COMMENTARY

Linking Scientific Evidence and Decision Making: A Case Study of Hand Hygiene Interventions

Nicholas Graves, PhD;[1] Kate Halton, PhD;[1] Katie Page, PhD;[1] Adrian Barnett, PhD[1]

We consider how data from scientific research should be used for decision making in health services. Whether a hand hygiene intervention to reduce risk of nosocomial infection should be widely adopted is the case study. Improving hand hygiene has been described as the most important measure to prevent nosocomial infection.[1] Transmission of microorganisms is reduced, and fewer infections arise, which leads to a reduction in mortality[2] and cost savings.[3] Implementing a hand hygiene program is itself costly, so the extra investment should be tested for cost-effectiveness.[4,5]

The first part of our commentary is about cost-effectiveness models and how they inform decision making for health services. The second part is about how data on the effectiveness of hand hygiene programs arising from scientific studies are used, and 2 points are made: the threshold for statistical inference of .05 used to judge effectiveness studies is not important for decision making,[6,7] and potentially valuable evidence about effectiveness might be excluded by decision makers because it is deemed low quality.[8] The ideas put forward will help researchers and health services decision makers to appraise scientific evidence in a more powerful way.

COST-EFFECTIVENESS MODELS

These provide signals about how to allocate a fixed budget between competing health programs when the objective is to maximize health benefits.[9] If a new program increases costs and reduces health benefits, it should never be adopted. If it saves costs and increases health benefits, it should always be adopted. It may, however, provide an opportunity to trade higher costs for additional health benefits. These 3 situations are shown in Figure 1. Whether a trade is worthwhile depends on how much decision makers are willing to pay for 1 unit of health benefit, such as a quality-adjusted life-year (QALY).[10] The dashed line in Figure 1 shows that this value is $50,000 per QALY, and this means that the dashed line is a threshold for a good decision.[11] Imagine a hand hygiene program that increases costs by $800,000 and generates an extra 16 QALYs. The cost per QALY gained is $50,000 ($800,000 divided by 16) and so the result, relative to existing practice at the origin, lies exactly on the threshold for good decision making. If the new hand hygiene program costs more than $50,000 per QALY, then it would be above the dashed line, and adoption would be a bad decision. If it costs less, it would be below the line, and adoption would be a good decision.

Information Required for Cost-Effectiveness Models

Multiple pieces of information are combined to make predictions of cost-effectiveness,[12] and we use hypothetical data shown in Table 1 to make our points clear. The first 4 parameters are used to estimate the increase in costs from a new hand hygiene program to cover 20,000 patients. The program implementation cost is $3,000,000 and is made by multiplying 60 by $40,000 and then adding $400,000 and another $200,000. The next 5 parameters are used to predict cost savings that would result from adopting the program. There would be 800 fewer infections among the 20,000 patients if hand hygiene were adopted (8% of 20,000 minus 4% of 20,000). Five bed-days are saved for each of the 800 patients, which, when valued at $500 together with the $250 treatment costs per case, gives a total economic savings of $2,200,000. The change to total cost is positive by $800,000, because we deduct $2,200,000 from $3,000,000. Predicting the change to health benefits requires information for the last 2 parameters in Table 1; 0.1% of the 800 patients enjoy an extra 20 years of life, meaning that the health benefits are 16 QALYs. If 0.8 people seems like a strange outcome, then remember that this is a modeling study.

Using the Information

Table 1 shows single values for 11 separate parameters used to estimate the model outcomes of $800,000 and 16 QALYs. We are not certain of these parameter values, because populations are variable. For the "treatment costs of infection" parameter, the mean value is $250, but the cost of treating some patients will be cheaper than the cost of treating others. The statistical distribution of this parameter is shown in Fig-

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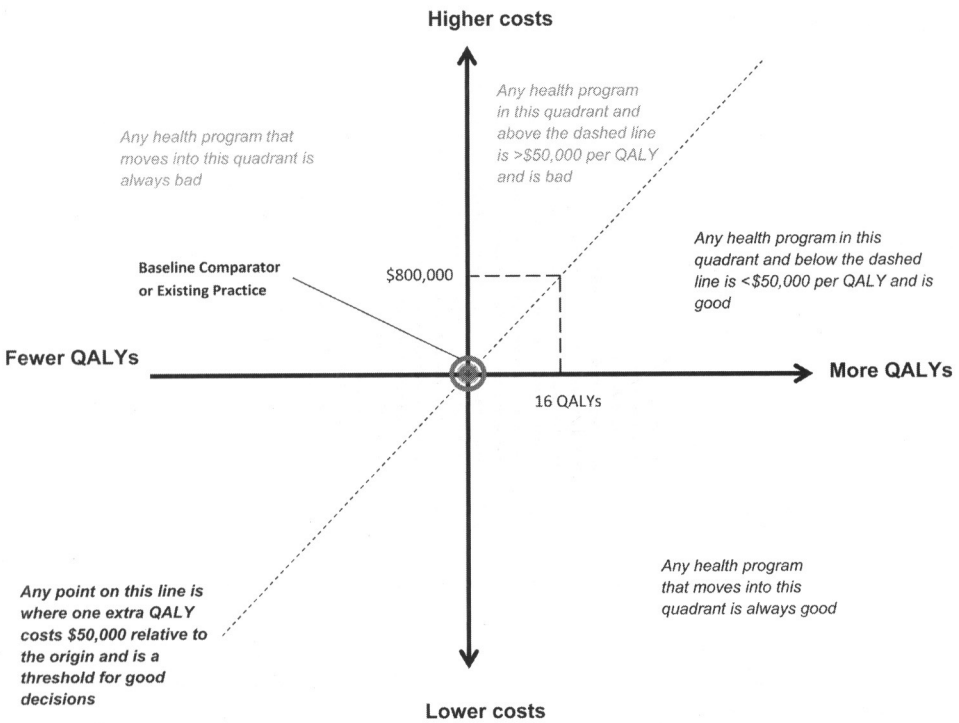


FIGURE 1. A summary of decision making outcomes. QALY, quality-adjusted life-year.

ure 2 and reveals that a small number of patients cost less than $150 or more than $400 to treat. All 11 parameters in the decision model have values distributed with uncertainty, and these uncertainties must be included if the model is to be useful.[13]

Evaluating the model is done by randomly picking a value from the distribution of each parameter and making a single prediction of cost-effectiveness. Imagine the first random pick from the parameter distributions arose from one end of the distributions. A very short prolongation of stay or very low value for program effectiveness, for example, would steer the cost-effectiveness estimate above the threshold line and show decision makers that adoption is not cost-effective; another random pick with different values might steer the estimate below the line, and the opposite conclusion would be drawn. After 1,000 random picks have been made, it is the proportion of results below the threshold line that show the probability that the decision is cost-effective. This is called probabilistic sensitivity analysis.[14] If the proportion of results below the threshold is greater than 500 (50%) of 1,000, then a rational

TABLE 1. Information Needed to Estimate the Increase in Costs from Adoption of a Hand Hygiene Program

How information is used, parameter	Parameter value
To estimate cost increases	
No. of extra staff	60
Wages per staff member	$40,000
Cost of all extra hand cleaning product	$400,000
Costs of coordination group	$200,000
To estimate cost savings	
Risk of infection with existing practice, %	8
Risk of infection with hand hygiene intervention, %	4
Extra days' stay due to infection	5
Value of a bed-day	$500
Treatment costs of infection	$250
To estimate health benefits	
Extra death risk for those infected, %	0.1
Years of life lost because of early death	20

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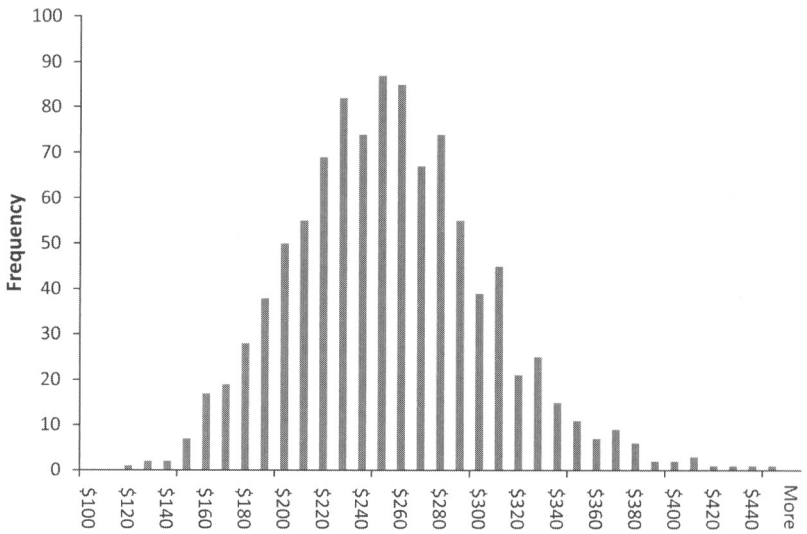


FIGURE 2. Statistical distribution for a model parameter.

and risk-neutral decision maker would maximize the chance of economic benefit by adopting the program.[15]

HOW THE DATA ON HAND HYGIENE EFFECTIVENESS ARE USED

This section is about the intervention effectiveness data for hand hygiene. We use hypothetical values of 8% and 4% in the decision model. Many studies of hand hygiene interventions have been published and included in reviews. A Cochrane Collaboration review by Gould et al[16] is thorough and up to date. The authors assess strategies to improve hand hygiene compliance; they extracted data from 4 studies[17-20] and excluded data from 129 studies. The authors judged the excluded designs to be insufficiently robust to attribute any observed changes to the intervention, with many words devoted to criticizing the quality of the studies, in line with Cochrane recommendations. That some results were not statistically significant at the .05 level was also a feature of the review, and the importance of this judgment is considered next.

Statistical Significance and Decision Making

We suggest that the threshold for statistical inference of .05 used to judge effectiveness is not important for decision making.[7] Imagine that the model parameters that describe the effectiveness of the hand hygiene intervention in Table 1 arose from a small trial whose 50 participants were assigned equally in a randomized trial. The relative risk is 0.5, and the 95% confidence interval is 0.05–5.17 (Table 2).

Many in the scientific community would disregard this evidence, because the level of confidence in the conclusion is a long way from the 95% level used to judge whether the observed difference in the outcome is real, or statistically significant. However, when the result from this small trial of 50 individuals is used in the cost-effectiveness model, we see in Figure 3 that 570 of the 1,000 resamples lie below the dashed threshold line, and so there is a 57% chance that adoption of the hand hygiene program is a good decision. Substituting estimates from the medium, large, and very large trials increases confidence in the decision to 71%, 74%, and 82%, respectively. A statistically significant result for the ef-

TABLE 2. Four Versions of the Effectiveness Parameters with Reducing Variances, by Study Size

Variable	Small	Medium	Large	Very large
No. of participants	50	400	800	1,600
No. of infections				
Hand hygiene group	1/24	10/190	20/380	40/760
Control group	2/23	16/184	32/368	64/736
Risk				
Hand hygiene	0.04	0.05	0.05	0.05
No hand hygiene	0.08	0.08	0.08	0.08
Relative risk (95% confidence interval)	0.50 (0.05–5.17)	0.63 (0.29–1.34)	0.63 (0.36–1.07)	0.63[a] (0.43–0.92)

[a] Statistically significant at the 5% level.

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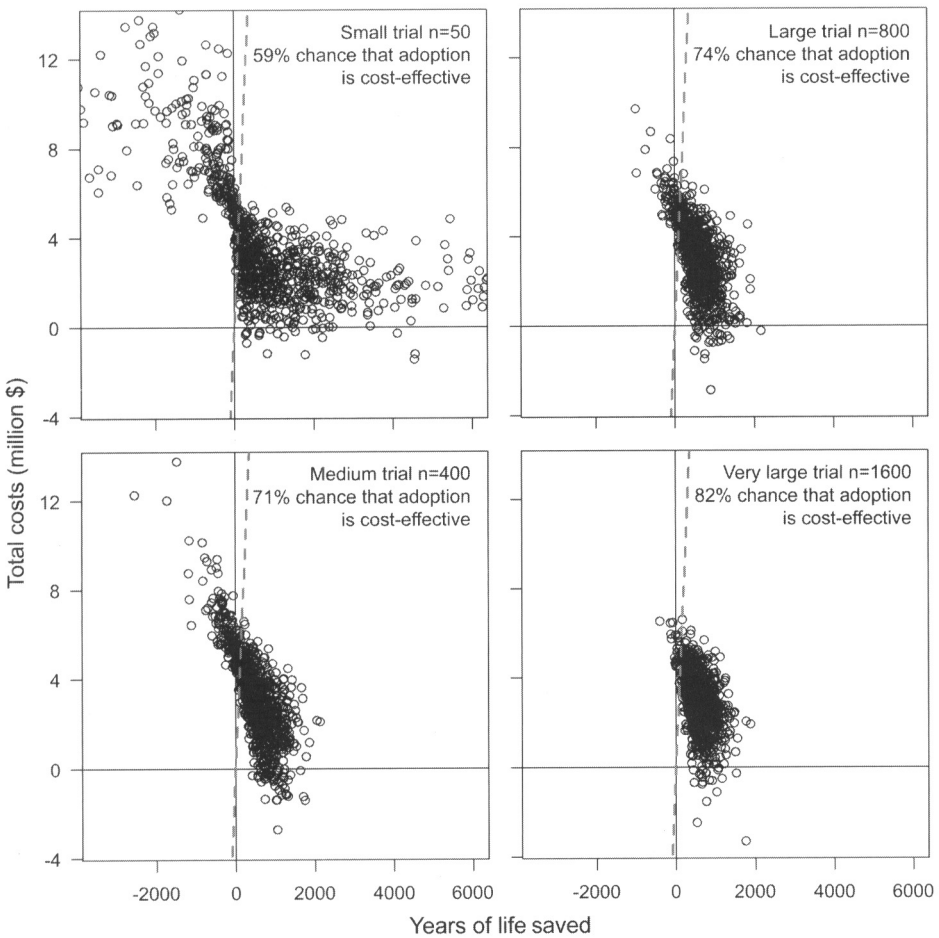


FIGURE 3. Decision making outcomes with uncertainty; data from 4 similar trials of different sizes are used.

fectiveness parameter is not required for the optimal decision to be made.[21] A decision maker might adopt the intervention on the basis of a 57% level of certainty, because the probability favors this, but the very small number of infections seen in the small trial may cause risk aversion. It might be that decision makers are comfortable at the 74% level of decision certainty provided by the medium-size trial of 400 patients. Investing in the large trials with 800 or 1,600 participants might not help decision makers much but would incur large data collection costs in an erroneous quest for a result that meets the arbitrary .05 criterion for statistical significance.

Valuable Evidence about Effectiveness Might Be Excluded

Gould et al[16] excluded 129 of the 133 studies because of their lack of rigor or relevance. Rigor summarizes issues that give rise to internal biases, and relevance summarizes issues that may threaten external validity. The strict quality control in the study by Gould et al[16] means that the estimates included may be less biased, but few data are available; thus, the variance around the parameter estimate could be very high, and the uncertainty in the decision could be large. An extreme example would be a situation in which all evidence is rejected as being of poor quality, thereby implying that nothing is known. This rather shortsighted conclusion ignores the fact that decision makers are still required to make a choice as to whether to adopt an intervention and will still use evidence to guide their decision, albeit with lower confidence. The opposite situation would be one in which most studies are included to guide decision making; variance and uncertainty among parameters would be reduced, but the model estimate might be strongly biased. Ideally, estimates are adjusted to reduce sources of bias, thereby allowing more information to be included, which reduces variance and decision uncertainty.

Turner et al[22] describe a simple method that allows for internal and external biases in evidence synthesis. The result is a bias-adjusted meta-analysis that emerges from methods that can be implemented routinely. Indeed, the authors suggest that, for each study, the bias elicitation process lasted 1 hour plus a minimum of 1 hour of preparation, with the completion of the bias checklist requiring at least 3 hours. This seems a good use of time for researchers and policy makers seeking to clarify the value of infection control pro-

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grams, because repeating the study to get a less biased result would be much more costly. Sutton et al[23] and Ades et al[24] have written specifically about including observational data for decision making. The inclusion of more evidence, adjusting its quality if required, will reduce uncertainty in decision making and may reduce the need for expensive new data collection.

CONCLUSIONS

We have considered how data arising from scientific research should be used for decision making in health services. In the cost-effectiveness modeling, it was assumed that decision makers are both risk neutral and rational, meaning that they should simply choose the option that maximizes expected benefits. In reality, decision makers are often risk averse,[25] have a preference for the status quo,[26] and are susceptible to a range of other judgmental and decision biases.[27] Changing healthcare policy is no easy task, and often the evidence that motivates the decision maker to "take the plunge" needs to be overwhelming.[28]

We conclude that decision makers may be uncomfortable adopting an intervention in which the outcomes are uncertain, particularly when this stems from highly influential parameters, such as the estimates of effectiveness for interventions.[29] This does not undermine our key message that less than perfect information can be used to make better decisions. Scientific studies contribute valuable information to decision making, but such studies alone cannot provide answers as to how scarce healthcare resources should be used. A broader framework is required that uses many data, often drawn from different sources in a cost-effectiveness modeling study.

The authors of the Cochrane review[16] that motivated us to write this article struggled with their conclusions. They failed to find evidence to support the effectiveness of hand hygiene interventions, but then recommended that hand hygiene programs be implemented and promoted. The recommendation was not based on the narrow evidence that they assembled for effectiveness. Instead, it implicitly incorporates a much wider range of considerations, including the cost-effectiveness and acceptability of hand hygiene programs. This is a common scenario, and we sympathize with the authors.

In this commentary, we have illustrated that an arbitrary threshold of .05 for statistical significance is not relevant for decision making and that studies of variable quality can contribute useful information to decisions. We call for high-quality modeling studies in the field of infection control interventions and recommend appropriate use of existing data to help decision makers increase health benefits from scarce resources.

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Address correspondence to Nicholas Graves, Professor of Health Economics, School of Public Health and Institute for Health and Biomedical Innovation, Queensland University of Technology, 60 Musk Avenue, Brisbane, QLD, 4059, Australia (n.graves@qut.edu.au).

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