THESIS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

Risk-Based Decision Model for Microbial Risk Mitigation in Drinking Water Systems

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Cover: Illustration of the risk-based decision model.

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Till Ellinor

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ABSTRACT

Microbial risks in drinking water systems can cause sporadic pathogenic infections and waterborne outbreaks resulting in large costs for society. In 2010 for example, around 27,000 persons were infected with *Cryptosporidium* in Östersund, Sweden. It is so far the largest waterborne outbreak in Europe, and societal costs were estimated at SEK 220 million (approx. 20 million €). To achieve a safe drinking water supply, assessment of microbial risks and, when needed, implementation of risk mitigation measures is necessary. However, drinking water systems are complex, and risk mitigation measures are expensive. A thorough evaluation of possible mitigation measures is thus essential for identification of the most suitable alternative and efficient use of societal resources. In this thesis, a risk-based decision model for evaluating and comparing microbial risk mitigation measures in drinking water systems is presented and illustrated using two Swedish case studies. The decision model combines quantitative microbial risk assessment and cost-benefit analysis in order to evaluate decision alternatives from the perspective of social profitability. The quantitative microbial risk assessment is complemented with water quality modelling and consideration of unexpected risk events, such as extreme weather events and combined sewer overflows, in order to reflex the complexity of drinking water systems. To facilitate transparent cost-benefit analyses, the effect of different health valuation methods on the output from the decision model is presented. In the decision model, health benefits and other benefits are monetised for each mitigation measure and compared to the costs for implementing the measure. It is possible to combine decision criteria such as tolerable risk levels and maximising the net present value when applying the decision model. The decision model integrates several scientific disciplines, thus constituting a novel approach to evaluate microbial risk mitigation measures in drinking water systems and provides a structured analysis that includes often neglected aspects. The model provides transparent and holistic decision support and facilitates well-founded decisions balancing risks, costs and societal benefits.

Keywords: quantitative microbial risk assessment, cost-benefit analysis, drinking water, contaminant fate and transport modelling, pathogen, health risk, economic valuation of health effects

Parts of the material in this thesis have previously been published in the licentiate thesis written by the author: V. Bergion (2017) *Development of a Risk-Based Decision Model for Prioritizing Microbial Risk Mitigation Measures in Drinking Water Systems* (Licentiate thesis), Chalmers University of Technology, Gothenburg.

LIST OF PAPERS

This thesis includes the following papers, referred to by Roman numerals:

I. Bergion, V., Sokolova, E., Åström, J., Lindhe, A., Sörén, K. and Rosén, L. (2017). Hydrological modelling in a drinking water catchment as a means of evaluation pathogen risk reduction. *Journal of Hydrology* 544: 74-85. DOI: https://doi.org/10.1016/j.jhydrol.2016.11.011

II. Bergion, V., Lindhe, A., Sokolova, E. and Rosén, L. (2018). Risk-based cost-benefit analysis for evaluating microbial risk mitigation in a drinking water system. *Water research* 132: 111-123. DOI: https://doi.org/10.1016/j.watres.2017.12.054

III. Bergion, V., Lindhe, A., Sokolova, E. and Rosén, L. (2018). Economic valuation for cost-benefit analysis of health risk reduction in drinking water systems. *Exposure and Health,* online. DOI: https://doi.org/10.1007/s12403-018-00291-8

IV. Chuquimia O. D.[1], Bergion, V.[1], Guzman-Otazo, J., Sörén, K., Rosén, L., Pettersson, T. J. R., Sokolova, E. and Sjöling, Å. (2019). Combining molecular analyses of fecal indicator bacteria and diarrheal pathogens with hydrodynamic modeling for microbial risk assessment of a drinking water source. *Submitted manuscript*.

V. Bergion, V., Lindhe, A., Sokolova, E. and Rosén, L. (2019). Accounting for unexpected risk events in drinking water systems. *Submitted manuscript*.

Division of work between the authors

In Paper I, Bergion, Sokolova and Åström were involved in designing the hydrological model. Bergion created the model, performed all the simulations and was the main author. Bergion, Rosén and Lindhe developed the risk management framework. Åström and Sörén provided substantial inputs regarding scenario design and development.

In Paper II, the research problem was formulated by Bergion, Lindhe, Sokolova and Rosén. Bergion, Lindhe and Rosén developed and designed the decision model. Bergion created the model, performed all the calculations, and was the main author. Sokolova performed the hydrodynamic modelling.

In Paper III, Bergion developed, designed and performed the method review and was the main author. Bergion, Lindhe, Sokolova and Rosén developed the approach used when applying the methods to the case study.

In Paper IV, Bergion, Sokolova, Sjöling, Sörén, Rosén and Pettersson defined the study set-up and scope of the sampling campaign. Bergion and Sokolova planned and conducted the sampling campaign and the filtration of water samples. Chuquimia,

[1] Both authors contributed equally

Guzman-Otazo and Sjöling performed the qPCR analysis. Bergion, Sokolova, Sjöling, Sörén, Rosén and Pettersson contributed with analysis and interpretation of data. Sokolova performed the hydrodynamic modelling. Bergion conducted the QMRA analysis. Bergion and Chuquimia contributed equally and were the main authors.

In Paper V, Bergion, Lindhe, Sokolova and Rosén developed the scenario-based approach for including unexpected risk events. Sokolova performed the hydrodynamic modelling and Bergion performed the hydrological modelling. Bergion incorporated the scenario-based approach, and the results from the hydrodynamic and hydrological modelling into the risk-based decision model and was the main author.

Other work and publications not appended

The author has contributed significantly to the following publications, which are not appended to the thesis (note that the author's surname was Johansson before 11 July 2015):

Åström J. and Johansson V. (2015) *GIS-based dispersion modelling of parasites in surface water sources* (in Swedish), Report 2015-07, Swedish Water and Wastewater Association, Stockholm (In Swedish: *GIS-baserad spridningsmodellering av parasiter i ytvattentäkter*).

Johansson V. and Sokolova E. (2015) *Modelling fate and transport of Escherichia Coli and Cryptosporidium spp. Using Soil and Water Assessment Tool*, In E-proceedings of the *36th* IAHR World Congress, The Hague, 28 June-3 July, p 1162-1169.

Johansson V., Rosén L., Lindhe A., Sokolova E., Åström J. and Lång, L.-O. (2015). *A decision support framework for managing microbial risks in groundwater supply systems* (*Abstract*), Presentation at the International Association of Hydrogeologists *42th* IAH Congress, Rome, 13-18 September.

Johansson V., Rosén L., Lindhe A., Sokolova E., Åström J. and Lång, L.-O. (2015). *Beslutsstöd för hantering av mikrobiella risker i grundvattensystem för dricksvattenproduktion – Koncept och ramverk* (*Abstract*), Presentation at the Grundvattendagarna, Gothenburg, 13-14 October.

Bergion V., Rosén L., Sokolova E., Lindhe A., Lång, L.-O. and Sörén, K. (2016). *Comparison of mitigation measures for microbial risk reduction using cost-benefit analysis for decision support* (*Abstract*), Poster presentation at the Nordic Drinking Water Conference, Reykjavík, 28-30 September.

Bergion V., Rosén L., Lindhe A. and Sokolova E. (2016). *Combining Quantitative Microbial Risk Assessment and Disability Adjusted Life Years to Estimate Microbial*

Reduction for Cost-Benefit Analysis (*Abstract*) Poster at the Society for Risk Analysis Annual Meeting, San Diego, 11-15 December.

Bergion V., Lindhe A., Rosén L. and Sokolova E. (2017). *Quantifying health effects of microbial risk reduction measures in a changing climate for cost-benefit analysis* (*Abstract*) Roundtable discussion at the International Water Association - Embrace the Water, a Cities of the Future Conference, Gothenburg, 12-14 June.

Sokolova E., Löwenström C.V., Hussain S.H., Bergion V. and Stenström T.A. (2017). *Hydrological Modelling of Microbial Water Quality Using Soil and Water Assessment tool* (*Abstract*) Presentation (By Stenström, T.A.) at the Integrated Water Resources Development and Management: Innovative Technology Advances for Water Security in Eastern and Southern Africa, Swakopmund, 25-27 October.

Bergion V., Rosén L., Lindhe A. and Sokolova E. (2017). *Kostnads-nyttoanalys av riskreducerande åtgärder för säker dricksvattenförsörjning* (*Abstract*) Presentation at the Forskning och innovation för säkert dricksvatten Conference, Stockholm, 29-30 November.

Bergion V., Lindhe A., Rosén L. and Sokolova E. (2018). *Economic valuation of health risk reduction in drinking water systems* (*Abstract*) Presentation at the 11th Nordic Drinking Water Conference. Oslo, 12-14 June.

Rosén L., Lindhe A., Bergion V., Sokolova E., Lång, L-O and Sköld, N-P (2018). *Comprehensive calculations of microbial risks in drinking water systems* (*Abstract*) Presentation (By Rosén L.) at the 11th Nordic Drinking Water Conference. Oslo, 12-14 June.

Bergion V., Lindhe A., Sokolova E. and Rosén L. (2018). *Economic valuation of health benefits for cost-benefit analysis in drinking water systems* (*Abstract*) Poster presentation at the International Water Association - World Congress & Exhibition. Tokyo, 16-21 September.

Bergion V. (2018) *A risk-based model for prioritisation of risk reduction measures in drinking water systems – model development, microbial risks* (in Swedish), Report 2018-12, Swedish Water and Wastewater Association, Stockholm (In Swedish: *Beslutsmodell för mikrobiella dricksvattenrisker, Verktyg för åtgärdsprioritering*).

Bergion V., Lindhe A., Sokolova E. and Rosén L. (2018). *Ekonomisk värdering av reducerad hälsorisk* (*Abstract*) Presentation (by Lindhe, A.) at the Forskning och innovation för säkert dricksvatten Conference. Malmö, 29-30 November.

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My daughter Edit, you bring joy every day!

Finally, Ellinor! In marriage everything is shared, and that goes for dissertations as well. Thank you for your patience in times of stress, encouragement in times of doubt and endless support. I love you!

Gothenburg, October 2019

Viktor Bergion

LIST OF NOTATIONS

The following notations are used in the main text of the thesis:

CBA	Cost-Benefit Analysis
CEA	Cost-Effectiveness Analysis
COI	Cost of Illness
CSO	Combined Sewer Overflow
DALY	Disability Adjusted Life Years
DWS	Drinking Water System
DWTP	Drinking Water Treatment Plant
Log_{10}	Logarithmic reduction, in this thesis reduction of pathogens, where 1 Log_{10} reduction = 90% reduction, 2 Log_{10} reduction = 99% reduction, etc.
MCDA	Multi-Criteria Decision Analysis
NPV	Net Present Value
OWTS	On-site Wastewater Treatment System
P_{inf}	Probability of infection
QALY	Quality-Adjusted Life Years
QMRA	Quantitative Microbial Risk Assessment
RAC	Risk Acceptability Criteria
Reduction	The term reduction incorporates (when dealing with pathogens) all processes, e.g. removal, inactivation adsorption, predation, which in some way lower the number of pathogens.
WHO	World Health Organization
WWTP	Wastewater Treatment Plant

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1 INTRODUCTION

1.1 Background

Potable water is essential to human health and life. In society today, we rely on what are sometimes complex and highly technical drinking water systems (DWSs) to deliver safe drinking water. Despite these advanced systems, waterborne outbreaks of gastrointestinal diseases and their relationship to DWSs have been documented throughout history (e.g. IWA 2016). One much-noted and re-echoed event was the link between cholera outbreaks and specific drinking water wells in Soho, London, made by John Snow in the mid-19th century (The John Snow Society 2016). Even nowadays, seemingly functional DWSs fail, resulting in waterborne disease. The most known and largest waterborne disease outbreak occurred in Milwaukee, US in 1993, where the pathogen *Cryptosporidium* infected more than 400,000 people (Mac Kenzie et al. 1994). Sweden has experienced several waterborne outbreaks of gastrointestinal diseases in recent decades (Guzman-Herrador et al. 2015), of which Östersund in 2010 was the largest documented waterborne outbreak in Europe, with 27,000 people affected (Widerström et al. 2014). Viewed from a global perspective, there were still over half a billion people in 2015 who were using unimproved[2] drinking water sources (United Nations 2015). Looking ahead, the United Nations have adopted 17 sustainable development goals to be achieved by 2030, one of which is to achieve *universal and equitable access to safe and affordable drinking water for all* (United Nations 2016). The bulk of the work related to these goals is expected to take place in regions where managed DWSs do not exist, and the water resources are exposed to hazardous and unregulated sources of pollution. However, the reported waterborne disease outbreaks in typically well-functioning systems show the importance of further improvements in all types of systems.

The availability of freshwater sources is dependent on the functions of the hydrological cycle. The fundamental processes involved in the hydrological cycle are being affected by anthropogenic activities related to climate change (Oki and Kanae 2006). Climate change and an associated increase in temperature, change in precipitation patterns, and in some areas increasing flood events and prolonged periods of drought, will have a negative effect on water quality and quantity (Coffey et al. 2014; Delpla et al. 2009; Jalliffier-Verne et al. 2017; Mohammed et al. 2019). To assure future water quality, assessment and adaptation to possible climate change scenarios need to be incorporated into drinking water management and related legislation (Coffey et al. 2014).

[2] Unprotected spring/dug well, small tank, tanker truck, untreated surface water, and bottled water (WHO/UNICEF 2017)

Substantial efforts are thus required to achieve the water-related sustainable development goals in a world where the climate is changing, and populations are growing. Efforts are necessary both in developing regions, where improved drinking water is not yet being provided, and in developed regions in an effort to manage and maintain already existing DWSs. Risk management, including the task of estimating and evaluating risk levels as well as analysing and implementing risk mitigation measures, is a key element in securing a safe and sustainable drinking water supply for future generations.

People with access to water supply systems use them at least as frequently as other public infrastructure services, such as roads, railways and electricity. In Sweden, as in many other industrialised countries, instant availability and good quality of potable water distributed through DWSs is generally taken for granted. The World Health Organization (WHO) concludes that uncritical use and reliance on technical systems often constitute an inadequate approach (WHO 2017). Whilst DWSs provide a life-sustaining infrastructure service, if they fail they can rapidly change into facilitators of waterborne diseases. Risk management of these DWSs is therefore essential for reducing health risks to drinking water consumers.

The outbreaks in Milwaukee and Östersund both resulted in substantial costs to society. Medical treatment costs and costs resulting from loss of production were estimated to be SEK 778 million[3] ($96.2 million) for the Milwaukee outbreak (Corso et al. 2003). The corresponding costs for the Östersund outbreak were estimated to be SEK 220 million (approximately $33.8 million[4]), including the personal cost of suffering from a gastrointestinal disease (Lindberg et al. 2011).

Microbial risks posed by pathogens in DWSs are always present and will continue to be present in the future, even though the magnitude of these risks can both increase and decrease. To mitigate these risks and to assure supply of high-quality drinking water, implementation of risk management and associated risk mitigation measures is of fundamental importance. The WHO (2017) argues that setting health-based drinking water quality targets should acknowledge the local conditions (social, cultural, environmental and economic) and also include the institutional, technical and financial aspects. Societal resources are limited and should be distributed in a fair and reasonable manner, and when allocated they need to be used efficiently. Hence, eliminating all risks is not feasible in practice, and prioritisations need to be made based on both the costs and effects of the measures employed. Two economic decision methods commonly used to evaluate risk mitigation measures and create decision support are cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA) (Cameron et al. 2011). In relation to risk management, the CEA criterion can be formulated as “How to reach a certain goal

[3] Converted from USD using an annual average (2003), $1= 8.09 SEK (SR 2017)
[4] Converted to USD using an annual average (2011) $1= 6.50 SEK (SR 2017)

at the lowest cost?". The CBA criterion can be formulated as "How to find the societally most profitable alternative from the point of view of cost and benefit?".

CBA compares all internal and external costs and benefits in order to find the most societally profitable alternative. Given that in most cases microbial risk mitigation measures in DWSs not only result in health benefits (Hutton 2001), but also in environmental and social benefits, there is a need to adopt a broad approach in order to encompass these benefits. Performing a CBA is one way of achieving more holistic decision support, emphasising the health benefits while also accounting for the other benefits. Quantitative microbial risk assessment (QMRA) can provide robust input for CBA with regard to the health benefits obtained via microbial risk mitigation measures (WHO 2016). DWSs are complex, and there are major uncertainties related to assessing the inherent microbial risks and the benefits of mitigating those risks. These uncertainties need to be included in decision-making process, favouring a probabilistic approach compared to deterministic approaches. A probabilistic quantitative microbial risk-based approach in combination with CBA to create decision support for risk management in a DWS is uncommon (Fewtrell and Bartram 2001). Nevertheless, the need for such approaches is emphasised in the WHO (2017) drinking water guidelines.

1.2 Aim and objectives

The overall aim of this work was *to develop a risk-based decision model for comparison of microbial risk mitigation measures in drinking water systems using quantitative microbial risk assessment in combination with cost-benefit analysis*. Key aspects of the decision model were to quantify health effects and the economic effects on a societal level. Specific objectives were to:

- set up a framework for risk-based decision support for microbial risk mitigation in drinking water systems;
- describe an approach suitable for comparing microbial risk mitigation measures using water quality modelling;
- combine quantitative microbial risk assessment (including source characterisation, water quality modelling and dose-response models) with cost-benefit analysis to create a risk-based decision model;
- identify additional methods, not used in the original set-up, that can be applied in the different compartments to facilitate the use of the decision model;
- identify and compare different methods for economic valuation of health effects and assess their impact on the decision model outcomes;
- consider uncertainties in the input data and results and take into account their effects on the decision model outcomes;
- apply the decision model to case studies to demonstrate and illustrate the model outcomes.

1.3 Scope

The scope of the thesis is to describe the quantitative risk-based decision model for microbial risk reduction in DWSs on an overarching level, and to present the theoretical background and practical applications of each component in the model. Five papers are appended to the thesis:

- **Paper I** – Hydrological modelling in a drinking water catchment area as a means of evaluating pathogen risk reduction.
- **Paper II** – Risk-based cost-benefit analysis for evaluating microbial risk mitigation in a drinking water system.
- **Paper III** – Economic valuation for cost-benefit analysis of health risk reduction in drinking water systems.
- **Paper IV** – Combining molecular analyses of fecal indicator bacteria and diarrheal pathogens with hydrodynamic modeling for microbial risk assessment of a drinking water source.
- **Paper V** – Accounting for unexpected events in drinking water systems.

Detailed information on components and methods in the risk-based decision model is provided in Paper II and Paper V. An in-depth description of hydrological water quality modelling is presented in Paper I. Health valuation methods are investigated in Paper III. Paper IV introduces sampling as part of the QMRA. Finally, Paper V includes unexpected risk events as part of the total risk analysis in the decision model. Figure 1 illustrates the relationship between methods and tools used in the decision model and the appended papers.

The thesis is structured as follows. Chapter 2 presents the theoretical background, including a description of the concepts of risk, microbial risk, DWS and decision analysis. In Chapter 3, the specific methods used in the decision model are presented in detail. Chapter 4 introduces and includes a brief summary of each appended paper. Chapter 5 describes the decision model and provides a qualitative comparison of the decision model and other available concepts for microbial risk assessment and decision models, mainly in Sweden. In addition, international decision models are identified and compared to the developed risk-based model. Chapter 6 provides an in-depth discussion of the model as well as suggested future work and recommendations for the drinking water industry. The conclusions of the thesis are presented in Chapter 7.

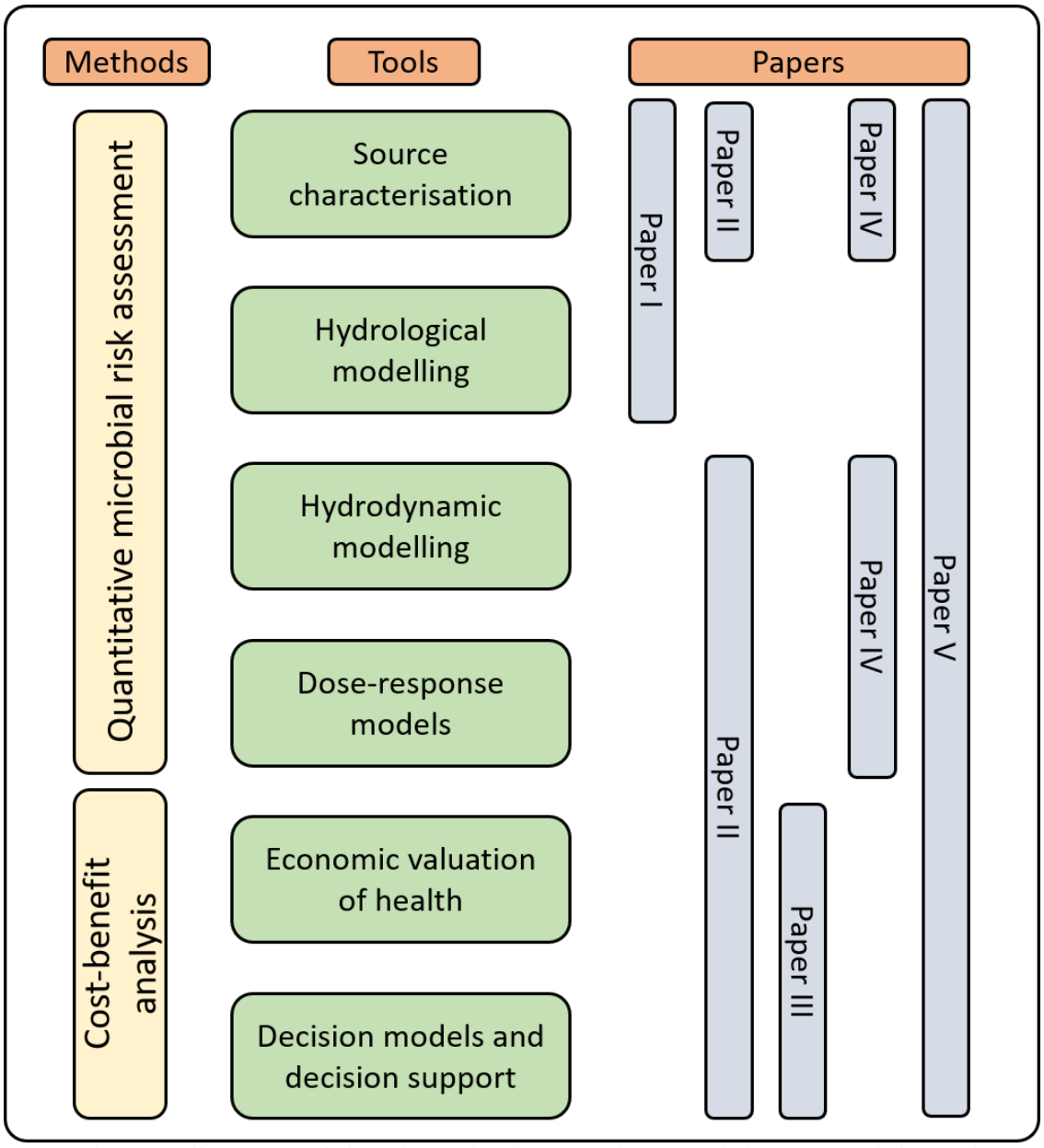

Figure 1 Schematic illustration of the relationship between the appended papers and the application of methods and tools used in the decision model.

1.4 Limitations

The long-term ambition of developing the decision model is to provide a flexible model that can be developed, and which is easier to adapt to each specific drinking water context. It also aims, when necessary, to include a more detailed analysis of all parts of the DWS in order to provide more comprehensive decision support. There are two different versions of the decision model used in the papers. The first version was presented in Paper II, where the combination of methods was illustrated, and the overall structure of the decision model was described. In Paper V, a second, enhanced version of the decision model was introduced. The second version also includes unexpected risk events and allows for the risk level to vary from one day to another. It should be noted

that there are still limitations on what the model includes and provides. The model does not include any analysis of risks associated with the drinking water distribution network. Three reference pathogens are used in order to describe the risk, which might underestimate the total risk since there are additional pathogens related to gastrointestinal disease. Waterborne pathogens that are not related to faecal sources, e.g. *Legionella*, that could be present in natural waters and microbial risks related to other factors (e.g. biofilm in distribution pipes), have not been addressed in this thesis. During the course of this work, additional and updated dose-response models have been published. The dose-response models applied in the QMRA tool developed for Swedish drinking water producers were used in this thesis (Abrahamsson et al. 2009; Åström et al. 2016).

2 THEORETICAL BACKGROUND

In this chapter, an introduction to the risk concept is presented, and microbial risks are explained in relation to the risk concept. Over the centuries, and in different cultures, the perception of uncertainties and the risk concept have changed and varied. In early civilizations, uncertainties related to natural disasters, crop yields, plagues, and wars were often attributed to divine forces. In contrast, modern society and the rapid development of human-controlled technical systems introduced a number of mathematical tools to express uncertainties and the associated risk (Zachmann 2014). The definition of risk[5] put forward by Kaplan and Garrick (1981) touches on the relationship between risk and uncertainties. However, uncertainties as part of the risk concept were not applied fully at that time, and were introduced later (Aven 2010). Aven (2012b) also provides an overview of the development of the risk concept and definitions. The definition of risk has been expressed in different ways, and in the latest ISO 31000 standard, risk is defined as an *effect of uncertainties on objectives* (ISO 2018). In this thesis, risk is defined as a function of *probabilities* and *consequences*, presented below in the *Decision Analysis* section.

2.1 Risk terminology in the context of drinking water

Given a rapid increase in the use and diversity of fields in which risk management has been practised during the past two decades, the terminology has to some extent been scattered and inconsistent (Leitch 2010). In the food industry, *risk analysis* is commonly used as an overarching term, including the entire process of identifying hazards, estimating risk levels, considering whether the risk levels are acceptable or not, analysing measures for risk mitigation, and implementing necessary measures (EFSA 2012; Haas et al. 2014). For technical systems, and the approach applied in this thesis, the term *risk management* is commonly used to describe the same overall process (ISO 2018). The former approach is generally used by organisations that need to separate the parties responsible for estimating risk levels from the parties responsible for making risk management decisions. However, regardless of the framework used, the steps and procedures included are very similar, and the major differences are merely linguistic. In this chapter, the risk terminology and definitions used in this thesis are explained. The decision problems considered in this thesis are to a large extent managed by the drinking water utilities, which can be both private and public. In Sweden, the drinking water utilities are owned by the municipalities through publicly controlled companies. It is common for drinking water utilities and municipal authorities to be responsible for the entire procedure in Sweden and there is no separation of decision-making and prior estimation of risk levels. Consequently, *risk management* is used here to describe the

[5] Illustrated by the questions: *What can happen*; *How likely is it to happen*; and *What are the consequences if it happens*?

overall process and to illustrate both the basic concept and the link to decision-making. The framework and definitions set out in the ISO standards are used (ISO 2018). The focus of the thesis is mainly on risk assessment (Figure 2), consisting of *risk identification*, *risk analysis*, i.e. estimation of probabilities and the consequences of identified risks, and *risk evaluation*. Figure 2 shows an illustration of a general risk management process, and the steps and related terms that are included are shown below. The feedback loop arrow symbolises the iterative process of risk management.

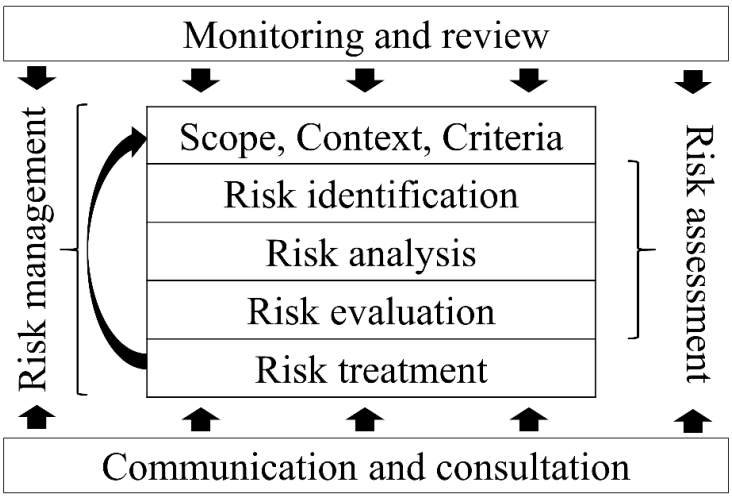

Figure 2 Risk management process adopted from ISO (2018)

In the following sections, the risk management process is explained in relation to a DWS. The purpose is to describe the different steps in risk management in relation to the applications to a DWS that are used in this thesis.

Scope, Context, Criteria

In drinking water management, the "scope, context, criteria" step consists in general terms of two items. Firstly, the purpose of the risk assessment and the possible decision problems are described. Secondly, the system is described, including system boundaries, catchment, source water, sources of pollution, already implemented measures for resource and source water protection, water treatment system, monitoring system, and distribution (also including reservoirs, internal piping, consumers, and water authorities) (Hokstad et al. 2009; WHO 2017). To illustrate the work in this thesis, the purpose of the risk assessment could be described as *investigating the pathogen load on a drinking water source*. Secondly, the system could be described as *focusing on wastewater from on-site wastewater treatment systems, wastewater treatment plants, and the contribution of combined sewer overflows*.

Risk identification

There are large numbers of different microbial risks that could be present in a DWS. Performing risk identification is the process of identifying these underlying hazards or hazardous events. Table 1 lists a number of hazardous events that might be present in a DWS.

Table 1 Examples of possible hazardous events and microbial risks in drinking water systems, adapted from Rosén et al. (2007) and Beuken et al. (2008)

In the catchment
Discharge of treated wastewater
Sewage overflows
Manure application
Run-off from agriculture and urban areas
Wild animals
Accident involving a vehicle carrying faecal waste tanks
At the drinking water treatment plant
Failure in treatment technology, thus affecting microbial barriers
Ineffective reduction in pathogens in microbial barriers
Erroneous operating procedures
In the distribution system
Intrusion of pathogens into reservoirs and pipes
Cross connections with wastewater pipes

Risk analysis

Microbial risk analysis can be performed using qualitative, semi-quantitative, and/or quantitative methods. A qualitative risk analysis lists the possible hazards and hazardous events and categorises the probabilities and consequences in a descriptive way. Semi-quantitative risk analysis extends the categories in a way that they can also be viewed numerically. In a quantitative risk analysis, as applied in this thesis, both probabilities and consequences attributed to each hazardous event are described using values that can be combined to calculate a risk level. The risk is thus seen as a combination of the probability and consequences of relevant hazardous events. In a mathematical context, the probability density function of a hazardous event, f_i, is combined with a consequence function that represents the consequences of that event, C_i. The risk (R_i) related to a hazardous event (i) could be calculated as:

$$R_i = \int C_i f_i ds$$

The risk is the expected consequences, also taking into account the probabilities of the occurrence of each hazardous event. The risk, for example from a CSO that causes waterborne infections, can thus be calculated using the probability of the CSO to occur and the number of infections that would result if the event occurred. These health effects (infections) can also be expressed in monetary terms as risk costs for organisations or for society.

In theory, to calculate the total risk, all possible (imaginable) events need to be included in the analysis. However, this is rarely feasible in practical terms, and instead estimations or approximation of the total risk can be used. A risk graph (Ale et al. 2015) is an

illustrative tool to approximate the total risk. A risk graph combines base risks (UR_0) with unexpected risk events ($UR_1 \ldots UR_n$) to capture the total risk in a DWS, and the total risk is represented by the area below the curve (Figure 3).

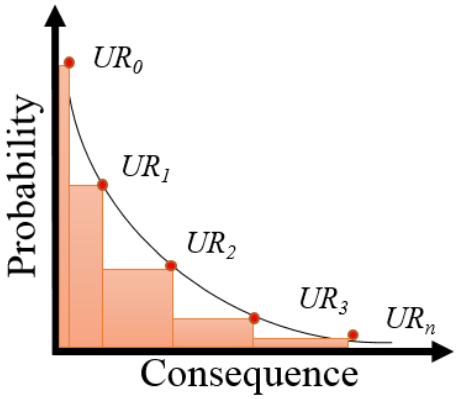

Figure 3 Illustration of the total risk from regularly occurring risk events (UR_0) and unexpected risk events occurring irregularly and occa*sionally ($UR_1 \ldots UR_n$), as presented in Paper V.*

In order to estimate and rank risks in drinking water settings, both semi-quantitative and quantitative methods are suggested (NHMRC 2011; WHO 2017). Semi-quantitative methods are commonly applied using risk matrices to illustrate the ranked categories (Hokstad et al. 2009; Lindhe 2010; NHMRC 2011; WHO 2017). Quantitative risk analysis of microbial risks is commonly performed using the QMRA approach (Haas et al. 2014).

Risk evaluation

The risk acceptability criteria (RAC) define the risk levels that can be accepted (Rosén et al. 2010). In a drinking water context, it is also referred to as the "tolerable burden of disease" and "reference level of risk" (WHO 2017). Acceptable risks are below the RAC, and the risks above the RAC need either to be treated, i.e. reduced, or tolerated. Different approaches to define acceptable or tolerable risk levels are discussed by e.g. Hunter and Fewtrell (2001) in the context of water-related infectious diseases and by e.g. Rosén et al. (2010) in the context of managing DWSs as a whole.

The initial task for risk managers, based on the risk analysis, is to perform a risk evaluation to determine if there is a need for risk treatment. A decision to implement risk mitigation measures is normally initiated based on comparison with the risk criteria defined in the *scope, criteria, context* step. A DWS could be found to have negligible risks, risks that are acceptable, risks that are unacceptable, and/or risks that need to be evaluated according to their tolerability. DWSs with only acceptable risks may remain in their present state and be handled using the principle of monitoring and continuous improvement according to the risk management framework. If unacceptable risks or risks that are not tolerable are present, risk mitigation measures need to be implemented. Tolerability/acceptability is also affected by changes in legislation, policies, and the risk perceptions of various stakeholders.

The *As Low As Reasonably Practicable* (ALARP) principle divides risks into three different categories: acceptable, unacceptable and those that fall within ALARP (HSE 1992). Risks in the unacceptable category need to be dealt with regardless of the cost or other measures necessary to reduce them, whilst the acceptable category can be handled within the framework of everyday routines. The risks that fall within ALARP need to be assessed in each case. Variables other than consequences and likelihoods, such as cost (Melchers 2001), time and physical difficulty reducing the risk, can be considered when adopting the ALARP approach (HSE 1992).

The WHO promotes a health-based approach to estimate RAC, incorporating financial, technical and institutional resources, as well as the local situation regarding economic, environmental, epidemiological, social and cultural aspects (WHO 2017). When setting health-based targets, a holistic approach should be adopted that reflects the fact that drinking water is only one of many routes for exposure to contaminants or pathogens (WHO 2017). Health-based targets can be measured in terms of health effects, water quality, performance targets, or specified technology targets. To set local risk acceptability levels, Disability Adjusted Life Years (DALYs)[6] of 10^{-6} could be used as a point of departure (WHO 2017). The Swedish regulation on drinking water (SFA 2017) states that:

> *"Drinking water should be healthy and clean. The drinking water is considered healthy and clean if: it does not contain microorganisms, parasites and substances in such numbers or concentrations that they may pose a risk to human health, and if the guidelines specified in Appendix 2, sections A and B, are fulfilled."*

However, the reference to Appendix 2 in the above regulation only mentions indicator organisms and the chemical characteristics of drinking water. In Sweden there are no health-based RAC for drinking water utilities that can be used as guidelines, e.g. for comparison with results from QMRA. Guidelines related to QMRA have been implemented in other countries (e.g. Netherlands and the USA) (Bichai and Smeets 2013).

The risk evaluation does not need to be benchmarked to RAC, as there are other aspects that can be used to evaluate risk mitigation measures. Decision methods, e.g. CEA and CBA (described further in the *Decision Analysis* section) evaluate risk mitigation measures using economic aspects. These decision models can be useful if there are several risk mitigation measures that fulfil the RAC and which need to be compared and ranked. This also applies where none of the risk mitigation measures can reach the RAC, but one of the mitigation measures needs to be implemented.

For each identified hazardous event, there can be none, one or several measures to reduce the risk. One measure can affect more than one hazardous event (Lindhe et al.

[6] Disability Adjusted Life Years (DALYs) are explained in detail in Chapter 3.

2013). Measures can remove the risk source, alter the uncertainties of the hazardous event, alter the consequences of the hazardous event, and/or distribute the risk between several parties (ISO 2018). Measures for risk mitigation need to be identified and characterised. Each decision alternative can consist of one or a combination of measures (ISO 2018). There is also the *reference alternative* to which each decision alternative is compared.

The measures can be hands-on, implementing best available technologies (BAT) or a new technological application; they can be newly developed or established methods transferred from other DWSs (Niewersch and Burgess 2010). Education, training, communication, information, legislation and research are other examples of measures that may reduce the risks in a DWS (Åström and Pettersson 2010; WHO 2017). Identification of possible measures needs to be adapted for each individual DWS, although there are suggestions regarding available risk mitigation measures (Åström and Pettersson 2010; Ball et al. 2010; Menaia et al. 2010; Niewersch and Burgess 2010; NZMH 2014). There is little information on methods or suggestions in the literature on how to identify new methods or how to optimise local tailor-made measures. To identify measures, drinking water managers and experts should be involved, and it is beneficial to include multi-disciplinary, trans-disciplinary and cross-disciplinary competences, and to communicate with stakeholders and people with knowledge of the specific DWS (Rosén et al. 2010). The WHO (2017) advocates the principle of *multiple barriers* to create a resilient system, supporting the principle that several barriers should be implemented in different stages in the DWS. Should one or several of the barriers fail, there are other that could compensate.

Risk treatment

Risk treatment is the process of implementing appropriate measures to mitigate the risk. Following implementation, if the residual risk is not acceptable or tolerable, further measures need to be implemented until the risk can be tolerated (ISO 2018). Implementing measures for risk mitigation in a DWS could represent a substantial investment, and the discussions and decisions should be made with the application of a holistic perspective with regard to risk as well as economic conditions, implementation time, and the ability to monitor the effects (WHO 2017). The decision analysis provides vital input in the form of support for decision-makers.

Monitoring

Monitoring and review are essential for sustainable risk management, ensuring that the implemented measures are effective. In addition, changes in policies, objectives, goals, or stakeholder preferences and/or risk perceptions need to be monitored. These changes can be triggered by various actors, such as pressure groups, research bodies, the media, and politicians. Physical changes in the DWS (both long term and acute) that alter the pathogen prevalence situation, pollution sources, transport routes, treatment process, distribution system, and/or consumer susceptibility to infections, are also variables that

should be monitored. These changes in a DWS could be within (internal) or outside (external) the risk managers' control. Pursuing opportunities related to research, investment and collaboration will almost certainly render a need for a risk assessment or a review of an existing assessment.

2.2 Uncertainties

Uncertainties are usually attributed either to natural variations in a system (aleatory), or to a lack of knowledge of a system (epistemic) (Bedford and Cooke 2001). As described in Section 2.3, DWSs are complex, typically generating both aleatory and epistemic uncertainties. Aleatory uncertainties, e.g. the variability of precipitation in a catchment or the presence of pathogens in a river, can be measured and statistically quantified in order to obtain a better understanding of the variability (NHMRC 2011). Epistemic uncertainties, e.g. lack of knowledge regarding statistical parameters describing variability, can be quantified using both statistical dispersion metrics (e.g. confidence intervals) and expert opinions (Bedford and Cooke 2001), and can be reduced by investigations. The difference between aleatory and epistemic uncertainties is not clear cut, and in a risk analysis both types of uncertainties can be quantified using probability as a metric. However, looking at uncertainties from a decision-making point of view, making the distinction between uncertainties that can be reduced (epistemic) and those that cannot (aleatory), could be of importance (Bedford and Cooke 2001). In some contexts, ambiguity and vagueness in the language or vocabulary that is being used can be described as a third type of (linguistic) uncertainty (Beven 2010).

Frequentist methods are used, strictly speaking, to investigate hard data in order to derive a point estimate for input variables. Uncertainties regarding this point estimate can be accounted for by providing statistical dispersion metrics (Bedford and Cooke 2001). A Bayesian approach adopts subjective (expert) judgements to establish probability distributions describing the input variables and their uncertainties (Aven 2012a). On a practical level, the difference between frequentist and Bayesian methods does not need to be substantial (Aven 2012a). However, one major theoretical difference is that frequentist methods aim to estimate an objective probability, while Bayesian methods assume that all probabilities are subjective (often expressed as *degree of belief*). The Bayesian methodology also facilitates updating of model variables as new data become available. In practice, the frequentist and Bayesian approaches are often mixed (Aven 2012a). In this thesis, the emphasis is on the Bayesian approach. However, frequentist methods are also adopted to facilitate the inclusion of both hard data and subjective estimations of statistical parameter values and associated uncertainties based on professional judgements.

2.3 Drinking water systems

Drinking water systems (DWS) or drinking water supply systems (Figure 4) are generally divided into three parts: source water(s), drinking water treatment plant(s) (DWTP) and distribution system(s) (Hokstad et al. 2009; Lindhe 2010), and can be extended to also include a fourth part, the drinking water consumers (NHMRC 2011). The source water part consists of both the catchment and the actual drinking water source. The catchment is the geographical unit receiving precipitation that is transported and discharged at the catchment outlet (Soliman 1997). The terms watersheds, drainage basin and catchment, despite small technical discrepancies, are considered to be synonymous. In this thesis, catchment or catchment area is used as the general term. Water sources can be surface water, groundwater, reclaimed wastewater, stormwater, brackish water, and saline water (Viessman et al. 2014). Groundwater sources can also be enhanced using artificial infiltration and induced recharge. DWTPs extract raw water from the source water and divert it through a series of treatment processes, producing drinking water that is provided to consumers using a distribution system.

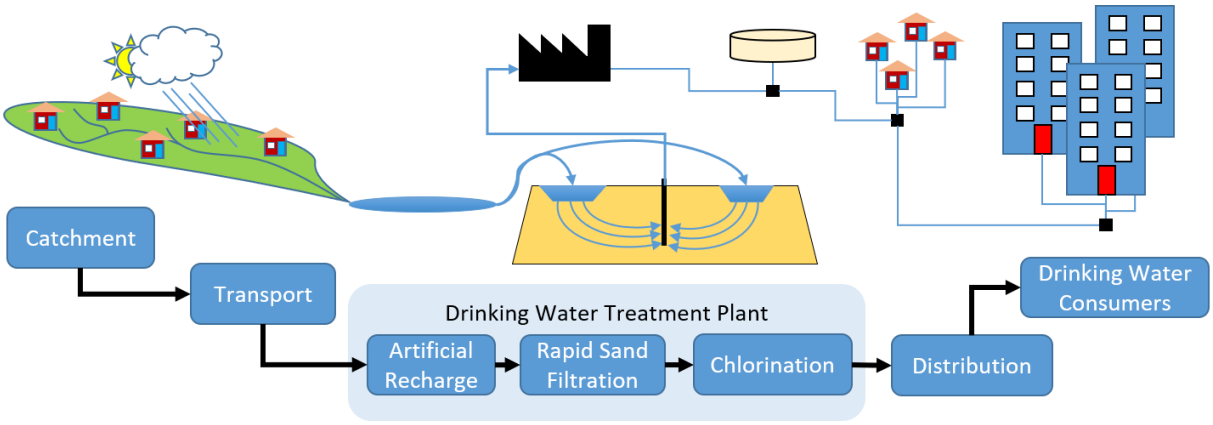

Figure 4 Illustration of a drinking water system using artificial groundwater recharge as source water.

Meteorological conditions, soil properties, etc., set the scene for determining which water sources are available and can be used. Combinations of different types of water sources, multiple DWTPs and/or several separated distribution systems, contribute to the diversity of DWSs. In Sweden, approximately half of the produced drinking water volume originates from groundwater (natural and artificially recharged in approximately equal proportions) and the other half from surface water. In general, surface water sources supply DWSs that have many consumers, while those using groundwater sources supply a smaller number of consumers.

Sources of microbial contamination that can be introduced into the DWS are commonly described as being present in the catchment and in the distribution system. Microbial risk mitigation measures can focus on either reducing the risk at the contamination sources, or being applied at the DWTP to reduce the final risk posed to drinking water consumers using barriers in the treatment.

2.4 Microbial risks in drinking water systems

Microbial risks in drinking water are typically described as events when pathogens are present in the DWS. This can be illustrated from a water utility point of view using the risk definition put forward by Kaplan and Garrick (1981). What is the *probability* that drinking water consumers will be infected by pathogens spread through the DWS, and what are the *consequences*, i.e. how many will be infected and what type of infection is considered? The magnitude of consequences to society could be valued and expressed in monetary terms as a basis for prioritising the allocation of economic resources. As the total absence of pathogens in the drinking water cannot be guaranteed, water utilities strive to minimise the presence and concentrations of pathogens, and thus also minimise the microbial risk in the DWS.

We can characterise waterborne pathogens differently, the most common way being to distinguish between bacteria, viruses, protozoans, and helminths/trematodes. Looking at the origin of these pathogens, it could also be important to identify whether they can be transferred only between humans or whether transfer between animals and humans is possible (zoonotic diseases). In Table 2, some of the most common waterborne pathogens are listed, including an indication of relevant animal hosts.

These pathogens originate predominantly from faecal sources, both animal and human. In a typical drinking water catchment, the faecal sources are human wastewater from on-site wastewater treatment systems (OWTS) and municipal wastewater treatment plants (WWTP); domestic animals, from grazing, application of manure as a fertilizer, and leakage from manure storage facilities; and wild animals.

Table 2 List of common waterborne pathogens, adopted from the WHO (2017) and Dufour et al. (2012)

Pathogen	**Potential animal hosts identified** [a]
Bacteria:	
Campylobacter jejuni	Cattle, swine, poultry, dogs, cats, wild birds
Escherichia coli O157:H7	Cattle and other ruminants
Salmonella enterica (not S. Typhi*)*	Poultry, swine, cattle, horses, dogs, cats and wildlife
Viruses:	
Norovirus	Potentially
Rotavirus	None
Adenovirus	None
Protozoans:	
Cryptosporidium spp.	*C.* parvum[b] can be found in cattle, and other animals
Giardia duodenalis	Cattle, beavers, porcupines, dogs and other animals

a) Note that the list is not comprehensive
b) Other species of *Cryptosporidium* associated with various animals have been found to infect humans

2.5 Microbial health risk quantification and monetisation

Probability of infection and *Disability Adjusted Life Years* (DALYs) are two health metrics commonly used for quantification of microbial health risks in drinking water systems (WHO 2016). These two are also used in the Swedish QMRA tool developed for drinking water producers (Abrahamsson et al. 2009; Åström et al. 2016). *Quality-Adjusted Life Years* (QALYs) is a third health metric that quantifies life quality (Robberstad 2009).

Probability of infection refers directly to the dose-response relationship of each specific pathogen. Based on controlled infection studies, e.g. for *Cryptosporidium (DuPont et al. 1995)* and norovirus (Teunis et al. 2008), the probability that a person will be infected given a certain dose is estimated. The infectious dose varies due to variations in infectivity between and within pathogen species as well as individual susceptibility in the population (WHO 2016). However, for practical reasons a population dose-response relationship is commonly used. To quantify the health risk reduction obtained from each risk mitigation measure, the change in probability of infection in combination with the exposed drinking water population can be used to calculate the reduction in the number of infections from each pathogen.

DALY and QALY are health metrics that combine mortality and morbidity. DALY is a well-established metric used by the WHO to estimate the burden of disease (WHO 2001). In contrast to DALYs, the weights used in QALYs are based on quality of life estimates instead of disability weights (Sassi 2006). In its simplest form, QALY can be described as the inverse of a DALY. However, the relationship is slightly more complicated, since different elicitation methods are commonly used for establishing quality weights for QALYs and disability weights for DALYs. Furthermore, DALYs are often calculated using age-weighting functions that are not used in QALYs (Sassi 2006). If no age weights are used in the DALY calculation, or if age weights are used in the QALY calculation, the inverse relationship becomes even closer (Robberstad 2009). The concept and relationship between DALY and QALY are illustrated in Figure 5.

DALYs are commonly estimated using internationally established disability weights, local age distributions, and local estimates of life span, where age weights are optional (Havelaar and Melse 2003; Kemmeren et al. 2006). Calculation of the QALY is based on health-related quality of life (also referred to as the quality weight) and the duration of that health state. Health-related quality of life is based on surveys, often using questionnaires and applying established methods, e.g. EQ-D5 (Aronsson et al. 2015). The EQ-D5 describes health-related quality of life using five domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), and ranks quality of life within each domain from 1-3 (1 being the highest quality of life). The EQ-D5 scores are assigned quality weights (0-1) to describe the quality of life of each specific health state. Multiplying the change in quality weight with the duration of health states results in the

QALY loss for that specific health state (Batz et al. 2014). The EQ-D5 scores and illness duration can be based on expert judgements from physicians or similar professionals. Batz et al. (2014) used expert judgements to describe the health-related quality of life and the illness duration for fourteen foodborne pathogens using the EQ-D5 approach. The EQ-D5 scores were converted to quality weights using national surveys representative of the US population. To quantify the health risk reduction from risk mitigation measures, the change in QALYs or DALYs obtained from each mitigation measure can be used.

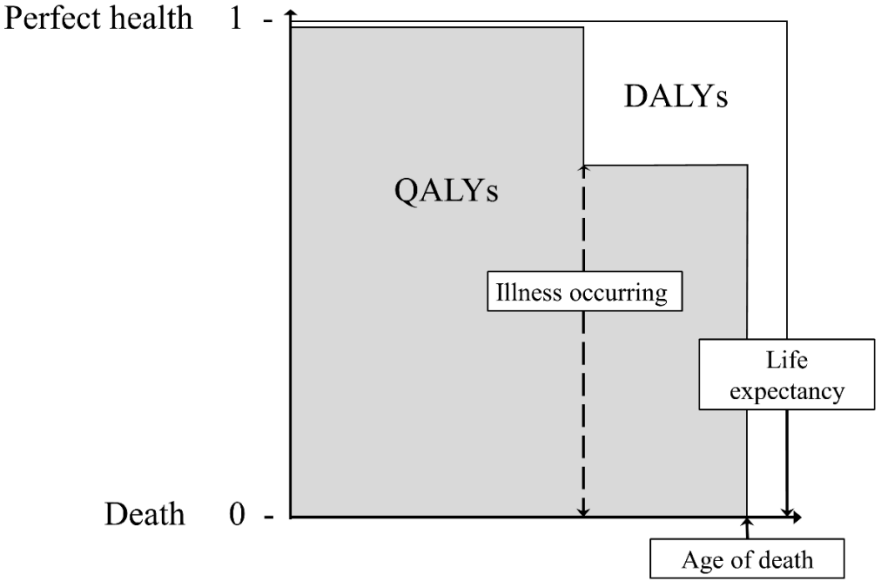

Figure 5 The conceptual relationship between DALYs and QALYs is illustrated. The white area represents the DALYs and the grey area represents the QALYs experienced during a lifetime. Adopted from Robberstad (2009).

Expressing the monetary values of non-market goods, such as health benefits, can be achieved using different economic valuation methods. Non-market goods can be categorised as both use (direct use, indirect use, and option values) and non-use (existence, bequest and altruistic values) values. To monetise health risk reduction, economic valuation methods can be used to express in monetary terms the avoidance of one infection, the avoidance of one DALY, or the gain of one QALY. The economic valuation can be performed using stated preferences (e.g. contingent valuation methods, choice experiment) and revealed preferences (e.g. cost of illness (COI), travel cost method, averted expenditure) to estimate the willingness to pay. Stated preferences investigate people's preferences when choosing between hypothetical alternatives, while revealed preferences seek to find a surrogate metric for valuing a non-market article or commodity based on real decisions. A detailed review of economic valuation for use in water resource management can be found in Birol et al. (2006).

The health benefit aspects are categorised into different types of costs that are avoided when implementing health risk mitigation measures. The aspects are: avoided cost of illness (medical costs and costs related to loss of production), avoided costs for averting

behaviour, and avoided costs related to the disutility of being ill (Figure 6). These four cost categories can be borne either collectively or privately.

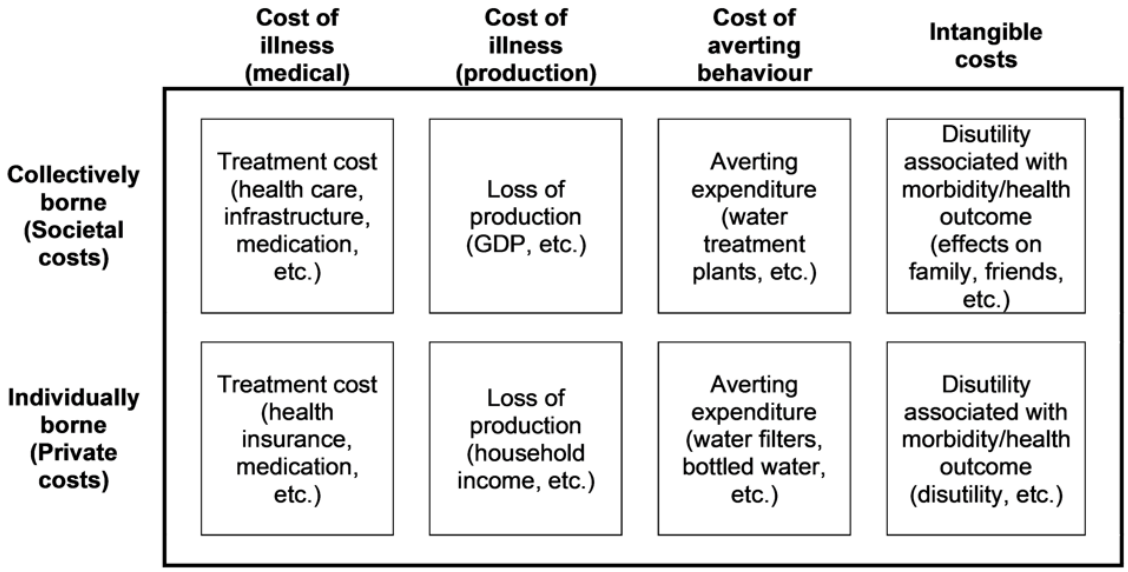

Figure 6 Aspects of health risk reduction. When implementing health risk mitigation measures, the resulting health benefits are in fact avoided costs. Adopted and adjusted from Seethaler (1999) and Hofstetter and Hammitt (2002) as presented in Paper III.

Different health risk economic valuation methods include the different aspects represented by the cells in Figure 6. As an illustration, the cost of illness method covers the aspects in columns 2 and 3, the willingness to pay method for avoiding an infection covers the bottom row, and the societal value of a QALY method covers all the cells. When monetising health benefits, the method should be chosen with care and stated clearly, since this choice can have an effect on the outcome of the decision model.

2.6 Decision analysis

A schematic illustration of the decision-making process is shown in Figure 7. The stakeholder values, goals, criteria and preferences initiate a decision-making process. Firstly, the decision problem is identified and formulated, and different decision alternatives are developed. Secondly, risk and decision analyses are performed to characterise the decision alternatives. Thirdly, the managers review the decision alternatives by comparing results from the risk and decision analyses. Finally, the decision-makers agree on a decision. Commonly, the decision-makers are identified in the initial step of the decision-making process. A decision-making process in relation to CBA has been described (Aven 2012a; Baffoe-Bonnie et al. 2008; SEPA 2008a), as has CBA in relation to risk management (e.g. Rosén et al. 2010). The risk assessment provides essential input for the risk and decision analyses, connecting the risk management process (Figure 2) to the decision-making process described in Figure 7 (Aven 2012a; Rosén et al. 2010).

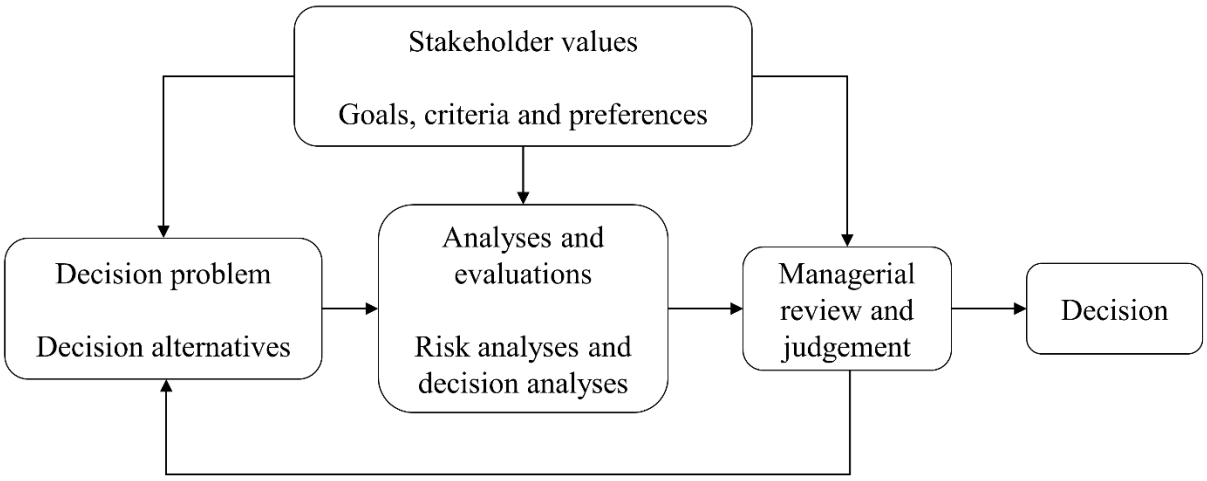

Figure 7 Decision-making process, adopted from Aven (2012a).

When selecting which risk mitigation measure(s) to implement, different decision support systems, decision rules and decision models are available. CEA, as mentioned in the introduction, is used to identify the alternative that achieves the objective of lowest cost. In a CEA, the cost of each risk mitigation measure is estimated. Given that each risk mitigation measure achieves the RAC, the least costly measure should be implemented.

Multi-criteria decision analysis (MCDA) is a method that can handle complex decision problems. Applying an MCDA approach can help prioritise the risk mitigation measures by evaluating appropriate criteria, without converting these criteria into monetary units. The mitigation measures are evaluated in terms of their performance against a set of selected criteria. The MCDA is a useful model when different effects expressed in different units need to be integrated into a total assessment, or when some effects are not possible to monetise.

To evaluate if measures are societally profitable and compare the costs and benefits of each measure to a reference alternative, a CBA can be applied. During the evaluation of the CBA results, the achievement of the RAC does not necessarily need to guide the decision, and the societally most profitable measure should be implemented instead. However, it is possible, and sometimes desirable, when applying a CBA, to reach specific RAC in order for the measures to be considered in the first place. Applying a CBA can be considered to estimate some form of societally tolerable risk level, where all risks have been reduced as much as is practically possible (considering the socio-economic net benefit). The principle of CBA has been used for centuries, although the terms costs and benefits were introduced in the early 20th century (Persky 2001). CBA has been used within a wide range of fields, including environmental policies, infrastructure projects, soil remediation, and company investment strategies. Terms such as benefit-cost analysis, policy evaluation, project appraisal, and socio-economic analysis, are more or less synonymous with CBA (Atkinson and Mourato 2008). If costs and benefits are estimated from a societal perspective, instead of a personal or company perspective, it

can sometimes be referred to as a social CBA (SCBA)[7] (Boardman et al. 2011). The term CBA is used as an umbrella term in this thesis, although there is an emphasis on a societal perspective.

In a CBA, the costs and benefits are estimated for a specified time horizon which, in the context of DWSs and microbial risk reduction, is often the life span of investigated risk mitigation measures. The time horizon often spans several generations. The costs and benefits are discounted into present values using a discount rate to include the change in monetary units over time.

Costs and benefits that occur when implementing risk mitigation measures in drinking water systems can be divided into health benefits/costs and non-health benefits/costs (Moore et al. 2010). Investment, operating, capital, and maintenance costs, as well as additional and external costs, e.g. due to negative effects on human health and ecosystem services, can be described as cost categories. A reduction in the operating cost, a reduction in capital expenditure, improvements in water supply service levels, improved aesthetic qualities, public goodwill, external benefits, e.g. due to improved health, increased provision of ecosystem services and social benefits, can be described as benefit categories (Baffoe-Bonnie et al. 2008).

When non-market goods, such as environmental or health benefits, are monetised, a so-called shadow price is commonly used. The shadow price is a price that should reflect the value of the non-market item and can be estimated using various methods. Stated preferences and revealed preferences are different concepts for estimating a shadow price, as described above in the description of economic valuation of health effects.

[7] The Swedish Environmental Protection Agency (SEPA 2008d) describes SCBA as follows: It *identifies and quantifies all consequences a measure has for different groups in society*. Socio-economic consequences are described as positive (socio-economic benefits) and negative (socio-economic costs). Monetised and non-monetised consequences should be included in an SCBA (SEPA 2008c), and preferably a rough estimation of the non-monetised consequences should also be made (SIKA 2005).

3 METHODS

In this chapter the specific methods applied in the risk-based decision model and in the Papers appended in this thesis are described. In some cases, a brief introduction to the method is included. Section 3.1 describe the overall framework of QMRA and Sections 3.2-3.5 describe the specific methods used as part of the QMRA in the decision model. Sections 3.6-3.7 include monetisation of health effects and a description of the CBA. Finally, in Section 3.8, uncertainty and sensitivity analyses are described.

3.1 Quantitative microbial risk assessment

Quantitative Microbial Risk Assessment (QMRA) is a well-established methodology (Haas et al. 2014) developed for quantifying the health effects of microbial risks. The methodology can be applied in many different settings, e.g. food production, recreational swimming, and drinking water production (e.g. Haas et al. 2014; WHO 2016), where there is a risk of pathogen infection of humans. The QMRA framework in water contexts consists of a four-step procedure (WHO 2016): problem formulation, exposure assessment, health effects assessment, and risk characterisation. A fifth, unifying, step - risk management – can be combined with the four initial QMRA steps (Haas et al. 2014). In a DWS, the presence of waterborne pathogens is identified first and formulated into a problem. In this step, it is possible to specify risk mitigation measures to be included later in the risk treatment. Secondly, the pathogens (hazards) that are present and their routes of exposure (hazardous events), including possible barriers in the system, are identified and estimated. Thirdly, the estimated pathogen concentration in the drinking water, the drinking water consumption rate, and the dose-response relationships are combined in order to estimate the health effects in the drinking water population. Finally, the risks are characterised by combining the exposure assessment (e.g. probability of infection) and the health effect assessment (consequences) to calculate the risk level[8]. The fifth risk management step relates to risk acceptability criteria (RAC), tolerable risk, and implementing measures for risk mitigation, discussed earlier in Section 2.1.

3.2 Source characterisation

There are several methods, both qualitative and quantitative, (e.g. using literature values, pathogen sampling, epidemiologically based methods) that can be used for source characterisation. In this section, the methodology for quantification of pathogen

[8] In drinking water contexts, the probability of infection is sometimes used to describe the risk, and a description of the health consequences is sometimes omitted from the analysis.

sources based on prevalence is described first. Sampling and qPCR analysis are then presented.

Prevalence-based source characterisation

Source characterisation quantifies pathogen sources in the drinking water catchment. Based on reported pathogen incidence from the Public Health Agency of Sweden, the pathogen concentration in wastewater effluents can be estimated (Paper I, Paper II, Paper V).

Pathogen sources were divided into OWTS, WWTP and animal sources. The method is applied for each pathogen included in the risk assessment. In the QMRA methodology implemented in the Swedish QMRA tool, three reference pathogens are often adopted to represent protozoan, bacterial and viral pathogens. The prevalence of pathogens in the human population was calculated as:

$$P_{human} = \frac{I \cdot U \cdot D}{365 \cdot 10^5 \cdot (1 - A)} \qquad (1)$$

where P_{human} was the prevalence, I was the incidence (per year per 10^5 inhabitants), U was the factor of underreporting, D was the number of days when excretion occurs during infection, and A was the proportion of asymptomatic infections. Incidence was expressed using a gamma distribution adopted from incidence data between 2006 and 2016 reported by the Public Health Agency of Sweden (PHAS 2017). The number of infections that are reported in the incidence represents only a fraction of the actual infections present in the population. Underreporting is illustrated (Figure 8) in the form of a report pyramid (Haas et al. 2014). The asymptomatic infections were only accounted for explicitly in Paper I. In Paper II and Paper V, the asymptomatic infections were set at 0 and were assumed to be included in the factor for underreporting (Voetsch et al. 2004).

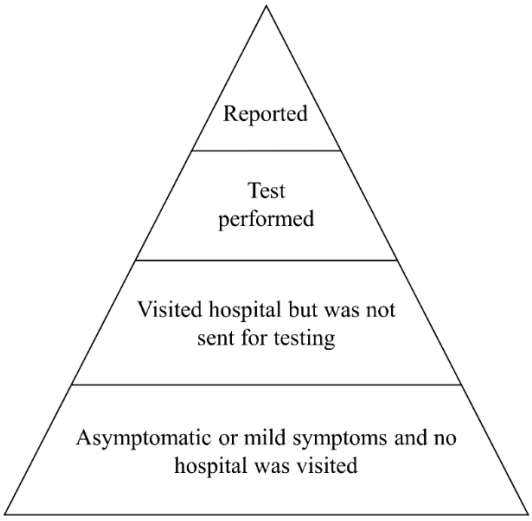

Figure 8 Illustration of the clinical report pyramid, adapted from Haas et al. (2014).

The pathogen concentration[9] in wastewater from the OWTS and the WWTP was calculated as:

$$C_{path} = \frac{P_{human} \cdot F \cdot C_{human}}{W \cdot 10^{R}} \qquad (2)$$

where C_{path} was the pathogen concentration in wastewater per day from either OWTS or WWTP, P_{human} was the prevalence in humans, F was the faecal production per person per day, C_{human} was the pathogen concentration in faeces from infected individuals, W was wastewater production per person per day, and R was the Log_{10} reduction in pathogens in OWTS or WWTP. The term *reduction* incorporates all the processes, e.g. removal, inactivation, adsorption, predation, etc., which in some way lower the concentration of pathogens.

Another approach was to use literature values of pathogen concentrations in wastewater in combination with the potential Log_{10} reduction in WWTP (Paper V). It is also possible to use literature values of pathogen concentrations in the wastewater effluent.

For animal sources, calculations similar to the ones used for human sources were performed using prevalence as a base. Site-specific data are preferable when estimating the pathogen load. However, there are few studies that actually quantify pathogens in animal faeces (Dufour et al. 2012). Extensive reviews of animal pathogen prevalence (e.g. Dufour et al. 2012; Ferguson et al. 2009) cannot provide local estimates. Nevertheless, they can be used to develop and evaluate models or methods (Paper II). In Paper IV, data on herd prevalence and excretion were used to estimate the concentration in manure (Lewerin et al. 2019). Equation 3 was used to calculate the pathogen concentrations in manure, applied either during grazing or via manure application as fertilizer:

$$C_m = \frac{\sum_{i=1}^{n} E_i \cdot P_i \cdot V_i \cdot N_i \cdot T_i}{\sum_{i=1}^{n} V_i \cdot N_i \cdot T_i} \qquad (3)$$

where C_m was the mean pathogen concentration in manure, E_i was the pathogen excretion rate in infected animals, P_i was the prevalence, V_i was the manure production per animal per day, N_i was the number of animals in the area, T_i was the number of days for manure accumulation each year, and i represented different domestic animal categories ($i=1…n$). The animals included depend on the local conditions. In Paper I, horses, suckler cows, heifers, steers, dairy cows, sheep, swine and poultry were included. Depending on local legislation, routines and procedures, the timing of annual manure load from grazing animals and from applying manure as fertiliser needs to be distributed accordingly. Further details of the calculations of animal faecal contribution can be found in Paper I.

[9] For OWTS, the source characterisation was adjusted in Paper I to adapt it to the SWAT model

Water quality sampling
Another approach to characterise and quantify pathogen sources in drinking water catchments was to conduct water sampling and analyse the water for faecal indicator organisms or pathogens. Indicator organisms can also be used to generate input pathogen concentrations for QMRA (Åström 2018; Petterson et al. 2016). Real-time Polymerase Chain Reaction (PCR) analyses can be used to confirm the presence of specific microorganisms and quantify their concentrations. In Paper IV, Real-time PCR was used to quantify DNA from *E. coli* and from several pathogens (*Salmonella spp*. *Campylobacter spp., Salmonella spp., and EHEC O157)* to investigate the microbial risks in the Lake Vomb catchment. The sequence of *E. coli ssrA* (*tmRNA*) was analysed by BLAST (NCBI 2019), and conserved regions and base pairs shared by several *Escherichia* and *Citrobacter* genomes were used to design primers specifically for coliforms. Primers for detection of *Salmonella spp.*, EHEC O157 and *Campylobacter spp*. were selected, as described in Paper IV. Since a molecular approach was used, the *ssrA* primers also detected the closely related genera *Shigella* and *Salmonella.* Specific PCR amplification was confirmed in all target genera. For *ssrA,* other members of *Enterobacteriaceae*, such as lactose negative *Edwardsiella, Erwinia* and *Yersinia,* as well as more distantly related bacteria, such as *Vibrio cholerae* and *Campylobacter* spp.*,* were not detected by the primers. Sampling was performed from February 2015 until May 2016, and water samples were collected once or twice each month and once a week during the summer. Sampling was identified as a different method of providing input in the source characterisation part of the risk-based decision model.

3.3 Water quality modelling

Three different approaches to water quality modelling are presented below. Each modelling approach represents a method that can be used to investigate the fate and transport of pathogens in water.

Factors important to the fate of pathogens are water/osmotic pressure, water temperature, pH, solar radiation, predation/grazing, and nutrients (inorganic and organic) (e.g. Ferguson et al. 2003; Hipsey et al. 2008). Transport of pathogens in catchments and in groundwater is affected mainly by adsorption/desorption to particles, pH, and hydrological, mechanical and biological movement (Åström et al. 2016; Ferguson et al. 2003). Hydrological surface water modelling investigates transport from sources on land to and within the surface waters in the catchment. Hydrodynamic surface water modelling estimates transport in water bodies, both within rivers and lakes. Groundwater modelling, using analytical or numerical models, investigates reduction in pathogens during groundwater transport. If several types of models are combined, they can describe the transport of pathogens, from both point and non-point sources on land and in water, to the drinking water intake. Hydrological modelling

(Oliver et al. 2016), hydrodynamic modelling (Sokolova et al. 2015), and groundwater modelling (Pang 2009) can aid microbial risk assessment of drinking water systems.

Hydrological modelling

Hydrological modelling of pathogen fate and transport can be performed using various models (Dorner et al. 2006) and can be helpful in analysing microbial risks for water quality management (Coffey et al. 2010a; Oliver et al. 2016). The Soil and Water Assessment Tool (SWAT) was ranked highest in terms of the performance of microbial contamination modelling (Coffey and Cummins 2007). The SWAT model has been used to assess the fate and transport of various microbial contaminants, e.g. faecal coliforms (Cho et al. 2012; Parajuli et al. 2009), *E. coli* (Bougeard et al. 2011; Coffey et al. 2010a; Kim et al. 2010) and *Cryptosporidium* (Coffey et al. 2010b; Jayakody et al. 2014; Tang et al. 2011). SWAT is a deterministic, semi-distributed, process-based hydrological model describing the hydrological cycle and the water transport in catchments (Nietsch et al. 2011). A sub-model for pathogen load is incorporated and linked to the hydrological cycle (Sadeghi and Arnold 2002). The SWAT model is based on a geographic information system (GIS) and can be combined with ArcGIS (Winchell et al. 2013) and QGIS (Dile et al. 2016) interfaces. In Paper I, the SWAT model was used to estimate the pathogen reduction in different microbial risk mitigation scenarios, adopting the Stäket catchment as a case study. In Paper V, the SWAT model was used to include non-point sources (grazing animals and application of manure for fertilisation) when applying the decision model in the Vomb DWS.

Hydrodynamic modelling

Hydrodynamic modelling can provide information on the fate and transport of pathogens within water bodies. In Paper II, hydrodynamic modelling was performed using the MIKE Powered by DHI MIKE 3 FM model. This model solves three-dimensional incompressible Reynolds averaged Navier-Stokes equations, invoking the assumptions of Boussinesq and of hydrostatic pressure (DHI 2011).

Groundwater modelling

To estimate pathogen reduction during groundwater transport, groundwater transport and inactivation models can be used. In Paper II, a groundwater virus transport model was implemented to represent pathogen reduction in artificial infiltration. Moreover, the methodology can also be applied to natural groundwater systems. The model has been incorporated into the Swedish QMRA tool (Åström et al. 2016) and is based on pathogen reduction due to dilution, attachment and inactivation (Pang 2009; Schijven et al. 2006).

3.4 Dose-response models

In this section, the dose-response models used in the decision model are presented. The application of dose-response models is based on the QMRA tool developed for Swedish drinking water producers (Abrahamsson et al. 2009). The methodology is based on the relationship between certain levels of exposure (i.e. pathogen dose) and health effects (response). The daily dose was calculated as:

$$D = C_{DW} \cdot V \quad (4)$$

where D was the daily pathogen dose from drinking water, C_{DW} was the pathogen concentration in drinking water, and V was the volume of ingested drinking water per person per day. The C_{DW} was estimated from the water quality model output and the Log_{10} reduction in DWTP barriers. The Log_{10} reduction in DWTP (Papers II, IV and V) was estimated using literature values in combination with expert judgements (by the authors) for each treatment step in the DWTP treatment chain. Probability density functions for pathogen concentration were used. The volume of ingested drinking water was calculated using a log-normal distribution (Westrell et al. 2006):

$$V = \exp^{Normal(\mu,\sigma)} \quad (5)$$

Where Normal (μ, σ) was a normal distribution (μ = -0.299 and σ = 0.57). An Exact Beta-Poisson model was used as a dose-response model assigned to each pathogen. The Exact Beta-Poisson model was expressed as:

$$P_{inf} = 1 - exp^{-r \cdot D} \quad (6)$$

where P_{inf} was the daily probability of infection, r was a sample from a Beta distribution with statistical parameters set for each pathogen, and D was the simulated daily pathogen dose that was ingested. Parameters (α, β) for r, i.e. the Beta distribution, were (0.024, 0.011) (Teunis et al. 2005), (0.04, 0.055) (Teunis et al. 2008) and (0.115, 0.176) (Teunis et al. 2002) for *Campylobacter*, norovirus and *Cryptosporidium* respectively. The annual probability of infection was calculated using (Paper II):

$$P_{annual} = 1 - \prod_{1}^{365} (1 - P_{\inf}) \quad (7)$$

where P_{annual} was the annual probability of infection per person. The P_{inf} was based on the same probability density function for all days of the year, although new values from the probability density function were calculated for each day of the year.

In Paper IV, the P_{inf} was allowed to vary between days, depending on the risk level, or scenario (S), in the drinking water system. The annual probability of infection (P_{annual}) (no unit) for each pathogen type (p) was then calculated as (WHO 2016):

$$P_{annual} = 1 - \prod_{1}^{s_1}\left(1 - P_{\inf,p,S_1}\right) \cdot \prod_{1}^{s_2}\left(1 - P_{\inf,p,S_2}\right) \cdots \prod_{1}^{s_i}\left(1 - P_{\inf,p,S_i}\right) \qquad (8)$$

where s_i (days) represented the duration of the scenario (S_i) with the specific probability of infection (P_{inf,p,S_i}). Note that the durations ($s_1+s_2+\ldots+s_i$) should total 365 days to represent one year.

3.5 Scenario-based approach to include unexpected risk events

Unexpected risk events are events occurring with an uneven, less predictable temporal distribution and typically with short and varying durations (e.g. accidental spills of faecal matter containing pathogens, technical system failures). The unexpected risk events have a certain annual probability of occurrence, and if they occur they do so at a specific time (scenario) during the year (Figure 9). These scenarios represent situations with different base load levels.

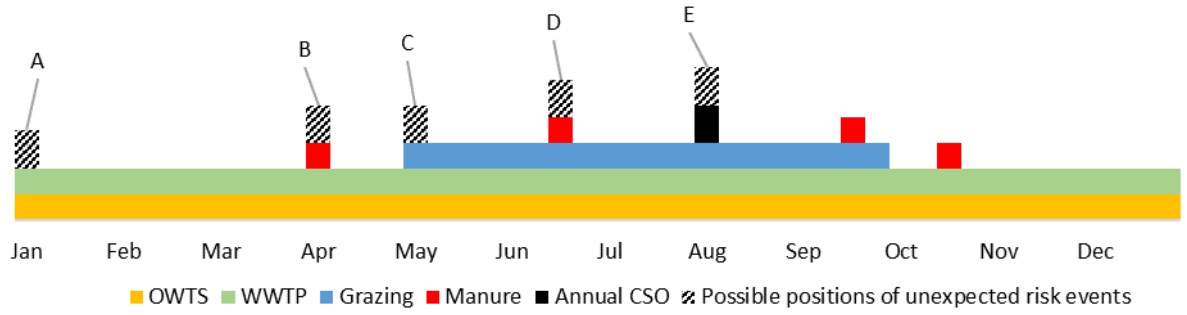

Figure 9 Schematic illustration of possible variation in base pathogen load (solid areas) and the positions of unexpected risk events (striped areas). Note that neither the height nor the length of the bars is to scale. A-E represent different scenarios that combine the different base load types. Adapted from Paper V.

In Figure 9, scenario *A* represents a situation where the base load consists of wastewater from OWTS and WWTP, while scenario *E* represents a situation where the base load consists of wastewater from OWTS, WWTP, grazing animals in the catchment, and the load from a CSO. For unexpected risk events that may occur on any given day during a year, the probability of an event occurring during a specific scenario is the number of days with that scenario during a year divided by the number of days in one year (365). Some unexpected risk events are restricted to specific times during the year, depending on the characteristics of the event.

To determine the position of the unexpected risk event, a discrete distribution, with the probabilities of occurrence for each specific scenario, was used in the Monte Carlo simulations (Monte Carlo simulations are described in Section 3.8 below). When the position was determined, the additional pathogen concentration was added to the tributary concentrations for the duration of the unexpected risk event (in this work assumed to be one day). To calculate the risk contribution from the unexpected risk

events, their probability of occurring was combined with the probability of them occurring during specific scenarios.

To calculate the increased annual risk ($\Delta P_{annual,p,g,URi}$), the addition to the total risk level from each pathogen (p) due to the unexpected risk event (UR_i) for each risk mitigation measure (g) was calculated as:

$$\Delta P_{annual,p,g,URi} = P_{annual,p,g,URi} - P_{annual,p,g,UR0} \qquad (9)$$

where $P_{annual,p,g,URi}$ was the annual probability of infection in the case of a risk event UR_i, and $P_{annual,p,g,UR0}$ was the probability of infection without any unexpected risk event (UR_0).

The total annual risk ($P_{annual,p,g,Tot}$) comprised the base load (UR_0) and the unexpected risk events (UR_i) in combination with their respective probability of occurrence, and was calculated as:

$$P_{annual,p,g,Tot} = P_{annual,p,g,UR0} + \sum_{i=1}^{3} \Delta P_{annual,p,g,URi} \cdot P_{occ,URi} \qquad (10)$$

where $P_{occ,URi}$ was the annual probability of occurrence of an unexpected risk event (UR_i).

3.6 Economic valuation of health risk reduction

The economic valuation of health risk reduction was conducted using either the monetisation of avoidance of a specific infection or by converting the infection to either QALYs or DALYs and then monetising the expected change in QALYs or DALYs. DALYs were estimated in this thesis without age weighting, using a Swedish age distribution (EU 2010), and a life expectancy of 81 years in combination with internationally established disability weights (Havelaar and Melse 2003; Kemmeren et al. 2006). In total, seven different health valuation methods were evaluated (Paper III). The two health valuation methods, *cost of illness adding disutility* (COI+) and the *societal value of a QALY* (SVoQ), were chosen to illustrate how the choice of health valuation method affects the decision outcomes using the decision model. COI+ was chosen since it represents a value close to what is applied in other contexts (e.g. traffic planning). The SVoQ was chosen since it encompasses all aspects (private and societal) of health risks and represents the societal willingness to pay for a QALY in relation to reimbursement for pharmaceuticals (Svensson et al. 2015). The health benefits using COI+ from each risk mitigation measure were calculated as:

$$B_H = DP_{annual} \cdot Cons \cdot COI + \qquad (11)$$

where ΔP_{annual} was the amount of reduction in the probability of infection achieved from the risk mitigation measure, *Cons* was the number of drinking water consumers connected to the DWTP, and *COI+* was the cost of illness with the addition of disutility, as presented in Paper III.

P_{annual} for each pathogen was converted into QALYs lost using a unit value (Equation 12) based on a US study of QALYs lost per infection (Batz et al. 2014). The number of QALYs lost per infection (Papers II, III and IV) was assumed to be 0.0035, 0.0163 and 0.0009 for *Cryptosporidium, Campylobacter* and norovirus, respectively.

$$QALY_{annual,p} = I_p \cdot Q_p \quad (12)$$

where $QALY_{annual}$ was the annual QALYs lost per infection, I was the number of infections in drinking water consumers per year, and Q was the number of QALYs lost per infection. The QALYs from each pathogen (p) were added to estimate the total QALYs. Health benefits, when monetising using the SVoQ, were calculated as:

$$B_H = \Delta Q \cdot SVoQ \quad (13)$$

where ΔQ was the positive change in QALYs achieved from the mitigation measure, and $SVoQ$ was the societal value of a QALY.

3.7 Cost-benefit analysis

If the decision is bound to result in costs and benefits over several years, a time horizon could be implemented. The costs and benefits from each year during the time horizon are added together using an appropriate discount rate. The net present value (*NPV*) of a certain measure compares the costs and benefits, all discounted into a present value (Baffoe-Bonnie et al. 2008). It should be noted that the terminal value, i.e. the costs and/or benefits that will occur after the studied time horizon, can be included as a benefit in the final year of the time horizon. In a CBA, the *NPV* of each measure is calculated (Equation 14) in order to compare decision alternatives:

$$NPV = \sum_{t=0}^{T} \frac{(B_t - C_t)}{(1+r)^t} \quad (14)$$

where T is the time horizon[10], B_t is the benefits during year t, C_t is the costs during year t, and r is the discount rate. Benefits can be split into arbitrary constituents depending on the application. In Papers II, III and IV, the benefits were estimated as:

[10] The time horizon of a CBA is usually the expected life span of the implemented measure, although if costs and/or benefits are likely to occur far into the future, a longer time horizon could be considered (Baffoe-Bonnie et al. 2008).

$$B_T = B_H + B_E + B_O \qquad (15)$$

where B_T = total benefits, B_H = benefits estimated from reduced negative health effects in drinking water consumers, B_E = benefits from increased treatment efficiency of nutrients, and B_O = other benefits. In the application presented in Paper II, B_O was not monetised, while B_H and B_E were monetised. Environmental benefits when using a simplified approach are calculated as:

$$B_E = \Delta N \cdot C_N + \Delta P \cdot C_P \qquad (16)$$

where ΔN and ΔP were the expected reduction (kg) in nitrogen and phosphorous discharge, respectively, due to each measure, and C_N and C_P were the unit value of the cost for discharging one kg of nitrogen or one kg of phosphorous into the recipient. In Papers II, III and IV, N_{red} and P_{red} were based on increased nutrient reduction in WWTP in comparison to OWTS, and C_N and C_P were based on literature estimates (SEPA 2008b).

B_O was not monetised using quantitative measures but was included using a qualitative list with short descriptions of each benefit. To illustrate the importance of these other benefits, an analysis of how large they need to be to produce a positive *NPV* can be included as part of the decision support.

Costs can be derived from e.g. literature, previous implementation of measures, and be obtained from relevant stakeholders, and are estimated for each measure. In Papers II, III and IV, costs were based on estimates from the literature based on previous investments (Kärrman et al. 2012) and information from relevant stakeholders.

3.8 Uncertainty and sensitivity analysis

In the risk-based decision model presented in this thesis, Monte Carlo simulations were used to include uncertainty. In a Monte Carlo simulation approach, multiple iterations (e.g. 10,000) are conducted, sampling values from the input probability distributions and resulting in outputs that are also described using probability distributions. An important part of the uncertainty analysis is the parameterisation of the input probability distributions.

Uncertainties in hydrodynamic modelling were estimated based on variations in the calculated Log_{10} reduction. The model was used to simulate a long period of time (5 years) in order to consider variations in the meteorological and hydrological conditions that determine the transport of pathogens from the source to the drinking water intake.

Not all uncertainties can be suitably described using probability distributions and different scenarios can be used instead. A scenario-based approach was used to

investigate the sensitivity of pathogen load (Paper I), discount rate (Papers II, III, V), health valuation method (Papers II, III, V), and time horizon (Papers II, III).

Sensitivity analysis investigates how changes in different input variables affect the output. Applying a Monte Carlo simulation approach enables a global sensitivity analysis to be made. However, a local sensitivity analysis can also be calculated manually to avoid heavy computations when applying Monte Carlo simulations using Equation 17 as suggested (Burgman 2005):

$$Sensitivity = \frac{\Delta V}{\Delta I} \cdot \frac{I}{V} \qquad (17)$$

where ΔV was the change in output value, V was the original output value, ΔI was the change in input variable, and I was the original input variable value. It presents the sensitivity as the percentage change in the output value due to the percentage change in the value of one input variable at a time. This does not provide any information regarding the uncertainty of the results, only on the sensitivity of the results to the different values of each input variable.

In Paper I, the hydrological SWAT model provides limited possibilities regarding uncertainty analysis due to its deterministic approach. A local sensitivity analysis of the SWAT model, altering input variables showed that hydrological variables related to run-off, plant-available water in soil, and soil evaporation processes had the greatest influence on the river water flow.

Sensitivity analysis was performed using the Spearman's rank correlation for the variables in the source characterisation and the CBA compartments in the risk-based decision model (Paper II). In Paper V, Spearman's rank correlation was used to calculate the effect of variation in input variables on the drinking water pathogen concentration, including the entire QMRA part of the decision model in the analysis. Equation 18 reflects the sensitivity of the output to each input variable and is calculated as the Spearman's correlation coefficient:

$$\rho = 1 - \frac{\left(6 \cdot \sum d_i^2\right)}{n\left(n^2 - 1\right)} \qquad (18)$$

where ρ was the correlation coefficient, d was the rank difference between the input and output, and n was the number of correlation sets. A ρ close to 1 shows high importance, and ρ close to 0 shows low importance. Spearman's rank correlation is only applicable when investigating monotonic relationships. Non-monotonic relationships can be investigated using different methods. Scatter plots were used to investigate the non-monotonic dose-response relationships in the decision model.

4 THE PAPERS

In this chapter, a brief overview of the appended papers is presented, including a summary of the results. Key aspects important to the risk-based decision model in relation to each publication are highlighted.

4.1 Paper I

In Paper I, a risk management framework was presented to describe the relationship between risk management and CBA as a form of decision support. The role of hydrological modelling in the risk management framework was also described. Pathogen reduction using different microbial risk mitigation measures was estimated using the SWAT hydrological model. As a case study, the Stäket catchment north-west of Stockholm in Sweden was used.

In more detail, fate and transport modelling of *Cryptosporidium* and the indicator bacteria *E. coli* was performed for the Stäket catchment to analyse four mitigation scenarios (M1-M4). Scenarios M1 and M2 simulated a 50 m vegetative filter strip adjacent to cropland and grazing areas, respectively. In scenario M3, all underperforming OWTSs were assumed to be restored and were assigned a microbial reduction of two Log_{10} units. In scenario M4, microbial reduction by means of the WWTPs was increased by one Log_{10} unit. Results showed that M2 and M3 did not result in a significant reduction in *Cryptosporidium* or *E. coli* water concentrations in the sub-basins, while M1 and M4 did. The magnitude of microbial reduction differed between sub-basins. For scenario M1, the Log_{10} reduction in water concentrations in different sub-basins ranged from 0 to 0.41 and from 0 to 0.46 for *Cryptosporidium* spp. and *E. coli*, respectively. For scenario M4, the Log_{10} reduction in water concentrations ranged between 0 and 1 for both *Cryptosporidium* spp. and *E. coli*. Looking at the catchment outflow, M4 resulted in the highest microbial reduction.

It was concluded that hydrological modelling can quantify the effects of microbial risk mitigation measures and provide input for QMRA. The presented risk management framework that was presented illustrated the possible role of CBA in combination with risk assessment to provide decision support.

4.2 Paper II

In Paper II, the risk assessment and decision analysis part of the risk management framework was described in detail. Source characterisation, hydrodynamic modelling, QMRA and CBA were described in a risk management and drinking water context.

These methods were combined to create a decision support model in order to evaluate and compare microbial risk mitigation measures. Uncertainties in input data and results were considered using Monte Carlo simulations. Lake Vomb in southern Sweden served as a case study to illustrate the risk-based decision model.

Four decision alternatives (A1-A4) for microbial risk mitigation were investigated. Three alternatives (A1-A3) represented connecting OWTSs in the catchment area (25, 50 and 75%, respectively) to the municipal WWTP. Alternative A4 represented installation of UV treatment in the DWTP. Based on the included costs and benefits, none of the alternatives resulted in a positive *NPV*. Nevertheless, the analysis showed that if non-monetised benefits reach SEK 800-1200 per connected OWTS per year, the median of the *NPV* would be positive with a 1% discount rate. Alternative A1 (25% of OWTSs connected to the WWTP) achieved the highest *NPV*, closely followed by A4 (UV treatment in the DWTP). However, comparing the microbial risk in terms of probability of infection to the WHO guidelines, only A4 would reduce the risk sufficiently at the 95th percentile. The application of the decision model illustrated the importance of the distributional and sensitivity analyses, in particular the need to apply scenario-based sensitivity analysis. Investigating variables such as discount rate, assumptions regarding OWTSs contribution to the total pathogen load, the economic valuation method used to monetise health effects, and how large the non-monetised benefits need to be to achieve a positive *NPV*, provides valuable information for decision-makers.

Paper II provides the foundation for the risk-based decision model described in this thesis. The decision model is a novel approach, combining QMRA and CBA and providing holistic and transparent decision support for prioritising microbial risk mitigation measures. The study identified the importance of including intra-annual variations in the microbial risk and investigation of the health benefit valuation method in future studies.

4.3 Paper III

The study presented in Paper III was conducted to provide a theoretical background to available health valuation methods. The study also tested the sensitivity of the decision model to changes in the health valuation.

Seven economic valuation methods for monetising health benefits were identified using a literature review. Applications of the identified methods were illustrated in a case study using literature exemplifications of each health valuation. Health benefit aspects included in each method were identified. Willingness to pay represents a person's willingness to pay to avoid certain illnesses and health states. Cost of illness covers the medical costs and costs related to loss of production. Cost of illness plus cost of disutility

comprise the cost of illness and adds the costs a person incurs due to disutility from being ill. The value of avoiding a DALY or QALY was estimated using both a private estimate (taking account of a person's willingness to pay) and a societal estimate (taking account of the societal willingness to pay). Results showed that the choice of economic valuation method affects the outcome of the decision model, changing the ranking of decision alternatives. The economic value of avoiding one infection was highest using the willingness to pay method and lowest using the value of a DALY (*Campylobacter*) or QALY (norovirus and *Cryptosporidium*).

Key results for the risk-based decision model, apart from the actual compilation of valuation methods, were that the choice of health valuation method affects the ranking of decision alternatives. In the event of any ambiguity with regard to the choice of economic valuation method, several methods can be included to provide a sensitivity analysis.

4.4 Paper IV

Paper IV presented a sampling campaign and its possible use for a QMRA of the Lake Vomb DWS. Water quality sampling took place between February 2015 and May 2016. Samples were taken once or twice each month, and during the summer sampling took place each week. The sampling locations were: wastewater from an OWTS; the three tributaries discharging into Lake Vomb; the drinking water intake in the lake; infiltrated water from the boreholes; and natural groundwater (not connected to the aquifer used for artificial groundwater recharge). Water samples were analysed using real-time PCR to detect the presence of and to enumerate *ssrA* gene copies representing the coliform group of Enterobacteriaceae, and the presence of DNA from *Campylobacter* spp., *Salmonella* spp., and EHEC O157. The *ssrA* gene was detected at all the sampling locations. *Salmonella* spp. was detected on a few occasions. None of the other pathogens were detected.

One of the initial objectives of the study was to investigate sampling as a method for quantifying pathogen concentrations as input for QMRA, which could then be implemented in the risk-based decision model. However, it was concluded that for this specific study, the pathogen concentrations were close to the detection limit, and the results of the analysis at these concentrations were assumed to be insufficient to form a basis for QMRA.

To investigate a different QMRA approach, an RAC based on a daily risk level (daily probability of infection $< 2.7 \times 10^{-7}$) was used to estimate acceptable *Salmonella spp*. concentrations in the raw water and in the infiltrated groundwater. Such evaluations can be useful when a worst-case scenario is investigated, or when drinking water utilities

have agreed on a specific RAC. This approach could be implemented into the risk-based decision model.

4.5 Paper V

In Paper V, an improved risk-based decision model was presented. The decision model in Paper II was further developed to include unexpected risk events. To achieve this, additional features, such as including both hydrological and hydrodynamic modelling and applying a daily risk level, were embedded in the decision model.

Unexpected risk events, occurring with an uneven and less predictable temporal distribution and with short and varying durations (e.g. accidental spills of faecal matter containing pathogens, and technical system failures), were included in the decision model using a scenario-based approach. The scenario-based approach acknowledges that the pathogen base load conditions vary during the year (using daily risk levels) and accounts for the possibility of unexpected risk events occurring during any day of the year. A linear increase in the risk level over time to serve as a climate factor was also included in the decision model. Four alternatives for microbial risk mitigation were investigated using the expanded risk-based decision model: (A1) installation of pumps and a back-up power supply to remove CSOs; (A2) installation of UV treatment in the DWTP; (A3) connecting 25% of the OWTSs in the catchment to the WWTP; and (A4) a combination of A1-A3. The same problem formulation and
decision model set-up was applied to two distinctly different DWSs. The first DWS was based on the Vomb DWS, and the second DWS (Alt. DWS) represented a DWS with different preconditions in terms of base load level and the pathogen reduction potential at the DWTP.

It was concluded that it was particularly important to include unexpected risk events in decision models for a DWS with a low pathogen base load, and consequently low pathogen reduction potential in the DWTP.

5 RESULTS

In this chapter the risk-based decision model is described. The model is built up from a combination of methods described in the method chapter. Key findings from the papers are presented and related to the decision model. Finally, the decision model is put into the context of tools commonly applied by the drinking water utilities in Sweden. These tools can serve as an alternative or as a complement to the developed decision model.

5.1 The risk-based decision model

The risk management framework as presented in Paper I (Figure 10) illustrates the decision-making process in relation to the risk management framework, as presented by ISO (2018), and the role of CBA in this context. The framework should be seen as a point of departure for comparing microbial risk mitigation measures in DWSs using a risk-based CBA as a decision model. The preconditions for the framework are the values, goals and criteria set by various stakeholders, as well as continuous improvement to achieve these goals. To ensure transparent risk management, documentation and communication of the process are essential. The main compartments in the framework are risk analysis, risk evaluation, and risk reduction/control. The risk-based decision model developed in this thesis makes up the left-hand side of Figure 10, including a QMRA for risk analysis and CBA as the decision model for evaluating risk mitigation measures. The right-hand side of Figure 10, risk reduction/control, is conducted by the decision-makers (e.g. drinking water utilities) using the decision support provided. In the case where a risk mitigation measure has been implemented, monitoring and continuous improvement is initiated. If the implemented measure does not result in an acceptable risk level, additional measures may need to be analysed and evaluated.

In Figure 11, an overview of how to link different methods to combine risk assessment and CBA is presented in accordance with the focus of this thesis. The description strives to be generic but is based on the Lake Vomb case study. The developed risk-based decision model was constructed using the presented risk management framework as a starting point. The decision model combines QMRA and CBA and is a powerful tool in the evaluation of microbial risk mitigation measures in DWSs. Included in the decision model are methods used for source characterisation (including unexpected risk events), water quality modelling (hydrological, hydrodynamic, and groundwater modelling), pathogen dose-response models, economic valuation of health effects, and economic evaluation of decision alternatives from a societal perspective using CBA. Each individual method is described in more detail in Chapter 3.

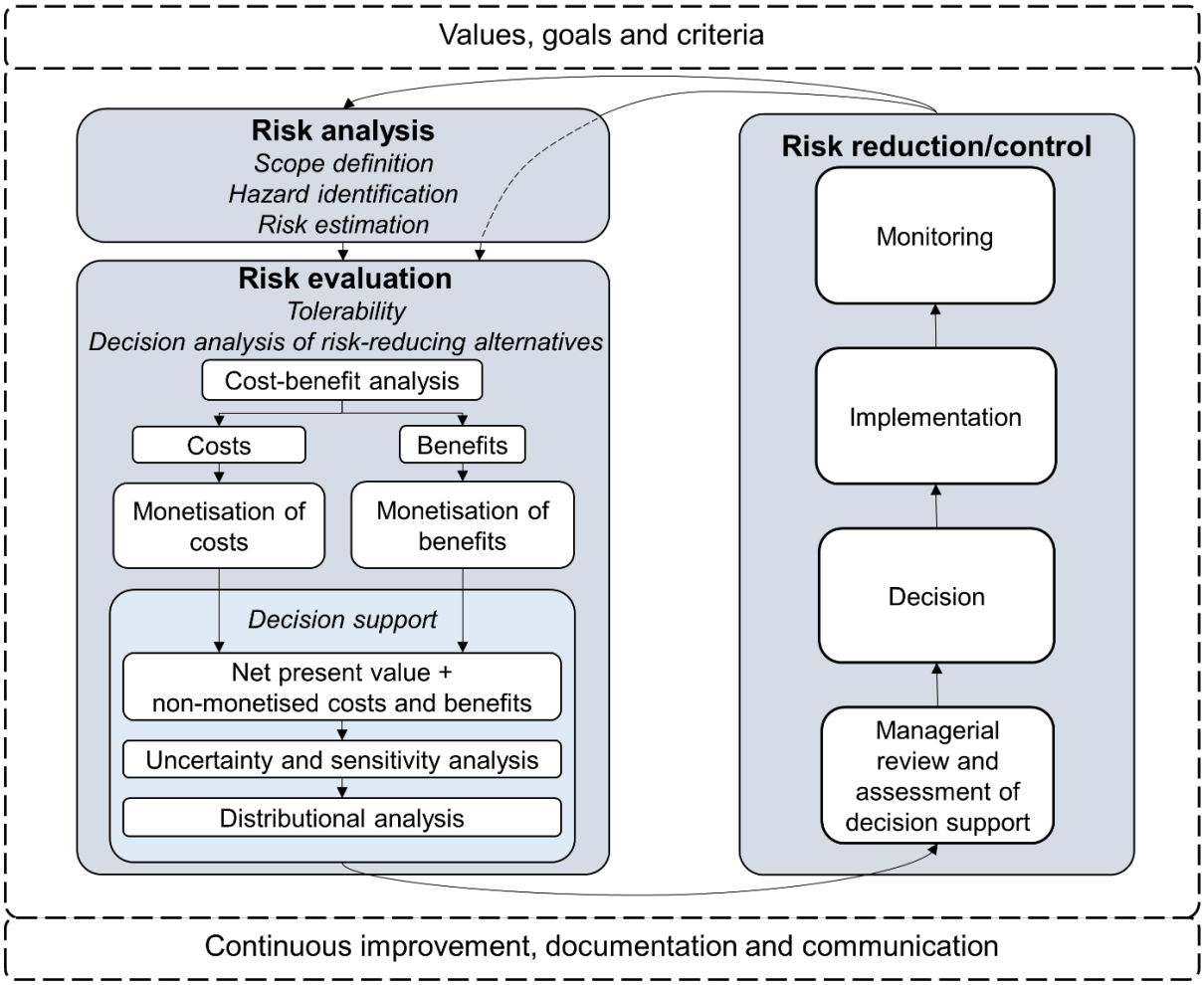

Figure 10 Risk management framework from Paper I. Risk assessment makes up the left-hand side, including risk analysis and risk evaluation. The right-hand side – risk reduction/control – is part of risk treatment.

Each compartment of the decision model can, depending on the local preconditions, specific hazards, and other aspects, be adapted to fit the conditions for the DWS that is being analysed. The clear structure presents an opportunity to tailor each compartment using the best available method for that application. To estimate the potential risk reduction, the set of methods is applied to the reference alternative and to each risk mitigation measure. The resulting change in health risk is monetised and included in the CBA. The CBA calculates the *NPV* to determine whether the risk mitigation measure is profitable from a societal perspective. In addition to the *NPV*, the decision model reports actual microbial risk levels in relation to RAC, uncertainties, distributional analysis, uncertainty and sensitivity analysis, etc. These aspects are all part of decision support and need to be considered by the decision-makers when comparing and prioritising risk mitigation measures in DWSs.

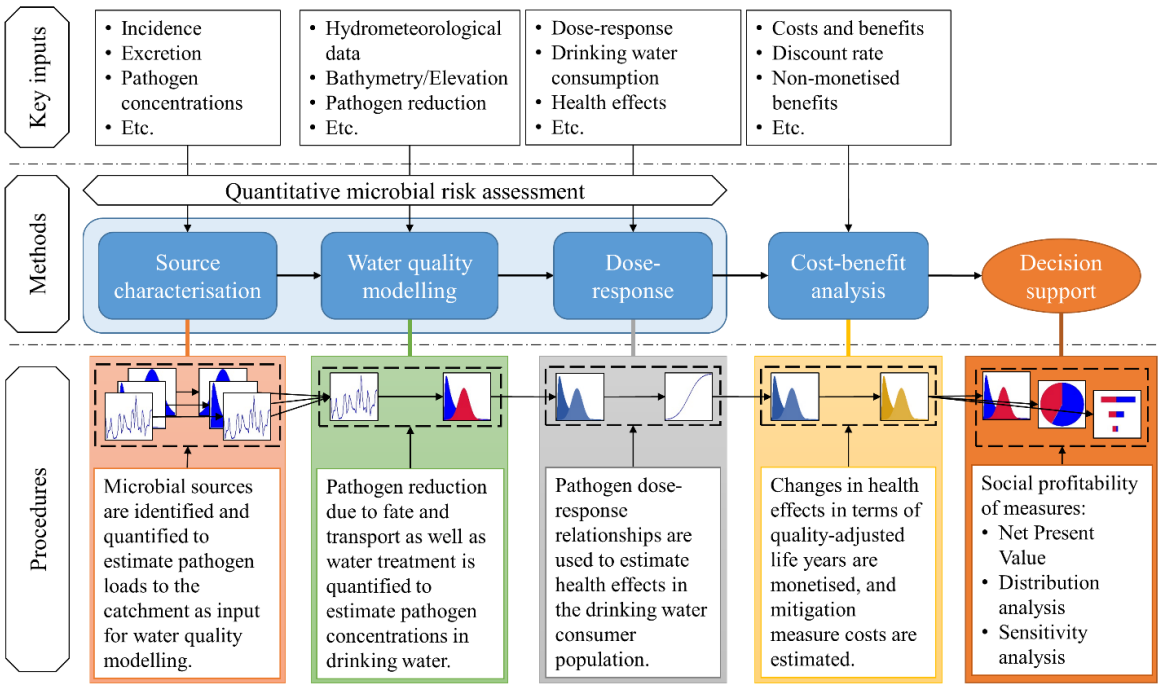

Figure 11 Illustration of the methods that were combined in the decision model, adjusted from Paper 2.

Source characterisation

An incidence-based quantification method was used for source characterisation (Paper I, Paper, II, Paper IV). Quantification can also be carried out using other epidemiological metrics or sampling, and it is also possible to use semi-quantitative or qualitative methods. Paper IV investigated the possibility of using sampling and real-time PCR to estimate the pathogen concentrations in natural water, raw water, and partially treated drinking water. Epidemiological methods may not capture the actual variability in pathogen concentrations that sampling can. However, sampling is tedious and expensive and is mainly performed to target faecal indicators. As a complement, water quality modelling may provide important input to the source characterisation of QMRA, when there are sampling limitations. In Paper V, the risk was based on daily risk levels, allowing for the inclusion of unexpected risk events as an addition to the pathogen base load. Including unexpected risk events produces a more comprehensive assessment of the microbial risk in the DWSs.

Water quality modelling

Three different approaches to estimate pathogen reduction during transport from risk sources were investigated and applied in this thesis. Hydrological modelling was used to describe the reduction achieved by the different risk mitigation measures (Paper I, Paper V). Hydrodynamic modelling estimated the reduction during transport in Lake Vomb from the point of discharge to the raw water intake point (Paper II, Paper IV). Groundwater modelling was conducted in order to estimate pathogen reduction by means of artificial infiltration (Paper II, Paper V). For water quality modelling the choice of models (hydrological, hydrodynamic, and groundwater modelling) is based on local requirements. The high demand for input data may be an obstacle for succeeding with water quality modelling.

Dose-response models

The same dose-response model, but with different parameters, was used for the three reference pathogens (*Campylobacter*, norovirus and *Cryptosporidium*). In Sweden, it is common to use reference pathogens to represent bacteria, viruses and protozoans. The dose-response model provides the probability of infection for each pathogen. The probability of infection can be used to calculate the number of infections occurring among drinking water consumers and to convert these into QALYs or DALYs. The pathogen dose-response models are based on existing studies and can be updated as new studies become available.

Cost-benefit analysis

The risk reduction achieved by each measure was monetised using seven methods for economic valuation of health effects (Paper III). The gain in QALYs or reduction in DALYs due to each measure was estimated and monetised using a private approach and a societal approach. The health effects in terms of reduced infections were expressed using the COI or the COI and adding the cost of disutility. Additionally, willingness to pay studies were investigated for use as input for monetising health effects. When choosing a method for economic valuation of health effects it is important to consider and be aware of which health effect aspects were included in the specific valuation method. If there is no requirement or preference for a specific valuation method, several methods should be applied in a sensitivity analysis. Environmental benefits due to an increased reduction in nutrients in a WWTP compared to an OWTS were also estimated and included (Paper II, Paper III and Paper V). In addition to health and environmental benefits, non-monetised benefits were identified. An important analysis involves investigating how large non-monetised benefits need to be in order to change the negative *NPV*s of risk-reduction alternatives (Paper II) to positive *NPV*s. The cost of investing in a wastewater pipeline were estimated based on a literature review of actual water and wastewater investments made in Sweden (e.g. Kärrman et al. 2012). The cost of increasing wastewater capacity in a WWTP, reducing CSOs, and adding treatment steps at the DWTP, were based on values provided by local stakeholders.

Decision support

The main part of the decision support base comprised the *NPV* reported from the CBA. However, the *NPV* needs to be complemented with results from the decision model (uncertainty and sensitivity analysis, distributional analysis, probability of infection, non-monetised benefits). Additional results from the decision model may be combined with specific criteria set for specific applications to compare risk mitigation measures. These criteria could be legislation, RAC etc., that need to be fulfilled in terms of specific limits for probability of infection for drinking water consumers and requirements regarding raw water quality.

Uncertainty and sensitivity analysis
Several different methods (e.g. manual approaches, Spearman's rank correlation, and scatter plots) need to be applied in order to test the sensitivity of the entire decision model. The Spearman's rank correlation can be complemented using scatter plots when there are non-monotonic relationships. Using manual or scenario-based sensitivity analysis is also important when testing preconditions that can vary considerably from case to case (e.g. changing the time horizon, or the pathogen base load in the DWS). As an example, changing the discount rate or the method for economic valuation of health effects can change the ranking order of the *NPV*s of the decision alternatives, making it important to highlight these choices for the decision-makers.

5.2 Comparing the decision model to other decision support methods

To benchmark the risk-based decision model, microbial risk assessment methods applied by Swedish water utilities were identified and characterised in order to facilitate the comparison. Three risk assessment methods were compared: the Microbial Barrier Assessment (MBA) approach (Norwegian Water BA 2014; SWWA 2015); the Swedish QMRA tool (Abrahamsson et al. 2009; Åström et al. 2016); and the risk-based decision model presented in this thesis. The risk-based decision model links the microbial risk assessment to a decision model, the CBA, to make an economic evaluation of risk mitigation measures from a societal perspective. However, the CBA can, if necessary, be substituted or combined with other decision models, such as cost-effectiveness analysis (CEA) and multi-criteria decision analysis (MCDA). To illustrate the differences, CBA, CEA and MCDA were characterised and compared. The comparison is qualitative and based on categories connected to key aspects of the risk assessment and decision methods.

The MBA approach is a model developed by the Norwegian Water BA and comprises source characterisation based on faecal indicator observations and an estimation of a Log_{10} pathogen reduction in the DWS using guidance tables. Based on the water quality sampling results and the number of consumers, a required Log_{10} pathogen reduction is determined and compared with the estimated Log_{10} reduction for the DWS.

The Swedish QMRA tool was developed to calculate the probability of infection for drinking water consumers. The tool consists of three main steps. Firstly, the pathogen sources are characterised using different approaches to estimate the pathogen concentration in raw water. Secondly, the pathogen Log_{10} reduction in the DWTP is calculated by defining each step in the treatment chain. Finally, the pathogen concentration in the treated drinking water is put into a dose-response model to estimate the probability of infection and DALYs for drinking water consumers.

The risk-based decision model presented in this thesis is based on the same QMRA principles as in the Swedish QMRA tool but adds the possibility of including QALYs as a metric for determining the health effects for drinking water consumers. It also considers the entire DWS, from source to tap, including unexpected risk events.

For the purposes of this comparison, the risk assessment methods (Table 3) were divided into the following key categories: source characterisation, water quality modelling, unexpected risk events, dose-response models, risk characterisation, and workload. *Source characterisation* refers to how the pathogen sources are identified and quantified at the drinking water source. *Water quality modelling* refers to whether the approach allows for specific fate and transport modelling of pathogens in order to estimate the effect of pathogen sources on drinking water quality. *Unexpected risk events* define how the approach considers events that occur with an uneven, less predictable temporal distribution and with short and varying durations (e.g. heavy precipitation events, accidental spills of faecal matter containing pathogens, and technical system failures). *Dose-response* states if this type of model is used. *Risk characterisation* refers to how the risk is evaluated, and what type of metric is used for reporting the risk. *Workload* is a relative assessment of how much effort is needed on the part of an organisation to perform the specific type of risk assessments.

Table 3 Comparison of the risk-based decision model presented in this thesis and common risk assessment approaches applied by drinking water utilities in Sweden.

	MBA	**Swedish QMRA tool**	**Risk-based decision model**
Source characterisation [a]	Q, SQ, WQO	L, Q-WQO	Q-PB, Q-WQO
Water quality modelling [b]	NA [d]	G [e]	G, HL, HD
Unexpected risk events	NA	Failure events	Scenario-based approach
Dose-response	NA	Yes	Yes (Own choice of model)
Risk characterisation [c]	Log_{10}	P_{inf}, DALY, Log_{10}	P_{inf}, DALY, QALY, Log_{10}
Uncertainty and sensitivity analysis	Manual	Included, manual is possible	Included, manual is possible
Workload	Low	Medium	High

a) Q = Qualitative, SQ = Semi-quantitative, WQO = Water Quality Observations, L = Literature-based, Q-PB = Quantitative prevalence-based, Q-WQO = Quantitative water quality observation-based.

b) G = Groundwater modelling, HL = Hydrological modelling, HD = Hydrodynamic modelling.

c) Log_{10} = Pathogen reduction at a drinking water treatment plant, P_{inf} = Probability of infection among drinking water consumers, DALY = Disability Adjusted Life Year, QALY = Quality-Adjusted Life Year.

d) Not available.

e) Addition to the QMRA tool (Åström et al. 2016).

The decision methods CEA, CBA and MCDA, are described in Section 2.6. The categories used here to compare these decision methods are listed in Table 4. *Compare measures* describes whether the approach can evaluate and compare mitigation measures. *Additional effects* refers to whether or not the method can include effects beyond the target risk reduction (e.g. environmental benefits in addition to health risk reduction. *Monetisation of costs* and *Monetisation of benefits* state whether or not the costs and benefits included need to be monetised. *Societal perspective* shows whether the method allows for a societal perspective when applied. *Ranking of measures* refers to whether the method can rank the evaluated risk mitigation measures. *Workload* is a relative assessment of how much effort is needed on the part of an organisation to use the different decision methods.

Table 4 Categories related to different decision methods.

	CEA	**CBA**	**MCDA**
Compare measures	Yes	Yes	Yes
Additional effects	No	Yes	Yes
Monetisation of costs	Yes	Yes	No
Monetisation of benefits	No	Yes	No
Societal perspective	Possible	Possible	Possible
Ranking of measures	Yes	Yes	Yes
Workload	Low-Medium	Medium-High	Low-Medium

The scope of each risk assessment method is not identical and the aim of the comparison is not to rank or rate the methods in relative terms. The comparison aims to put the developed decision model into the context of already existing tools and methods. The MBA and the QMRA tool aim to evaluate the risk level and can be used to evaluate the effect of microbial risk mitigation measures. The QMRA tool provides a more detailed approach compared to the MBA. In the QMRA tool, uncertainties can be included as an integral part of the results, while in the MBA the uncertainties can be addressed using scenario approaches. Neither the MBA nor the QMRA tool is able on their own to evaluate the mitigation measures using economic methods. The risk-based decision model translates results from the QMRA to the CBA and allows for a decision analysis that includes socioeconomic aspects. The decision model also allows for additional options when choosing methods for source characterisation (adds prevalence-based methods), unexpected risk events (the scenario-based approach is open for all types of risk events), and health effect quantification metrics (adds QALY). As a result of this flexibility, the workload involved in implementing the decision model is estimated to be high. However, the flexibility also makes it possible to design the decision model on a very basic level, reducing the effort needed to set it up.

In a strict form, the CEA and CBA aim to evaluate a specific mitigation measure or decision alternative to a reference alternative and not to compare several measures, which is done by means of an MCDA. CEA evaluates the effectiveness of the measure

in relation to the costs of implementing it, and CBA evaluates whether the total benefits achieved will be outweighed by the cost of implementation. However, both CEA and CBA are highly suitable for use when measures are also being compared, since the results in terms of cost-effectiveness ratios and *NPV*s are easy to compare between measures. As regards additional effects and monetisation of costs and benefits, it is only CBA that requires all of them. This is also reflected in the medium-high estimation of the workload. None of the methods have a societal perspective due to their traditional design. However, if necessary it is quite straightforward to adapt all the methods to an approach that includes a societal perspective.

6 DISCUSSION

In this thesis, several methods were combined into a risk-based decision model to provide decision support in the evaluation of microbial risk mitigation measures in drinking water systems. The decision model provides a clear structure for how quantitative microbial risk assessment and cost-benefit analysis can be combined. The combination provides transparent and holistic decision support that aims to optimise the societal benefits. The combination of methods, integrating several scientific disciplines, provides a novel approach for comparing microbial risk mitigation measures. The decision model represents a risk-based approach and provides useful information for drinking water utilities. Implementing the decision model in the drinking water sector will help decision-makers map microbial risks in the DWS. The decision model will also help ensure societal resources are used efficiently when mitigating microbial risks, and will facilitate integrated water resource management. Furthermore, the CBA approach enables comparison and coordination with other sectors, thus making it possible to optimise use of societal resources. This section includes a discussion of the methods included in the decision model, as well as uncertainties and practical implications.

6.1 Quantitative microbial risk assessment

In Sweden, it is common to use reference pathogens to represent bacteria, viruses and protozoans, as is the case in the Swedish QMRA tool. The same approach was applied in this thesis. The assumption is that if the DWTP can reduce the risk of the occurrence of a specific type of bacteria to an acceptable level, the risk of occurrence of other bacteria is also reduced to the same acceptable level. The same argument applies to viruses and protozoan pathogens. However, the drinking water utilities need to acknowledge that the total microbial risk level comprises the risk from all waterborne pathogens, i.e. also pathogens that cause gastrointestinal disease not included in the reference pathogens, as well as pathogens that cause other types of illnesses. Hence, QMRA results need to be interpreted with the awareness that the reported risk level is based on the specific pathogens that are included, and that there may be additional risks that are not included in the decision model results. Nonetheless, if being part of an overall risk management approach, the decision model can help in structuring risk assessment and indicate when it is necessary to act.

Including unexpected risk events is essential in a comprehensive microbial risk assessment (Tolouei et al. 2019), especially in the case of DWSs with a low pathogen load and low pathogen reduction at the DWTP (Paper V). In the case of DWSs with a high pathogen load and high pathogen reduction at the DWTP, the unexpected risk events have less impact, as reported in Paper V. However, unexpected risk events in combination with sub-optimal treatment at the DWTP could be of importance for

microbial risk assessment even in the case of these robust DWSs (Taghipour et al. 2019). The scenario-based approach to inclusion of these unexpected risk events presented in Paper V is based on well-established risk assessment principles. However, including unexpected risk events in QMRA for drinking water in a structured way, along with the application in the Vomb case study, is a novel approach. The unexpected risk events investigated in Paper V were based on actual events and known microbial risks present in DWSs. It was, however, difficult to estimate the magnitude and probability of occurrence of these events, and the estimation was based on previous statistics relating to such events, or on expert judgements by the authors. In Paper V, none of these unexpected risk events were of the magnitude that they would lead to a major waterborne outbreak. Nonetheless, outbreaks have occurred, both in Sweden and in other countries. The characterisation of the unexpected risk events in terms of probability of occurrence and duration, as presented in Paper V, may not have been severe enough to penetrate the pathogen barrier in the DWTP. It is relevant to evaluate the risk on a daily basis, allowing for a finer time resolution and thus including unexpected risk events that cause brief pathogen peaks of a more severe nature, including events that may cause large waterborne outbreaks.

Lack in quality and availability of data may constitute an obstacle for local applications of the decision model. The reduction by OWTSs and WWTPs was described using existing studies (Ottoson et al. 2006; SEPA 2002), assuming that the OWTSs were fully functional. This description could be improved with the inclusion of local information on the performance of these systems, e.g. the proportion of underperforming or old OWTSs in the catchment. Information on the prevalence and excretion of pathogens and their variability, both for humans and animals, is scarce (Chappell et al. 1996; Ferguson et al. 2009; Xiao and Herd 1994). The high degree of variability in the available estimates impacts on the output of the decision model, especially in the case of pathogen concentration in human faeces, since it ranges over several Log_{10} units. High variability and the lack of data quality stresses uncertainty analysis of the decision model results.

Pathogen sampling and analysis can also be used to quantify the pathogen load and may be the most accurate method for describing local concentrations. In Paper IV, real-time PCR was used to analyse pathogen concentrations. During the course of this work, it was decided not to use the quantified pathogen concentrations as input for QMRA. The decision was based mainly on two factors. Firstly, the detections were often on or close to the detection limit. This, in combination with the low sampling volume (1 L) and the dilution required (sometimes 100-fold), resulted in highly variable and sometimes also unrealistically high pathogen concentrations at certain sampling locations. Secondly, the real-time PCR method as performed in this study cannot distinguish between viable and non-viable pathogenic bacteria. Consequently, the infectivity of the detections could not be confirmed. This decision was applicable to this specific sampling campaign and case study. It has not been concluded that it is not possible to use these types of quantification methods in other settings, or to adjust parts of the analysis. Additional validation of the

method using larger sample sizes and simultaneous culture assays of *Salmonella* and coliforms is needed before using these results as input for QMRA.

Since it is tedious and expensive to perform pathogen sampling, it is rarely done. However, pathogen analysis is developing rapidly, and advanced techniques such as metagenomics will be more readily available and affordable in the near future (Castro et al. 2018; Koch 2016). Developments such as these may facilitate the use of water quality observations as input for decision models such as the one presented in this thesis.

A large part of the total pathogen reduction occurs during transport from the faecal source to the raw water intake. Estimating this reduction requires extensive input data, and the associated uncertainties are typically large. In Paper I, a deterministic approach was used for hydrological modelling of pathogen transport within the catchment, and the input uncertainty using probabilistic methodology was not considered. In order to perform more detailed uncertainty and sensitivity analyses of water quality modelling, a stochastic approach has been suggested by e.g. Benham et al. (2006). In Paper II, a probability density distribution was fitted to the data on Log_{10} reduction during transport over time in Lake Vomb to account for the variation in this variable in the Monte Carlo simulations. In Paper II, the reduction in artificial groundwater infiltration was estimated using simple analytical stochastic groundwater modelling, performed with the aid of Monte Carlo simulations, and taking into account uncertainties in variables and their effect on pathogen reduction. In Paper V, a stochastic approach was applied that involved resampling the results from hydrological modelling. However, these approaches do not enable a detailed sensitivity analysis of the variables in the hydrodynamic and hydrological models. It is possible to perform local sensitivity analyses (for each water quality model individually) as well as scenario-based analyses.

The QMRA, including the dose-response relationships, is widely used and is promoted by the WHO for water safety management (WHO 2016). However, it should be highlighted that the methodology is based on just a few dose-response relationships adopted from specific empirical infection studies for each pathogen. In the latest version of the Swedish QMRA tool (Abrahamsson et al. 2009; Åström et al. 2016), it is possible to investigate both a high and a low infectious dose for *Cryptosporidium* and *Campylobacter*. For norovirus, no such sensitivity analysis is currently possible. In the case of Lake Vomb in this thesis, norovirus accounts for the majority of the microbial risk, and the infectivity assumptions can impact on the magnitude of the health effects. Consequently, the dose-response relationships used in QMRA need to be up to date and, if possible, different levels of pathogen infectivity should be investigated. Furthermore, the use of different dose-response relationships for children and adults may increase the accuracy of the risk assessment (Teunis et al. 2005).

QMRA is a useful means of understanding the decision problems, and mapping and determining the magnitude of the health risk reductions achieved through mitigation

measures. The quality of any model is directly dependent on the quality of the model input, and given the many assumptions in the risk-based decision model, the risk assessment results (probability of infection, number of infections, etc.) should be interpreted while considering these uncertainties. However, the ranking of risk mitigation measure *NPV* does not necessarily show the same uncertainty and may provide more robust decision support.

The lost QALYs per infection were estimated based on US data (Batz et al. 2014). However, it is preferable to use local (Swedish) values. The Swedish experience-based values for health-related quality of life (EQ-5D) have been described (Burström et al. 2014). However, the Swedish data was not used due to the fact that the authors (Burström et al. 2014) did not recommend converting those values into QALYs, as the study set-up did not allow the replies to be anchored between 0-1. When QALY is used to quantify health effects, it is assumed that each lost QALY is the same regardless of the total number of QALYs lost, the point during the life span the loss of QALY is experienced, and the type of illness that caused the loss of QALY (Hofstetter and Hammitt 2002). In the light of the decreasing willingness to pay for a QALY, as reported in the literature (Haninger and Hammitt 2011; Ryen and Svensson 2015; Sund and Svensson 2017), the relationship between the severity and duration of the health effects and the number of lost QALYs experienced is not necessarily linear. Nevertheless, QALY is suggested as a starting point for prioritising and allocating resources (Hofstetter and Hammitt 2002).

6.2 Cost-benefit analysis

Economic valuation of health effects is a difficult task, and the values adopted should therefore always be clearly stated, and a sensitivity analysis should be performed (ASCC 2008). Investigation of seven different methods for economic valuation of health effects (Paper III) showed that the choice of method impacts on the decision model results. If there is no clear guidance on what method of economic valuation to use, several health valuation methods should be applied in a sensitivity analysis. The societal value of a QALY, recommended in Paper V, was estimated using a societal perspective, i.e. also taking into account effects beyond the health sector. One could argue therefore that this monetisation of health effects can be applied to any type of setting when comparing alternative options for optimisation of societal benefits. In Paper V, cost of illness with the addition of cost for disutility was included in a sensitivity analysis. This method was chosen since cost of illness is a widely used method and adding the cost of disutility broadens the number of aspects included in the economic valuation. Another possible approach for estimating the cost of an infection is to use cost estimates of waterborne outbreaks. Evaluation of a waterborne norovirus outbreak in Lilla Edet in Sweden resulted in ≈ SEK 3,600 per case (Larsson et al. 2014), while the cost of illness adding disutility for a norovirus case in this thesis was ≈ SEK 6,000, and the economic valuation

method SVoQ resulted in ≈ SEK 1,100 per norovirus case. For *Cryptosporidium* the cost for a case was ≈ SEK 8,100 for the reported cost of a waterborne outbreak in Östersund (Lindberg et al. 2011), ≈ SEK 26,200 for the cost of illness with the addition of disutility in Paper III, and ≈ SEK 4,400 using the SVoQ method in Paper III. It should be noted that the economic aspects included in the outbreak investigations differed both from each other and from the aspects included in the cost of illness adding disutility and the SVoQ method. Hence, the choice of method is an essential part of the decision model and needs to be presented transparently. To provide a more detailed analysis, specific applications may require a division of the health benefits into several categories, e.g. reduced medical and hospitalisation costs, reduced discomfort from being ill, reduced production loss etc.

In a CBA, not all benefits are included in the *NPV*. As a result the analysis regarding the additional benefits required to achieve a positive *NPV* (Paper II) provides important decision support information. Given the difficulty of monetising non-market goods, this approach provides a straightforward and illustrative way of placing the *NPV* from the CBA in relation to the non-monetised benefits. As presented in Paper II, if the non-monetised benefits were estimated at SEK 800-2,400 per OWTS per year, depending on the risk mitigation measure and the discount rate, the *NPV* would be positive.

Factors in addition to the *NPV* and non-monetised benefits, such as legislation (e.g. environmental legislation, the European Bathing Water Directive) might influence the decision can be taken into account when applying the decision model. These additional factors and are important aspects of the decision-making process, as they may provide valid grounds for departing from decisions based solely on the *NPV*, resulting in prioritise measures with negative *NPV*s. As regards environmental targets for example, the alternatives presented in Paper II (A1-A3) and Paper V (A1 and A3) provided substantial reductions in nitrogen and phosphorus discharge into the water sources. The benefits deriving from a reduction in nutrient discharge were included in the CBA. Thus, if the health risk reduction on its own does not result in a positive *NPV*, adding these environmental benefits might do so. Regardless of whether an acceptable risk is sought, if water quality guidelines are achieved, or if environmental targets need to be met, a CBA provides useful decision support to compare the decision alternatives.

6.3 Uncertainty and sensitivity analysis

It is important to evaluate the uncertainties in order to learn how to improve the model and interpret the modelling results. Value of information analysis can be performed by targeting model inputs that include uncertainty that can be reduced if additional investigations are performed (Yokota and Thompson 2004). The uncertainty analysis can also investigate the output uncertainty, including parameters such as standard deviation, variance, etc. The results from different scenario-based sensitivity analyses

aimed at investigating alternative inputs (e.g. discount rate, economic evaluation method for health effects) play an important role in strengthening the uncertainty analysis.

The sensitivity analysis identifies the variables that have the greatest impact on the outputs of the different methods used in the decision model. Variables that should be investigated further are identified and, if possible, the uncertainties related to these variables should be reduced. In the Lake Vomb case study (Paper II), concentration in faecal matter, estimated pipe length, and pipe cost per metre were the variables that had the greatest impact on the outputs. Local sensitivity analysis is suitable for deterministic models and simpler non-probabilistic models. Monte Carlo simulation facilitates a global sensitivity and uncertainty analysis, making it possible to simultaneously analyse the contribution to the total uncertainty of each specific input variable represented by a probability distribution. These analyses are essential procedures to describe uncertainties in the decision model and to provide detailed decision support.

6.4 Practical implications

Methods often applied by Swedish drinking water utilities are the microbial barrier analysis (MBA) and the Swedish QMRA tool for drinking water systems. The MBA, the Swedish QMRA tool, and the decision model include different quantitative or semi-quantitative microbial risk assessments. The QMRA tool and the decision model are very similar with regard to the quantitative microbial risk assessment, where the major difference lies in source characterisation and water quality modelling. The major addition provided by the decision model is the dimension that includes unexpected risk events and provides an economic aspect by adopting a societal perspective when evaluating microbial risk mitigation measures.

In Sweden, there are no national guidelines on the acceptable microbial risk level. Consequently, the microbial RAC needs to be set on a local level. The RAC could also be set based on faecal indicator bacteria related to the monitoring programme. The risk-based decision model does not require an RAC to function, but it can estimate how likely it is that the set RAC will be reached for each evaluated risk mitigation measure. It is also possible to identify the mitigation measure that fulfils the RAC and has the highest *NPV*, and thus excluding mitigation measures that do not reach the RAC. If a risk mitigation measure results in a positive *NPV*, it can be interpreted that the risk mitigation measure is worth implementing when evaluating societal profitability, regardless of whether the RAC is reached or not. In Paper IV, an RAC set for a daily risk was investigated. This is a possible approach for drinking water utilities, especially if they are seeking to investigate some form of worst-case scenario.

One major aspect for drinking water utilities to consider when applying the risk-based decision model is that funding, in terms of who pays the mitigation measures was not

addressed in depth in this thesis. For investments in a DWTP and a WWTP, the cost distribution is quite straightforward in Sweden, as it is laid down in law that the water utilities, and thus the consumers, are required to meet the investment and maintenance cost. For other risk mitigation measures, such as connecting private OWTSs, the funding is not as clear-cut. Depending on local regulations, the private OWTS owner may meet the cost of the connections, even if the risk reduction benefits are secured by the drinking water consumers. The allocation of costs and benefits is important, especially from a legal or fairness perspective. The distributional analysis provides a clear overview of the parties that secure the benefits and the parties that meet the costs.

7 CONCLUSIONS, RECOMMENDATIONS AND FURTHER WORK

This section is devoted to the overall conclusions of this thesis. Recommendations regarding application of the risk-based decision model and possible further developments of the decision model are also presented.

7.1 Conclusions

The overall aim of this thesis was to present a comprehensive risk-based decision model for drinking water systems from catchment to consumer in order to compare microbial risk mitigation measures. The decision model combines quantitative microbial risk assessment and cost-benefit analysis. Important aspects were the economic quantification of health effects and evaluation of decision alternatives with the adoption of a societal perspective. The main conclusions are:

- The presented combination of quantitative microbial risk assessment (source characterisation, water quality modelling, and dose-response model) and cost-benefit analysis provides a comprehensive description of the drinking water system and a practical approach to evaluate and compare possible microbial risk mitigation measures within the framework of the risk management process.

- Microbial risk mitigation measures in drinking water supplies may have several effects, not only linked to the drinking water quality. By applying cost-benefit analysis, all effects may be identified, quantified and monetised, which highlights the overall effect of each measure and enables an evaluation of whether mitigation measures are societally profitable or not.

- To consider uncertainties is an essential part of the decision model given the limited access to data and due to natural variations in drinking water systems. The applied Monte Carlo approach makes it possible to consider uncertainties in inputs and outputs. However, to be able to interpret and capture the uncertainties in the results, application of a combination of different uncertainty and sensitivity analyses could be necessary.

- Even though there may be large uncertainties in the results from risk assessment and decision analysis, the case studies presented in this thesis show that the decision model is well suited to rank of risk mitigation measures.

- Prevalence-based risk source characterisation provides important input for drinking water systems where pathogen observations are missing.

- Water quality modelling can be incorporated into the decision model and is a useful part of risk assessment when evaluating microbial risk mitigation measures and as a complement to pathogen observations.

- The choice of health valuation method impacts the decision model results. An evaluation of seven health valuation methods applied in the decision model concluded that the choice can alter the net-present value rank order of risk mitigation measures. By applying several valuation methods the sensitivity of the result can be assessed.

- It is important to include unexpected risk events to enable a complete description of the risk. In this thesis, unexpected risk events posed a greater risk to drinking water systems with a low pathogen base load and low pathogen removal potential at the drinking water treatment plant compared to drinking water systems with a high pathogen base load and high pathogen removal potential at the drinking water treatment plant.

- The decision model results in terms of net present value, uncertainty and sensitivity analyses, and distributional analysis could be combined with additional information (e.g. relevant legislation, risk acceptability criteria, microbial risk level in the drinking water system) to provide comprehensive decision support when comparing microbial risk mitigation measures.

- The presented risk-based decision model is generic and flexible and can be tailored to different drinking water systems and decision problems. It allows for the integration of other methods that could be applied to risk assessment and decision analysis. Prevalence-based risk source characterisation, for example, can be replaced by methods based on pathogen observations, and the cost-benefit analysis can be replaced or complemented by a multi-criteria decision analysis.

7.2 Recommendations

When applying the risk-based decision model, either in its entirety or using specific methods separately, the following recommendations may prove useful:

- An essential part of risk management is to set local risk acceptability criteria (e.g. a maximum level for the probability of infection for drinking water consumers) in order to determine when risk mitigation is necessary. However, the risk-based decision model is applicable for evaluating risk mitigation measures regardless of whether there are any acceptability criteria or not.

- Risk calculations should be based on a varying daily risk level in order to incorporate unexpected risk events (e.g. combined sewer overflows) and to allow for different base risk levels.

- In the case of no consensus on which health valuation method to use, several methods should be applied in a sensitivity analysis. The recommended methods from this thesis are the societal value of a quality adjusted life year and the cost of illness adding the cost for disutility. The former is recommended since it includes all health effect aspects, and the latter is recommended since the cost of illness is a well-established method and the addition of the cost for disutility provides a comprehensive valuation.

- The decision model provides a clear structure of both the microbial risks and risk mitigation measures in drinking water systems. It is possible to apply the entire model or to choose specific parts, depending on the problem formulation. Models are useful in helping us understand problems and focus on those parts that are of importance in the specific application. However, models can never fully describe reality, making it important to acknowledge the model limitations.

- To gain the most from risk management, organisations need to fully commit to all stages in the risk concept, especially adapting the iterative process and continuous improvement.

7.3 Further work

The risk-based decision model expands the quantitative microbial risk assessment approach to include water quality modelling and evaluation of microbial risk mitigation measures in combination with a societal cost-benefit analysis for comprehensive decision support. To further develop the model and to make it more applicable, there are important aspects that need to be considered. Firstly, in its present state the decision model is technically possible for drinking water utilities to apply, although it is not fully applicable in practice. A combined tool, including all the different tools and methods, could make the decision model available for use in practice for drinking water utilities. Secondly, there are further developments within each method and tool, as described below, that could enhance the quality and practical applicability of the decision model:

- The possible methods to apply in each step of the decision model can be further investigated and additional methods can be included. It may also be necessary to develop procedures for deciding which specific methods should be used in each compartment of the decision model, depending on the local setting of the drinking water system.

- Environmental benefits were included using a unit value per avoided nutrient discharge, and more detailed approaches for environmental benefits could thus be applied. Including these additional benefits (e.g. environmental and social) highlights what is a key component in the decision model, i.e. the possibility of including other benefits apart from target risk reduction.

- Including the effects of climate change on microbial risks can be important for drinking water systems. The present decision model structure includes a linear increase in risk based on the increased heavy precipitation events, but more detailed approaches could be investigated. The inclusion of quantitative microbial risk assessment and cost-benefit analysis in the decision model provides a structure that can include long-term effects and future changes in risk levels.

- Stochastic water quality modelling as an integrated part of the decision model should be investigated. Adopting a stochastic approach would include uncertainties in the model input variables, and uncertainties in the final outputs would be described. However, these methods are demanding in computational terms, and simpler approaches may also be of interest to avoid restricting possible applications of the decision model.

- In its present state, the risk-based decision model does not include any risks in the drinking water distribution network. Many of the risks in the distribution network are related to unexpected risk events (e.g. intrusion events, pipe failures) occurring with uneven temporal distributions. Including this part of the drinking water system would provide even more comprehensive decision support.

- Dose-response relationships could be adapted to different groups with varying susceptibility to pathogens, e.g. immunocompromised and children, to increase the accuracy of the risk assessment. It could also be of importance to investigate change in pathogen infectivity over time.

- As a continuation of the technical drinking water system, the inclusion of consumer aspects (e.g. consumer composition in terms of age, susceptibility to infections and health status) into the decision model could be explored.

- For the uncertainty analysis, it would be beneficial to adapt a comprehensive method applicable to the entire decision model. Dividing uncertainties into aleatory and epistemic would identify uncertainties that can be reduced.

- Input variables with a large contribution of uncertainty to the decision model results should be prioritised in further investigations to reduce uncertainties in the derived decision support for the studied drinking water system.

- The decision model could be improved by formally describing the procedures for including other decision criteria, such as legislation and how to include non-monetised benefits. To combine cost-benefit analysis and multi-criteria analysis as a decision model would broaden the approach and provide even more comprehensive decision support.

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