Methodology for Risk-Benefit Analysis in Research

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Submitted 18th June 2023, Accepted 22nd January 2024 and Published 07th March 2024

ABSTRACT

Risk-benefit analysis in the context of research activities has recently become a mandatory exercise. It is an integral part of the more extensive exercise, the scientific and ethical review for research approval and subsequent monitoring and evaluation exercises. However, how to undertake the process remains a largely subjective process that results in somewhat 'incomplete' inventories of potential risks and benefits for many research activities. There is also the challenge of computing an overall study risk-benefit score when objective and subjective measures of risks, benefits, severity, and magnitude are involved. This study employed the integrative literature review methodology to summarize past empirical and theoretical literature to provide a more comprehensive understanding of a phenomenon. The result is a simple, concise, and practical guide for identifying research risks and benefits, the computation of risk scores, benefit scores, and the overall risk-benefit score in a research activity. These scores are subsequently utilized to compute the study's overall risk-benefit analysis score. This step-by-step process for the computation of a risk-benefit ratio will introduce clarity in the process of risk-benefit analysis in order to help ascertain if specific risk probabilities and their severity have been correctly assessed. Conversely, the approach is also helpful in ascertaining if study benefits and their magnitude have been adequately assessed and rated.

Keywords: *Risk, Benefit, Severity, Magnitude, Risk-Benefit Analysis, Methodology*

I. INTRODUCTION

The Declaration of Helsinki by the World Medical Association in 1964 emphasizes the issue of risk-benefit analysis. The declaration acknowledges that medical and other types of research, in general, examine interventions and use procedures that involve risk. In this regard, the declaration states that such research must only be conducted if the importance of the work outweighs the risks to the research subjects. The implication is that carefully examining the predictable risks and benefits to the participants must precede all research. Once these risks have been identified, the researcher must continuously monitor, assess, and document them. Research studies must only proceed if the researchers are confident that the risks have been adequately assessed and can be satisfactorily managed. If the risks outweigh the potential benefits, the researcher must decide whether to proceed, modify, or stop the research activity (World Medical Association, 2022).

Identifying risks and benefits in a study is a precursor to the risk-benefit analysis exercise. The risk-benefit analysis exercise aims to help the investigators and other stakeholders decide whether the research activity is worth undertaking. If the risks far outweigh the benefits, then there is little or no justification to proceed with a research activity. Therefore, risk-benefit analysis compares the risks likely to occur in a research activity with the anticipated benefits (Kirch, 2008). In a risk-benefit analysis, both the probability (likelihood of occurrence) and magnitude (impact) of possible harm or benefits may vary from minimal to significant *(*UCLA Office of the Human Research Protection Program, 2020).

Risk

Every research activity inevitably faces adverse events or circumstances that may hinder its successful conduct or cause harm and loss to the research subjects, the investigators, the environment, and society. They are not guaranteed to occur, but their identification enhances preparedness to address them if and when they occur. They are referred to as risk, defined as "*the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study."* (UCLA Office of the Human Research Protection Program, 2020).

Risks in research fall into six broad categories: (i) Physical risks such as physical discomfort, pain, injury, illness, or disease; (ii) Psychological risks such as anxiety, depression, guilt, shock, loss of self-esteem, and altered behavior, (iii) Social risks such as alteration of relationships, embarrassment, loss of respect, stigmatization, negative labeling and loss of opportunities, (iv) Economic risks such as incurring unbudgeted expenditure, loss of income, and damage to employability, (v) Confidentiality risks such as injury and illegal invasion of privacy and compromise of personal dignity, and (vi) Legal risks such as revelation of past, present or intended conduct that the subjects or others may be criminally or civilly liable for or by requiring activities for which the subject or others may be criminally or civilly liable (University of Oregon, 2023).

Benefits

Research activities are intended to positively and gainfully impact the study participants, their communities, and society. It is, therefore, essential to identify and communicate them to study participants and other relevant stakeholders interested in the research activity. This exercise is essential in trying to justify the need for a research activity when the same activity also presents risks to the participants, investigators, the environment, and society. Benefits are therefore defined as "*a helpful or good effect, something intended to help, promote or enhance well-being; an advantage"* (UCLA Office of the Human Research Protection Program, 2020).

Some examples of benefits arising from a research study include (i) Direct benefits to the participants, such as access to research outputs and interventions, free services, products, equipment, and treatment where applicable, (ii) Benefits to the community or society such as access to interventions, economic gain from communal intellectual property, infrastructure development and capacity building, and (iii) Benefits to the researcher such as gaining qualifications such as degrees, publications, growth of networks and improved standing in the society and profession (National Ethics Advisory Committee-New Zealand, 2022).

Probability of a Risk or Benefit

Determining the likelihood of occurrence or probability of a risk or benefit occurring is one of the significant challenges in the risk-benefit analysis exercise. That said, the probability or likelihood of an event can be established objectively or subjectively. Objective probability is computed mathematically (Investopedia, 2022a) as a ratio of the number of events of interest to the total number of outcomes, i.e., *probability of event to happen P(E) = Number of events of interest / Total Number of outcomes*. Therefore, to compute the probability, one has to know or at least make an educated guess of the number of events of interest and the total number of outcomes in the activity or exercise (BYJUS, 2022). Subjective probability is derived from an individual's personal judgment, experience, or gut feeling about whether an event is likely to occur. It involves no mathematical calculations, differs from person to person, and contains a high degree of personal bias (Investopedia, 2022b).

Magnitude

The magnitude of risk or benefit, otherwise referred to as the consequence, degree, significance, or weight, is yet another aspect of the risk-benefit analysis process that is difficult to ascertain objectively. The magnitude, consequence, degree, significance, or weight can be viewed from a quantitative or qualitative perspective. From a quantitative perspective, magnitude is measurable objectively in quantities such as the number of occurrences, weight, height, volume, or distance, among other measures that can be expressed numerically (Collins English Dictionary, 2022). From a qualitative perspective, magnitude is established subjectively to express the extent or level of qualitative experiences such as pain, happiness, sadness, improvement, and satisfaction, among others, using words such as intense, substantial, significant impact, immense, vast, and extraordinary among others (Collins English Dictionary, 2022).

Risk-Benefit Analysis Approaches

A common and easy-to-use approach for risk assessment is using risk assessment matrices. A risk assessment matrix, also known as a Probability and Severity risk matrix, is a visual tool based on two intersecting factors: the *likelihood or probability* that the risk event will occur and the potential *magnitude or impact* that the risk event will have on an individual, community, or entity such as a business. Therefore, risk assessment matrix helps visualize the probability vs. the severity of a potential risk. Depending on likelihood and severity, risks can then be categorized as high, moderate, or low (Auditboard Inc., 2022). These matrices can be developed in various dimensions, such as 3 x 3, 4 x 4, or 5 x 5.

An example of a 5 x 5 risk assessment matrix is one developed by Safetyculture (2022). The approach uses a 5-point scale to assess both risks and their probability. The respective scores are multiplied to arrive at a risk score. The levels of risk in the approach are as follows: Rare, Unlikely, Moderate, Likely, and Almost certain. The levels of impact are insignificant, minor, significant, major, and severe. The risk scores are computed as a product of the probability and impact: 1 – 4: Acceptable, 5 – 9: Adequate, 10 – 16: Tolerable, and 17 – 25: Unacceptable. The risk matrix is presented in Figure 1.

Figure 1:
5×5 Risk Matrix Sample

Impact
How severe would the outcomes be if the risk occurred?

Probability
What is the probability the risk will happen?

	Insignificant 1	Minor 2	Significant 3	Major 4	Severe 5
5 Almost Certain	Medium 5	High 10	Very high 15	Extreme 20	Extreme 25
4 Likely	Medium 4	Medium 8	High 12	Very high 16	Extreme 20
3 Moderate	Low 3	Medium 6	Medium 9	High 12	Very high 15
2 Unlikely	Very low 2	Low 4	Medium 6	Medium 8	High 10
1 Rare	Very low 1	Very low 2	Low 3	Medium 4	Medium 5

Soon, Stephens and Rodgers (2021) proposed a quantitative benefit-risk analysis and benefit-risk ratio using real-world data. The approach multiples the occurrence or probability (likelihood) of harm and the consequent severity of the harm during the administration of a therapy to arrive at a quantified value of risk. The probabilities are derived from a probability scale, while the severity levels are derived from the Clavien Dindo Severity Scale, where Grade 1 is minimal severity, with Grade 5 resulting in death. The resulting assessment is interpreted as shown in Figure 2. The output risk index in this matrix takes three values: High (H), Medium (M), and Low (L).

Figure 2:
Clavien Dindo Risk Matrix

		Clavien Dindo Severity Levels				
		Grade I	Grade II	Grade III	Grade IV	Grade V
Probability Levels	Frequent (5)	M	M	H	H	H
	Probable (4)	L	M	H	H	H
	Occasional (3)	L	M	M	H	H
	Remote (2)	L	L	M	M	M
	Improbable (1)	L	L	L	L	L

Related work by Chung and Kutty (2022) entitled "*Benefit-Risk Determination: A Quantitative Approach*" proposes a computation of a risk-benefit ratio. The ratio computation is preceded by assigning frequency and magnitude/severity to each benefit and risk. The formulae are presented in Figure 3.

Figure 3:
Benefit-Risk Ratio Calculation

Benefit Value	=	*Frequency x Magnitude*
Risk Value	=	*Frequency x Severity*
Benefit-Risk ratio	=	$\frac{\text{Benefit Value}}{\text{Risk Value}}$

(Chung & Kutty, 2022; Moon et al., 2021; SafetyCulture, 2022)

Risk-Benefit Assessment in Research

A risk-benefit assessment of proposed research is required for two key reasons: to verify the scientific/social validity of the research and to ensure that the risks that the participants are exposed to are necessary, justified, and minimized (King et al., 2008). Existing methods are categorized into qualitative, quantitative, and hybrid methods.

Qualitative methods

Component Analysis: This method comprises four steps: breaking down a protocol or proposal into its constituent parts, evaluating each component for risk and benefits, weighing the risks and benefits, and concluding with an overall risk-benefit assessment. The components can include intervention procedures and data collection methods, among other protocol aspects. The risks and benefits can be assessed from physical, social, economic, or ethical perspectives (Bernabe et al., 2012). The approach has several challenges, such as subjectivity in identifying the components, deciding on the level of granularity of the components, the interdependence of components making isolated assessment difficult, quantifying the risks and benefits, comparing risks and benefits from different categories such as psychological, social and ethical, the uncertainty and variability of risks and benefits among participants, the lack of a universally acceptable threshold for what is an acceptable net risk, integrating perspectives of all stakeholders, and documenting the process in order to ensure transparency.

Net Risk Test: This method compares the overall benefits of the research to the overall risks. The first step is identifying risks and benefits. These are direct and indirect, short or long-term, physical, psychological, social, and ethical. The risks and benefits are then evaluated for their likelihood and severity. The next step is to compute the net risk by assigning numerical values to the likelihood and severity or through a subjective assessment. The final step is making a decision based on the net risk value. A positive net risk implies that the benefits outweigh the risks, while an adverse net risk indicates that the risks outweigh the benefits (Coleman, 2021). The approach has challenges due to the subjective evaluation of the likelihood and severity, difficulty in quantifying risks and benefits, and the context-specific nature of risks and benefits.

Quantitative methods

Cost-Benefit Analysis: This method assigns monetary values to both risks and benefits, allowing for a more objective comparison. The process begins with identifying risks and benefits, whether direct or indirect, as well as tangible or intangible. A monetary value is then assigned to each risk and benefit. The net risk or benefit is then then computed. A positive value implies that benefits outweigh risks and vice versa. When practical, the approach provides a more objective comparison of the available options (Špačková & Straub, 2015). However, the approach has some challenges, such as difficulty quantifying risk types, such as pain, or benefits, such as good health. The need to discount future risks and benefits to the present value requires complex assumptions and computations. The approach also faces ethical challenges associated with prioritizing economic considerations over human life or well-being.

Decision Trees: This method uses a branching diagram to visualize the potential outcomes of different decisions in a risk-benefit context. The process begins by identifying the main decision or problem being faced. Once this is done, the next step is to branch out with possibilities, each representing a potential option or course of action. These options are then assigned a probability and value, positive for benefits and negative for risks. The process is repeated until all potential risks and benefits have been identified. The path with the highest net benefit represents the best action (Miro, 2023). The approach is advantageous in providing visual clarity of the decision scenarios, flexibility to adjust for new scenarios, combining quantitative and qualitative assessments, and promoting risk awareness due to the visualization. Decision trees, nevertheless, have challenges in assigning accurate probabilities and values to the risks and benefits, complexity when dealing with a high number of risks and benefits, and difficulty in capturing all possible options and outcomes.

Hybrid methods

Multi-Criteria Decision Analysis (MCDA): This method combines elements of qualitative and quantitative methods simultaneously and is valuable for complex situations where there is a need to assess diverse risks and benefits. The process begins with identifying the criteria, such as expected benefits, risk severity, ethical issues, and economic impact, and the stakeholders expected to provide input on the criteria. The next step is to score the identified options quantitatively, qualitatively, or using both approaches. The criteria are then weighted to reflect their relative significance in the specific context. The scores are then aggregated into a single score for each criterion to allow for an objective comparison (Chisholm et al., 2021). However, the method suffers subjectivity in the weighting criteria, getting accurate and comparable data for all criteria, and the complexity created by combining different methods.

Delphi Technique: This method is a systematic and structured approach for gathering expert input to inform risk-benefit analysis. The process begins with defining a research question or the specific risk-benefit dilemma to be addressed. Next, the panel of experts with the relevant knowledge and experience is selected. The experts are then engaged in three rounds: the first round to fill in an anonymous questionnaire to rate potential risks and benefits, the second round to give feedback and aggregate the responses from the first step, and the third and subsequent rounds to refine and improve on the previous inputs. The process is valuable because it is structured and iterative, provides anonymity and objectivity, provides rich data and insights, and achieves transparency and stakeholder engagement (Linstone & Turoff, 2002). However, the method is time-consuming, has the potential for bias, suffers the challenge of achieving consensus on opinions, and has limited generalizability.

These current approaches for risk-benefit analysis in the research reviewed have several challenges. They do not provide explicit categories of risk and benefits in research. They do not guide on the integration of the objective/quantitative and the subjective/qualitative assessment. Concerning assessing risks and benefits in a study, current methods do not provide an explicit guideline on how to compute and interpret these scores. The methods do not provide an explicit guideline on computing and interpreting the risk-benefit ratio. The interpretation provided by current methods is mainly subjective and does not adopt heat-maps to aid in interpreting the risk and benefit scores and the risk-benefit ratio.

II. METHODOLOGY

This study employed the integrative literature review methodology**,** which summarizes past empirical or theoretical literature to provide a more comprehensive understanding of a phenomenon (Broome, 1993). The approach comprises five steps: problem identification, literature search, data evaluation, data analysis, and presentation (Whittemore & Knafl, 2005). The problem for the study was identified through an extensive review of the literature on risk-benefit assessment in general and that specific to risk-benefit assessment in research. The general research question for this study was, therefore: "*What is a suitable approach for conducting a Risk-Benefit analysis using a combination of objective and subjective measures for risks, benefits, severity, and magnitude?*"

The specific research questions for this study were: What are the operational definitions of key concepts in risk-benefit analysis? and What is a suitable approach for the computation of an overall risk-benefit score for a study? Literature for the study was obtained from an online search for sources in the broad area of risk-benefit assessment. Keywords used in the search were as follows: risk, benefit, probability, magnitude, risk-benefit assessment, risk-benefit methodology, risk-benefit methods, and risk-benefit analysis. The results of the literature search were evaluated using the content analysis method. *Content analysis* is an approach that is used to determine the presence of certain words, themes, or concepts within some given qualitative data. (Columbia University, 2020). The data analysis stage of the study employed the mapping and interpretation approaches that are part of the broader framework analysis methodology. The critical steps in this regard included analyzing the search results to identify patterns, relationships, and themes related to risk-benefit analysis. These results were further interpreted in light of the research questions (Hassan, 2022). The findings of the analysis are presented in prose, tables, formulae, and images to enhance the interpretation of the risk-benefit scores.

III. RESULT

Methodology for the Computation of Risk-Benefit Ratio

The computation of the Risk-Benefit ratio can be done as follows;

1. Stage 1 – Risk Assessment
    1. Step 1 – Identify the risks
    2. Step 2 - Assess the likelihood/probability of their occurrence
    3. Step 3 - Assess the potential level of severity or magnitude
    4. Step 4 - Compute the item risk score
    5. Step 5 – Compute the overall risk score for the study
2. Stage 2 – Benefits Assessment
    1. Step 1 – Identify the benefits
    2. Step 2 - Assess the likelihood/probability of their occurrence
    3. Step 3 - Assess these potential levels of severity or magnitude
    4. Step 4 - Compute the item benefits score
    5. Step 5 – Compute the overall benefit score for the study
3. Stage 3 - Risk-Benefit ratio computation

These steps are discussed in detail in the following sections.

Risk Assessment

Step 1: risk identification

Outline any risks that the participants, researcher, research assistants, data, third parties, and environment, among others, that are likely to manifest in the study. As many risks as possible from as many relevant dimensions should be identified to ensure a comprehensive and balanced assessment.

Step 2: determine the likelihood/probability of the risk occurring

This step has two options: the objective or the subjective approach.

1. Objective Approach
    a) Compute the likelihood/probability (a value between 0 - 1).

   b) Multiply the probability obtained by 5 for use on a 5-point scale during the risk assessment stage.
2. Subjective Approach
   a) Define a five-point risk likelihood rating scale with level 1 signifying very minimal chances of occurrence and level 5 signifying certainty of occurrence.
   b) Rate the likelihood of the risk using the five-point risk likelihood rating scale.

Step 3: determine the severity of the negative impact if the risk manifests

This step has two options: the objective or the subjective approach.

1. Objective Approach
   a) Compute the ratio of the adverse occurrences to the total number of occurrences.
   b) Multiply the ratio obtained by 5 for use on a 5-point scale during the risk assessment stage.
2. Subjective Approach
   a) Define a five-point severity rating scale with level 1 signifying very minimal if any, negative impact and level 5 signifying very adverse negative impact.
   b) Rate the severity of the risk using the five-point impact rating scale.

Step 4: compute the risk scores

The item risk score can be established by multiplying the risk likelihood score by the risk severity score as follows:

Item Risk Score = Risk Likelihood x Risk Severity

The risk score should be computed for each risk identified in the project.

A visual assessment of the risk score can be done using a risk assessment matrix presented in Table 1, where green represents low risk, yellow represents medium risk, and red represents high risk. Green implies that the risk is insignificant, while red represents significant risk such that the study must be reconsidered.

Table 1:

Risk Assessment Matrix

		Risk Severity				
		Very Minimal Negative Effects (1)	**Some Negative Effects (2)**	**Significant Negative Effects (3)**	**Adverse Negative Effects (4)**	**Very Adverse Effects (5)**
Risk Likelihood	**Very Low (1)**					
	Low (2)					
	Medium (3)					
	High (4)					
	Very High (5)					

Step 5: compute the average risk score for the study

The computation of the average risk of the study involves the division of the sum of all the item risk scores computed in step 1 by the total number of risks identified, as shown below.
Average Risk Score = Total Item Risk Scores / No of Items

Benefits Assessment

Step 1: identify benefits

Outline benefits that the study participants, researcher, research assistants, data, environment, and the community / general public may experience. As many benefits as possible from as many relevant dimensions should be identified to ensure a comprehensive and balanced assessment.

Step 2: determine the likelihood/probability of the participant benefiting from the study

This step has two options: the objective or the subjective approach.

1. Objective Approach
    a) Compute the likelihood/probability (a value between 0 - 1).
    b) Multiply the probability obtained by 5 for use on a 5-point scale during the risk assessment stage.
2. Subjective Approach
    a) Define a five-point benefit likelihood rating scale with level 1 signifying very minimal chances of occurrence and level 5 signifying certainty of occurrence.
    b) Rate the likelihood of the benefit using the five-point benefit likelihood rating scale.

Step 3: determine the benefit's magnitude in the event it occurs

There are two options at this step: the objective or the subjective approach

1. Objective Approach
    a) Compute the ratio of the beneficial occurrences to the total number of occurrences.
    b) Multiply the ratio obtained by 5 for use on a 5-point scale during the benefits assessment stage.
2. Subjective Approach
    a) Define a five-point magnitude rating scale with level 1 signifying very minimal magnitude and level 5 signifying very high magnitude.
    b) Rate the magnitude of the benefit using the five-point magnitude rating scale.

Step 4: assess the benefits

The benefit score associated with a specific item can be established by multiplying the benefit likelihood score by the benefit magnitude score as follows:
Item Benefit Score = Benefit Likelihood x Benefit Magnitude

A visual assessment of the benefits score can be done using a benefits assessment matrix in Table 2, where red represents low benefit, yellow represents medium benefit, and green represents high benefit. Green implies that the study has significant benefits. Red indicates that the benefit is not significant, and the study must be reconsidered.

Table 2:
Benefit Assessment Matrix

		Magnitude of the Benefit				
		No Benefits (1)	**Few Benefits (2)**	**Average Benefits (3)**	**Significant Benefits (4)**	**Very Significant Benefits (5)**
Likelihood of Benefiting	**Very Low (1)**					
	Low (2)					
	Medium (3)					
	High (4)					
	Very High (5)					

Step 5: compute the average benefits score for the study

The computation of the study's average benefit score involves dividing the sum of all the item benefit scores computed in steps 1 – 4 by the total number of benefits identified, as shown below.
Average Benefit Score = sum of benefits score / total no of benefits

Compute Risk-Benefit Ratio

The overall Risk Benefit Ratio for the study can be computed as follows;
Risk-Benefit Ratio = Average Risk Score / Average Benefit Score
The score can be interpreted as follows:

- Score 0.5 and below - Low-Risk Ratio - Proceed
- Score 0.6 – 1.9 - Medium Risk Ratio - Proceed with great caution
- Score 2.0 and above - High-Risk Ratio - Not advisable to proceed

A visual assessment of the risk-benefit ratio can be done using a risk-benefit ratio assessment matrix presented in Table 3. Red represents studies that have a significant risk compared to the benefits. It is only advisable to proceed with these studies if measures are taken to reduce the anticipated risk levels. Studies in the green area have significant benefits and relatively low risks. They are, therefore, worth proceeding. Studies in the yellow area are on the borderline. They can proceed with the researcher's discretion and caution as they can quickly degenerate to the high-risk benefit region.

Table 3:
Risk-Benefit Ratio Matrix

		Minimal Benefits				Average Benefits				Very High Benefits				
		1	**2**	**3**	**4**	**5**	**6**	**8**	**9**	**10**	**12**	**15**	**20**	**25**
Minimal Risks	**1**	1.0	0.5	0.3	0.3	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.0
	2	2.0	1.0	0.7	0.5	0.4	0.3	0.3	0.2	0.2	0.2	0.1	0.1	0.1
	3	3.0	1.5	1.0	0.8	0.6	0.5	0.4	0.3	0.3	0.3	0.2	0.2	0.1
	4	4.0	2.0	1.3	1.0	0.8	0.7	0.5	0.4	0.4	0.3	0.3	0.2	0.2
Average Risk	**5**	5.0	2.5	1.7	1.3	1.0	0.8	0.6	0.6	0.5	0.4	0.3	0.3	0.2
	6	6.0	3.0	2.0	1.5	1.2	1.0	0.8	0.7	0.6	0.5	0.4	0.3	0.2
	8	8.0	4.0	2.7	2.0	1.6	1.3	1.0	0.9	0.8	0.7	0.5	0.4	0.3
	9	9.0	4.5	3.0	2.3	1.8	1.5	1.1	1.0	0.9	0.8	0.6	0.5	0.4
Very High Risk	**10**	10.0	5.0	3.3	2.5	2.0	1.7	1.3	1.1	1.0	0.8	0.7	0.5	0.4
	12	12.0	6.0	4.0	3.0	2.4	2.0	1.5	1.3	1.2	1.0	0.8	0.6	0.5
	15	15.0	7.5	5.0	3.8	3.0	2.5	1.9	1.7	1.5	1.3	1.0	0.8	0.6
	20	20.0	10.0	6.7	5.0	4.0	3.3	2.5	2.2	2.0	1.7	1.3	1.0	0.8
	25	25.0	12.5	8.3	6.3	5.0	4.2	3.1	2.8	2.5	2.1	1.7	1.3	1.0

IV. DISCUSSION

This paper presents a generic, simple, and practical approach for undertaking risk-benefit analysis. The approach addresses the challenge associated with making assessments of risks and benefits as well as their impact and magnitude in scenarios where quantification is challenging. In cases where risk and benefit probabilities, as well as their impact and magnitude, can be quantified, the approach only requires the conversion of the probabilities to a five-point scale for subsequent analysis. In cases where risk and benefit probabilities and their impact and magnitude cannot be quantified, a five-point scale is used to rate and score them. The output of both the objective and subjective approaches is a score on a five-point scale. The risk and benefits scores are then averaged for the final step, the risk-benefit analysis score computation. The availability of a risk-benefit ratio is of great benefit primarily to the researcher, who can objectively assess their study. The ratio will also assist reviewers in making judgments and advisories to researchers on their studies. These advisories can include requests for revisions of an approach, mitigation measures, or, in some cases, the cancellation of the entire study.

Conclusion

The step-by-step process for the computation of a risk-benefit ratio will introduce clarity in the process of risk-benefit analysis. This clarity will help ascertain if specific risk probabilities and their severity have been correctly assessed. Conversely, the approach is also helpful in ascertaining if study benefits and their magnitude have been adequately assessed and rated.

REFERENCES

Auditboard Inc. (2022). *What Is a Risk Assessment Matrix? And Why Is It Important?* https://www.auditboard.com/blog/what-is-a-risk-assessment-matrix/

Bernabe, R. D. L. C., van Thiel, G. J. M. W., Raaijmakers, J. A. M., & van Delden, J. J. M. (2012). The risk-benefit task of research ethics committees: An evaluation of current approaches and the need to incorporate decision studies methods. *BMC Medical Ethics*, *13*(1), 6. https://doi.org/10.1186/1472-6939-13-6

Broome M.E. (1993). Integrative literature reviews for the development of concepts. In B.L. Rogers & K. Knafl (Eds.), *Concept Development in Nursing*, (2nd ed., pp. 231-250). W.B. Saunders Co

BYJUS. (2022). *Probability in Maths—Definition, Formula, Types, Problems and Solutions*. BYJUS. https://byjus.com/maths/probability/

Chisholm, O., Sharry, P., & Phillips, L. (2021). Multi-Criteria Decision Analysis for Benefit-Risk Analysis by National Regulatory Authorities. *Frontiers in Medicine*, *p. 8*, 820335. https://doi.org/10.3389/fmed.2021.820335

Chung, B., & Kutty, J. (2022). *A Quantitative Approach to Benefit-Risk Determination*. https://www.rqmplus.com/blog/a-quantitative-approach-to-benefit-risk-determination

Coleman, C. H. (2021). *Risk-Benefit Analysis*. https://api.semanticscholar.org/CorpusID:253525316

Collins English Dictionary. (2022). *Magnitude definition and meaning*. https://www.collinsdictionary.com/dictionary/english/magnitude

Columbia University. (2016, August 3). *Content Analysis*. Columbia University Mailman School of Public Health. https://www.publichealth.columbia.edu/research/population-health-methods/content-analysis

Columbia University. (2020, November 13). *Promoting Academic Integrity*. Columbia CTL. https://ctl.columbia.edu/resources-and-technology/resources/academic-integrity/

Hassan, M. (2022). *Framework Analysis—Method, Types, and Examples*. https://researchmethod.net/framework-analysis/

Investopedia. (2022a). *Objective Probability Definition*. Investopedia. https://www.investopedia.com/terms/o/objective-probability.asp

Investopedia. (2022b). *Subjective Probability Definition*. Investopedia. https://www.investopedia.com/terms/s/subjective_probability.asp

King, N. M., Churchill, L. R., Emanuel, E. J., Grady, C., & Crouch, R. A. (2008). The Oxford Textbook of Clinical Research Ethics. *Emanuel, Ezekiel*, pp. 514–526.

Kirch, W. (Ed.). (2008). Risk-Benefit AnalysisRisk-benefit-analysis. In *Encyclopedia of Public Health* (pp. 1263–1263). Springer Netherlands. https://doi.org/10.1007/978-1-4020-5614-7_3033

Linstone, H., & Turoff, M. (2002). *The Delphi Method: Techniques and Applications*.

Miro. (2023). *Decision Tree Analysis in Risk Management*. Https://Miro.Com/. https://miro.com/diagramming/decision-tree-analysis-in-risk-management/

Moon, J., Stephens, V., & Rogers, K. (2021). *A Quantitative Benefit-Risk Analysis & Benefit-Risk Ratio Using Real World Data: Part I*. https://www.outsourcedpharma.com/doc/a-quantitative-benefit-risk-analysis-benefit-risk-ratio-using-real-world-data-part-i-0001

National Ethics Advisory Committee, New Zealand. (2022). *Research benefits and harms*. https://neac.health.govt.nz/national-ethical-standards/part-two/8-research-benefits-and-harms/

SafetyCulture. (2022). *5x5 Risk Matrix: Importance and Examples*. SafetyCulture. https://safetyculture.com/topics/risk-assessment/5x5-risk-matrix/

Špačková, O., & Straub, D. (2015). Cost-Benefit Analysis for Optimization of Risk Protection Under Budget Constraints. *Risk Analysis: An Official Publication of the Society for Risk Analysis*, *35*(5), 941–959. https://doi.org/10.1111/risa.12310

UCLA Office of the Human Research Protection Program. (2020). *Conducting Risk-Benefit Assessments and Determining Level of IRB Review|*. https://ohrpp.research.ucla.edu/assessing-risks/

University of Oregon. (2023). *Examples of Potential Risks to Subjects*. https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/examples-potential-risks-subjects

Whittemore, R. and Knafl, K. (2005). The integrative review: updated methodology. Journal of Advanced Nursing, 52: 546-553. https://doi-org.rosalindfranklin.idm.oclc.org/10.1111/j.1365-2648.2005.03621.x

World Medical Association. (2022). *Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/