes of thought: "System 1" which is fast, instinctive, and emotional; "System 2" which is slower, more deliberative, and more logical. We often substitute an easy question for a more difficult one, so that System 1 can provide a fast answer based on a heuristic. Unless we become skeptical, System 2 will lazily endorse the conclusion without bothering to supervise. Little progress would be made if System 2 questioned everything. However, once we become skeptical and engage System 2, we can become focused on a problem and tune out other stimuli.

Likewise, throughout this chapter, we have tried to appeal to the intuitive reasoning of our readers—hoping to pique their interest in following up with the more technical details.

2 Scientific Writing and Author Guidelines for Scientific Journals

While the evidence-informed decision-making process is usually initiated with the identification of a research question and a literature review, this ignores the knowledge creation process and the importance of having high-quality studies that report findings in a way that facilitates a critical evaluation. Author guidelines and peer-review contribute to this process.

The structure of scientific articles has evolved over many years into a standardized structure known as Introduction/Methods/Results and Discussion (IMRD) [36]. This structured style facilitates finding relevant information as needed on the part of the users of the evidence, and serves as a general template for reporting study results.

As most author guidelines require that the conclusions be supported by the results presented, it is important to identify a specific research question in the introduction and link the research goal, methods, and results to the conclusions. When describing the methods, author guidelines usually require that methods be described in enough detail that another researcher with access to the data could reproduce the results.

The description of the analytical method is usually limited to a couple of paragraphs, with the methodological details provided as a reference or in an appendix. The methods section also includes a description of the study data and how it was created. Last's ***Dictionary of Epidemiology (3rd ed)*** [21], describes validity as the degree to which the inference drawn from a study is warranted. There are three primary threats to validity: bias, confounding, and chance. Of note, the dictionary lists over 30 types of bias, most referring to the underlying processes that generated the data. A review article on how to assess epidemiological studies [38] provides additional information on terminology and a discussion on assessing both internal and external validity for different study designs.

When introducing novel methods, author guidelines request additional information on utility (when should this novel method be used) and that a sub-section on empirical validation be included [31]. A reference should be provided for any theoretical or simulated validation exercise. The data-based validation exercise should include a comparison of the results for the novel method against commonly used methods or the gold standard for the specific application.

Guidelines for the reporting of study results depends on the study design and study objectives. This topic is discussed in more detail in the following section. Generally, when estimated parameters do not correspond to observable data, parameters should be converted to an observable quantity, including units of measure. Print journals often limit results to either a figure or table. Figures provide a visual interpretation which can facilitate communication, while studies that report point estimates along with a measure of precision such as a 95% confidence interval (CI) are more likely to be included in the knowledge translation documents prepared for the decision-making committee members, or used as parameter values to inform mathematical modelling studies. Providing the table as a supplementary file in an online journal may be a solution.

P-values are usually not used in the summary of evidence in a critical review [25]. Numerous misinterpretations of p-values and confidence intervals [12] have prompted the American Statistical Association (ASA) to publish a statement on p-values [37] where they recommend caution when reporting p-values, emphasize the need for careful interpretation of p-values in the context of the whole study design, and encourage the use of alternative approaches, such as those that emphasize estimation over testing. Many journals have responded with updated author guidelines that request that authors avoid solely reporting the results of statistical hypothesis testing, such as p-values [16].

The discussion section is tightly structured containing paragraphs to: summarize the main results; identify study limitations; compare results to those from other studies and state conclusions. The paragraph on study limitations should include a discussion of the potential risk of bias and potential confounders not included in the study design.

It should be noted that "conclusions about the validity of a study require wisdom and rigor to apply expert judgment based on knowledge of the subject matter and of the methodology" [32]. With new analytical methods emerging quickly, the task of assessing validity will increasingly fall to experts with skills in both the analytical and subject matter domains.

The issue of conveying study quality for mathematical modelling and health-economic studies is more complex and recommendations less developed. Typically, scenarios and sensitivity analysis are used to convey uncertainty. Reporting guidelines specific to these study designs are discussed in the next section.

3 Reporting Guidelines

An international initiative was set up in 2006 to promote good reporting practices, including the wider implementation of reporting guidelines. The EQUATOR (**E**nhancing the **QUA**lity and **T**ransparency **O**f health **R**esearch) Network was motived by concerns "that deficiencies in reporting make it difficult, if not impossible, to assess how the research was conducted, to evaluate the reliability of the presented findings, or to place them in the context of existing research evidence" [35]. Many journals now request that the appropriate reporting guideline be used by authors and reviewers [16].

The EQUATOR network [9] consists of an online library of reporting guidelines and check-lists organized by study type, as well as guidelines for the reporting of statistical results. The SAMPL (Statistical Analysis and Methods in Published Literature) Guidelines [20] suggest two guiding principles: (1) describe statistical methods in enough detail to enable a knowledgeable reader with access to the original data to reproduce the published results; (2) provide enough detail that the study results can be incorporated into other analyses such as meta-analyses. Some newer additions to the network include RECORD and CHEERS (Consolidated Health Economic Evaluation Reporting Standards). The RECORD guidelines are an extension of the

STROBE guidelines for observational studies that use routinely-collected health data as the main data source. These databases provide a wealth of information that previously was very costly to obtain.

Studies based on mathematical models, including health-economic studies, pose a particular challenge for reviewers, as an empirical measure of precision, or an empirical study with which to compare results, may not available to assess the study quality. Early attempts to development guidelines on best modelling practices by the ISPOR-SMDM Modeling Task Force [5] tended to be rather technical and required an in-depth familiarity with mathematical modelling. Results of theoretical validation efforts or simulations remain mostly out of the reach of policy decision-makers.

Often, mathematical models are used to help assess harms and benefits of a potential intervention for which we have some data, but for which there are also data gaps. Models are often the only option short of a pilot study, as they can link existing data along with other assumptions derived in part from expert opinions, and provide much needed insight on potential outcomes. The CHEERS guidelines are a welcome addition, as they are written for reviewers who may have a health-science background. Though written for cost-effectiveness studies, CHEERS is also recommended for studies that report on modelled output [16].

It is worth noting that the development of the CHEERS guideline was motivated as well by commonly observed deficiencies in reporting. A central requirement in CHEERS is to provide a list of all parameters and assumptions used to inform the model. It is important that the reference is to the original study (or meta-analysis) rather than another modelling study, as many details in the original manuscript are needed to assess whether a referenced estimate is applicable for the use it is put to in the model. The range of uncertainty (95% CI) associated with each parameter is required for the sensitivity analysis. As the omission of structural assumptions can limit the quality of an assessment, suggestions to address this issue are discussed in the next section.

Cost-effectiveness studies usually include a summary measure of the net costs and benefits of an intervention over the patient's life-time, with the net benefits reported as a Quality-Adjusted Life Year (QALY) estimate. The QALY accounts for both life years gained and the improvement in quality-of-life for the rest of the patient's life. In addition to the full itemization of all assumptions, these studies should list all the harms and benefits going into the QALY estimate, as well a providing the standard disability weight for each harm and benefit. Itemizing the QALY contributions and resource requirements on an annual basis would be helpful for assessing operational considerations such as budgets, resource constraints, and the expected timing of benefits. Itemization is required so that reviewers can reproduce the QALY estimate and confirm whether all potential harms and benefits have been included. Suspicions that important harms or benefits were omitted can result in unnecessary discord among the decision-making committee.

The ISPOR-SMDM Modeling Task Force's guidelines on best modelling practices identified the issue of not accounting for operational considerations, such as short-term resource constraints, or the use of model parameters rather than actual data to describe the intervention scenarios, as one of the limitations of many modelling studies [5]. Suggested solutions include cross-disciplinary collaboration to identify possible resource constraints and the development of more complex models that include realistic time-tables for the implementation of an intervention and link model parameters to actual data.

4 Guidelines for Development of Health Policy Recommendations: Grading the Evidence

Systematic reviews provide a comprehensive overview of the available evidence relevant to a policy decision. The GRADE (Grading of Recommendations, Assessment, Development and Evaluations) approach was first published as a six-part series in 2008 [14], and has continued to expand, becoming the most widely adopted tool for grading the quality of evidence [34]. The complete set of guidelines are available online [17]. These guidelines outline the importance of framing the question, selecting appropriate outcomes and describe how to rate the quality of evidence based on risk of bias, publication bias, imprecision (or random error), inconsistency and indirectness. While most data-scientists are not involved in assessing the quality of the evidence, the GRADE guidelines provide an understanding of how a study may be assessed.

To summarize the evidence from each individual study, the GRADE approach reports the estimated impact of the intervention, usually with the lower 95% CI, and uses a 4-point scale for quality of evidence (very low, low, moderate, high). All harms and benefits associated with the intervention are itemized. After weighing all harms and benefits, operational considerations, and the quality of evidence, the recommendation is rated on its impact (strong, weak). The summary part of the GRADE system is an impressive knowledge translation tool, supported by years of experience of diverse experts, including behaviour science [13]. Additional evidence-based tools for these tasks are available online from The National Collaborating Centre for Methods and Tools (NCCMT), McMaster University, Canada [25] and the BMJ Publishing Group [1], among others. The resulting health-policy guidelines are widely disseminated in various online libraries, for example, the Public Health Agency of Canada [30], the Canadian Medical Association Infobase [7], university libraries or disease specific associations.

As the evidence base is much less developed for public health interventions compared with clinical health where randomized control trials are the gold standard, the demand for more evidence on the costs and benefits has increased, coupled with a demand for guidelines for assessing these studies. For example, the National Advisory Committee on Immunization (NACI) is updating its public health recommendation process for vaccines to include economic analyses [24], and provides online access to additional reporting and assessment guidelines.

The GRADE Working Group has recently published their 30th guideline, an overview of the GRADE approach for assessing the certainty of modelled evidence

[3]. To accommodate GRADE prinicples, the credibility of a model itself and the certainty of evidence for each of the model inputs should be assessed, for example by applying GRADE to each model input and identifying those parameters to which model outputs are most sensitive. However, the information required to assess someone else's model is often missing or difficult to obtain. To identify assumptions implicit in the model structure, the working group envisioned comparing the outputs of multiple models, or attempting to identify the 'ideal' model in order to include less obvious parameters or assumptions in the sensitivity analysis.

When the model outputs are sensitive to the model type or structure, or require inputs for which the values are unknown, a full GRADE evaluation may be premature. In this case, the model output could be viewed as hypothesis-generating, similar to how ecological studies are viewed. The identification of which parameters and model structures are responsible for the most uncertainty, through theoretical validation, simulation exercises and sensitivity analyses, would help document the most important data gaps where better-quality data is most needed. In some cases, such as for pandemics, or environmental events such as a hurricane, the data inputs can change quickly. Input parameters that are not likely to be consistent over time should be flagged when assessing inconsistency. A more complex model may be required to link the usual model inputs to available surveillance data. Once linked, thresholds could be set to alert officials when the modelled output is likely no longer reliable enough—prompting a quick reassessment. When model type seems to be responsible for substantial variation in model outputs, a direct comparison of model outputs for different model types is needed.

5 Post-Decision Consensus Building and Public Health Messaging

As the COVID-19 pandemic has illustrated, convincing the public to co-operate with a policy decision can be just as important as getting the policy recommendation right. In this phase, public health officials often look for persuasive explanations that support the recommended policy and are easily understood. While the importance of consistent messaging from politicians and scientific experts cannot be underestimated, decades of research in risk-communication shows that many factors are involved in gaining the public's compliance and that too often these messages do not work as intended. For example, before modifying their own behaviour, people need a good perception of their own risk, they need to trust the message, and they need to be empowered to take preventive measures [10].

The risk-communication research literature is large and diverse, however, as with most academic bodies of literature, it is typically out of the reach of researchers from other disciplines as well as public health officials. To bridge the gap, the

US Food and Drug Administration (FDA) published a guide to facilitate evidence-based risk-communication [10]. Risk-communication is distinguished from public-relations communication by its commitment to accuracy and its avoidance of spin. While "spin" is often associated with media consultants who develop deceptive or misleading messages to influence the public, spin in media coverage of research can often be traced to the abstracts [33]. Statements in research articles that intentionally or unintentionally overstate the beneficial effects of an intervention were found to be mainly related to misleading reporting or misleading interpretation of the study results [15]. These same issues were cited by the GRADE working group as motivating guideline development.

Solutions may lie in closer compliance with reporting guidelines among editors, reviewers, and authors. As many of us observed during the COVID-19 pandemic, health communication appears to have been designed to persuade people more than to inform them. Generally, the more certainty there is about the balance between the advantages and disadvantages of the change in behaviour, and the greater the potential for harm to others (e.g., transmission of infectious diseases or drunk driving), the more likely it is that persuasion is justified [29]. Too much spin, for example, by not disclosing uncertainties, distorts what is known, inhibits research to reduce important uncertainties, and can undermine public trust in health authorities. However, sometimes persuasion is not effective enough and mandates are used [10], for example with helmets for motorcycle or bicycle use, or COVID-19 vaccine passports to help persuade more people to get vaccinated.

A formal evaluation of the message using focus groups, as well as consulting experts in risk-communications can reduce the risks that a message backfires or undermines public trust [28]. Even early in the COVID-19 pandemic, participants of a focus group identified problems with the current public health messaging, such as inconsistency, lack of transparency, and lack of the supporting scientific data presented by a trustworthy source [11]. Of note, the participants perceived that public health officials were over confident in presenting model projections when a hopeful prediction turned out to be wrong, or lost trust in officials when predictions looked too dire or the intervention too severe. Admitting mistakes is rare, though insightful. For example, the Modelers' Hippocratic Oath, written in response to the role of Quants and their mathematical models in the 2008 stock market crash [8] reflects on behavioural biases that led the group to inadvertently put a bit of spin on their work. One of the cognitive biases that affects our decision making is the IKEA effect, where people place a disproportionately high value on products they partially created [27]. It is named after IKEA, where consumers assemble the modular furniture themselves. Confirmation bias, where one tends to search for and interpret information in a way that confirms one's prior beliefs, is one of the many cognitive biases—that is, errors in logic that arise from using personal beliefs or experiences to make quick decisions, or in Daniel Kahneman's terminology, System 1 hijacks our critical thinking process.

6 Summary

Increasingly peer-reviewers are encouraged to specifically explain whether and how the manuscript could be improved to follow the appropriate reporting guidelines more closely. As guidelines are open to interpretation, and even statistical methods are based on some assumptions, a classroom discussion is a good setting to become familiar with the relevant guidelines and to hear a range of interpretations. While, as research scientists, we may not be formally asked to do a criterial review of the evidence, some familiarity with this process provides an understanding of how the quality of the evidence as reported in our studies could be assessed and how it contributes to a policy decision. The knowledge translation process is highly dependent on the quality of the studies and the completeness of the reporting. Often access to the data and strong statistical skills are required to assess imprecision and risk of bias inherent in the methodology. If these topics are not addressed in the study report, they usually cannot be assessed in the critical review, thus risking a downgrade in the quality of the evidence. Researchers with the appropriate statistical or mathematical modelling skills and domain-specific skills can improve the quality of these important critical reviews.

New analytical methods are quickly emerging, and these pose a challenge for the critical review process. If the results from a novel method are not compared to results for the commonly used methods or the gold standard, these details are not available for translation and critical reviewers would have difficulty interpreting the study results. For modelled output, reviewers are looking at questions such as: how reasonable the assumptions are, whether the timelines for implementation of an intervention are realistic, whether input parameters are measurable, or which factors were accounted for in the model—questions identified by the ISPOR-SMDM Modeling Task as operational concerns.

Part of gaining more familiarity with reporting guidelines includes participating in group discussions, or for a more hands-on approach, peer-reviewing manuscripts, conducting a method comparison study, or a systematic review of studies that use new or different methods or modelled output. The demand for forecasts of hospital resource requirements during COVID-19 epidemic waves provides one example of the importance of familiarity with critical review and reporting criteria. A systematic review of COVID-19 forecasting studies found that half of the studies did not report the quantitative uncertainty of their predictions; 25% did not conduct an evaluation of their short-term forecast, and most did not evaluate their forecasts over a period of time that included varying epidemiological dynamics [26]. It is promising to see that there are also a number of recent studies that compared the accuracy of the forecasts of different models over an extended forecast period by using period-comparison methods such as the weighted interval score (WIS) [2], and included forecast periods over varying epidemiological dynamics [23]. Collaboration between forecasters and knowledge-users has led to insightful discussions. For example, as public health is generally interested in the peak characteristics of an epidemic wave, the need for alternative measures of accuracy is increasing being recognized. The issue is that typical error-based metrics, such the mean-squared error averaged over the full time-series can lead to poor performance in assessing the precision of predictions of the timing and magnitude of the epidemic peak [6, 22].

Spin in the media can influence the public, and can often be traceable to research abstracts. As the public generally views independent researchers more trustworthy than government officials, data-scientists, with a good understanding of the information that the reporting and grading guidelines are looking for, should be well placed to gain public trust by providing an informative rather than persuasive presentation of the supporting evidence.

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