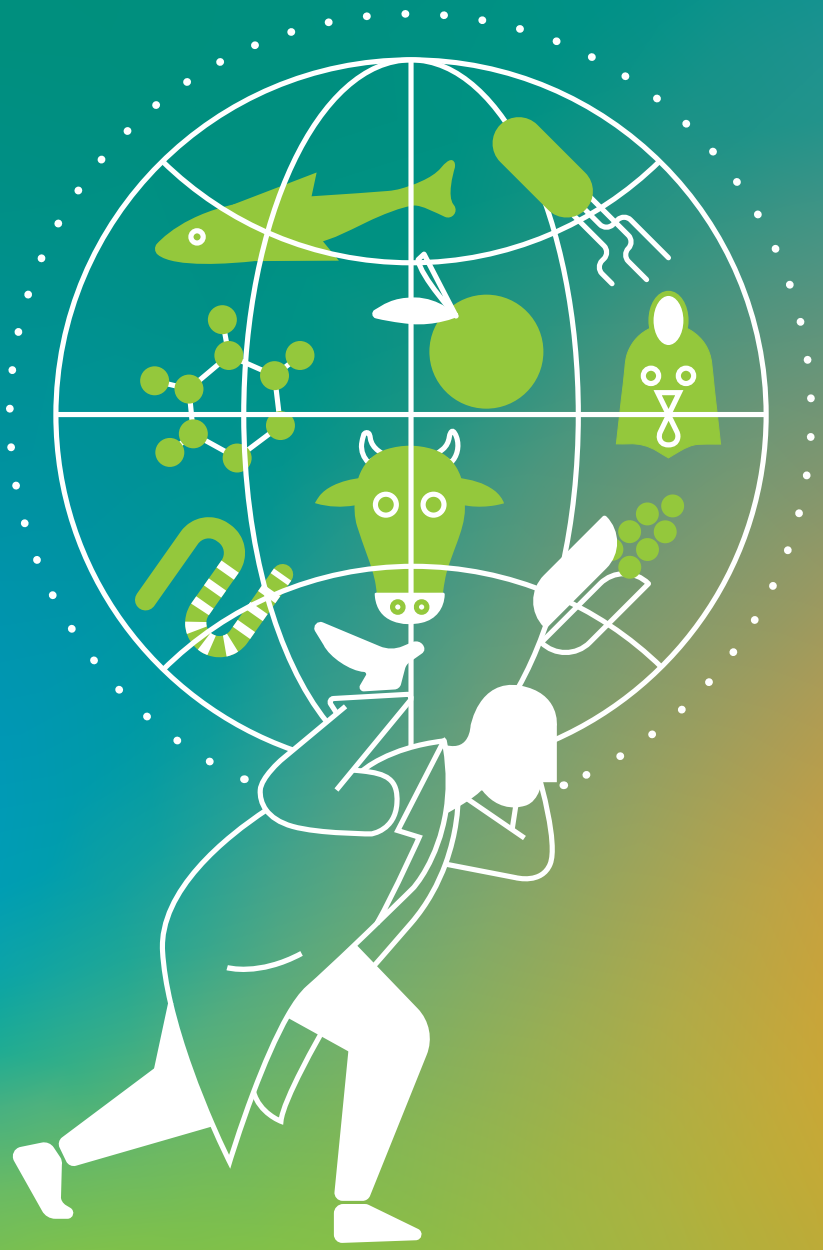
World Health Organization



Estimating the burden of foodborne diseases: A practical handbook for countries

A guide for planning, implementing and reporting country-level burden of foodborne disease

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PREFACE

Estimating the burden of foodborne diseases is an essential component of efforts to rank risks of foodborne diseases, establish food safety priorities, and efficiently allocate resources for disease prevention. To obtain a better insight into the global and regional burden of foodborne diseases, in 2007 WHO established an initiative to estimate the global burden of foodborne disease. As a result, the first-ever WHO estimates of the global burden of foodborne diseases were published in 2015, prepared by the Foodborne Disease Burden Epidemiology Reference Group (FERG). The burden of disease of 31 hazards, including 11 diarrhoeal disease agents, seven invasive disease agents, ten helminths, and three chemicals and toxins, was estimated using three different metrics: incidence, mortality, and disability-adjusted life years (DALYs). These estimates highlighted food safety priorities in different parts of the world, and have been used in further analysis, including of the economic burden of unsafe food.[1]

The initiative also aimed to strengthen the capacity of countries to assess their burden of foodborne disease, and to increase the number of countries that have undertaken such a study. Such assessments allow more efficient allocation of resources to prevention, intervention and control measures, and all countries are encouraged to begin working towards preparing their own estimates, with or without simplifications, to the extent that expertise and resources allow. Regardless of the level of development and available resources, it is essential that harmonized approaches are used so that experiences can be shared, estimates compared and food safety policy improved. This handbook provides guidance on assessing the burden of foodborne diseases caused by microbiological agents commonly transmitted through foods. It is particularly intended for use at national level, and gives a complete picture of the requirements, enabling factors, challenges and opportunities involved, and the steps in the process. It also aims to foster harmonization of methodologies for estimating foodborne disease burden across countries.

The organization of the handbook reflects as far as possible the sequence of steps to be followed in carrying out a national burden of foodborne disease study.

- Chapter 2 describes the concept and overall approach of burden of foodborne disease studies, covering the goal and objectives, the principal elements and steps, and the requirements and enabling factors for implementation.
- Chapter 3 outlines the activities involved in planning and initiating a national burden of foodborne disease study. It describes the rationale and steps of a national situation analysis, the variables to be considered when defining the context for the study, the resources and staffing required and the selection of hazards to include in the study.
- Chapter 4 describes the data requirements for a national burden

[1] Jaffee S, Henson S, Unnevehr L, Grace D, Cassou E. The safe food imperative: accelerating progress in low- and middle-income countries. Agriculture and Food Series. Washington, DC: World Bank; 2019.

of disease study, lists potential data sources, and suggests strategies for data collection and for addressing data gaps.
- Chapter 5 describes all steps involved in calculating the burden of foodborne diseases in a country. It describes how to calculate incidence, mortality and DALYs and estimate and address the potential associated uncertainties, and refers to relevant software.
- Chapter 6 suggests an approach to estimating the proportion of the total disease burden that is due to foodborne transmission.
- Chapter 7 outlines what needs to be considered when describing and interpreting the results of a burden of foodborne disease study. It includes suggestions for presenting the output of the study and discussing assumptions and limitations, and provides examples to illustrate discussion points.
- Chapter 8 suggests formats for presentation and communication of the results of the study for different target audiences, and outlines the tools available for communicating risk and translating scientific knowledge to policy-making.

These elements and activities are likely to be dynamic and interactive, and should be adapted to the national context, taking into account the country's capacity for public health surveillance and the availability of data. While estimating DALYs should be the aspirational goal for national studies, intermediate steps, such as estimating incidence and mortality of foodborne diseases, will be valuable in assessing their public health impact relative to other diseases. A burden of disease study will also help identify data gaps, engage with food safety stakeholders across the country and align efforts, promoting communication and data-sharing.
Throughout this handbook, examples of country studies are presented to illustrate how national burden of foodborne disease studies have been implemented in different parts of the world. Five annexes provide more detailed information on technical aspects.

National burden of foodborne disease studies are critical to fill data gaps identified in global and regional efforts, focus efforts on the national context, and produce estimates based on local data that are as accurate as possible. They can also flag needs and data gaps in food safety systems, and promote cooperation and communication among stakeholders in food safety. All countries, whatever their current level of development and expertise, are encouraged to start working towards implementing such studies to the extent possible. This may mean starting at a basic level and working towards continuous improvement and expansion as resources allow. Involvement of relevant stakeholders, decision-makers and social scientists to support the technical study team from the earliest stages will promote communication and collaboration, and support knowledge translation and the development of science-based policies.

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ABBREVIATIONS AND ACRONYMS USED IN THIS HANDBOOK

BoD	burden of disease
CAREC	Caribbean Epidemiology Center
CARPHA	Caribbean Public Health Agency
CFIA	Canadian Food Inspection Agency
CSTF	Country Studies Task Force
DALY	disability-adjusted life year
DW	disability weight
EAggEC	enteroaggregative *Escherichia coli*
EHEC	enterohaemorrhagic *Escherichia coli*
EPEC	enteropathogenic *Escherichia coli*
ETEC	enterotoxigenic *Escherichia coli*
FAO	Food and Agriculture Organization of the United Nations
FBD	foodborne disease
FERG	Foodborne Disease Burden Epidemiology Reference Group
FOCAL	Foodborne Disease Epidemiology, Surveillance and Control in African Low- and Middle-Income Countries
GBD	global burden of disease
GDP	gross domestic product
GHE	global health estimates
GIFT	Global Individual Food Consumption Data Tool
GNI	gross national income
GUI	graphical user interface
HACCP	hazard analysis critical control point

IBS	irritable bowel syndrome
IFRC	International Federation of Red Cross and Red Crescent Societies
IHME	Institute for Health Metrics and Evaluation
LMIC	low- and middle-income countries
NA	not applicable
NGO	nongovernmental organization
NT	non-typhoidal
PAF	population attributable fraction
PAHO	Pan American Health Organization
PHAC	Public Health Agency of Canada
PTO	person trade-off
RA	reactive arthritis
RIVM	National Institute for Public Health and the Environment (Netherlands)
RLE	residual life expectancy
SEYLL	standard expected years of life lost
spp.	species
STEC	Shiga-toxin-producing *Escherichia coli*
TTO	time trade-off
UN	United Nations
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VAS	visual analogue scale
VSL	value of a statistical life
WFP	World Food Programme
WHO	World Health Organization
WTP	willingness to pay
YLD	years lived with disability
YLL	years of life lost

EXECUTIVE SUMMARY

Estimating the burden of foodborne diseases is an essential component of efforts to rank risks of foodborne diseases and establish food safety priorities. National burden of disease studies allow countries to allocate resources more efficiently to prevention, intervention and control measures. WHO encourages all countries, whatever their level of development, to begin working towards preparing their own estimates, to the extent that expertise and resources allow. The use of harmonized approaches across countries will allow experiences to be shared, estimates to be compared, and – ultimately – food safety policy to be improved.

This handbook provides detailed guidance on assessing the burden of diseases caused by microbiological agents commonly transmitted through foods. It is particularly intended for use at national level, and gives a complete picture of the requirements, enabling factors, challenges and opportunities involved, and the steps in the process. It also aims to foster harmonization of methodologies for estimating foodborne disease burden across countries.

The goal of a national burden of foodborne disease study is to rank and prioritize foodborne diseases based on their overall public health impact in the population. The objectives of such a study are to:

- estimate the burden of disease for selected foodborne hazards;
- develop a framework for routine updating of estimates and evaluation of trends; and
- provide a baseline against which food safety interventions can be evaluated.

Burden of disease can be expressed using various indicators, such as incidence, mortality, societal costs and summary measures of population health. In this document, the disability-adjusted life year (DALY) is proposed as the ultimate summary measure for quantifying the population health impact of foodborne diseases. The DALY measures the healthy life-years lost as a result of diseases or risk factors. It combines information on morbidity, mortality and disability caused by diseases. While some countries may not yet have the resources or capacity to estimate DALYs, it should be an aspirational goal, and any step towards it – such as estimating incidence or mortality – is valuable.

A burden of foodborne disease study has six main elements: planning; data preparation; calculations; attribution; interpretation; and dissemination. These elements and activities are likely to be dynamic and interactive, and should be adapted to the national context, taking into account the country's capacity for public health surveillance and the availability of data.

While certain aspects of the work – data collection, calculations and generation of DALYs, for example – are often assigned to a specialized agency or group with specific skills, it is important to engage a broader group of actors in the overall process. The engagement of these national stakeholders is crucial, not only because they can provide valuable input, but also to generate interest and recognition of the usefulness of the estimates produced. Stakeholders include a range of organizations with a role and interest in food safety, such as governmental institutions, academia, representatives of food business operators and consumer organizations.

National burden of foodborne disease studies may generate a large number of estimates, and it is crucial to provide detailed results. Uncertainty in the estimates should also be described. To the extent possible, the results should be interpreted by experts in the fields of clinical medicine, public health, epidemiology, food science and food safety, and other relevant areas.

To ensure that the results of the study are used to their full potential, they should be presented and communicated to a range of audiences, including scientists, policy-makers, food business operators, the media and the general public. The messages and format of the presentations should be tailored to the specific target group.

National burden of foodborne disease studies are critical to fill data gaps identified in global and regional efforts, focus efforts on the national context, and produce estimates based on local data that are as accurate as possible. They can also flag needs and data gaps in food safety systems, and promote cooperation and communication among stakeholders in food safety. In the longer term, information on burden of foodborne disease should be a fundamental component of a systematic approach to food safety, such as the risk management framework advocated by the Codex Alimentarius Commission. Such an approach can improve both public health and trade.

1

INTRODUCTION

INTRODUCTION

WHY ESTIMATE THE BURDEN OF FOODBORNE DISEASES?

Despite increased political attention to food safety in recent decades, foodborne disease still causes a substantial public health, economic and social burden throughout the world, particularly in low- and middle-income countries (LMIC). Reducing the burden of foodborne diseases depends on informed policy-making, political commitment, and effective intervention strategies focused on the most critical food safety problems. This means that the most important diseases and sources of exposure need to be identified and ranked according to their public health impact.

Estimating the national burden of foodborne disease is an essential component of reduction efforts. The results will provide the evidence needed for an efficient allocation of both resources and efforts to prevention measures. Burden of disease estimates can also support the development of national risk-based food safety systems, and promote participation in activities for setting international food standards and in trade organizations. They are useful for identifying food safety system needs and data gaps, and thus in setting priorities for development of national infrastructure and capacity. Finally, they rely on engagement with multiple stakeholders, which can help to unify and align national efforts to improve food safety.

Estimating the burden of foodborne diseases is challenging in several ways

1	There are over 250 foodborne hazards, including microbiological hazards, such as bacteria, viruses and parasites, and chemical contaminants that either occur naturally or result from environmental pollution, processing, packaging, transport or storage of foods
2	Only a fraction of those who fall ill from eating contaminated food seek care, are treated and are reported to public health authorities
3	The health effects of foodborne hazards are highly complex, reaching far beyond acute gastroenteritis, with some hazards leading to sequelae such as kidney failure, liver disease, neurological disease or cancer
4	Pathogens commonly classified as foodborne may also cause disease through other pathways, such as contaminated water, contact with animals, or environmental routes
5	Many countries do not have the robust surveillance systems and data required for these analyses
In most LMIC, data are held by specific stakeholders, and may not be easily accessible to other relevant stakeholders, and data reporting systems are not standardized, hampering data-sharing and collection	

To obtain a better insight into the global and regional burden of foodborne diseases, WHO established the Foodborne Disease Burden Epidemiology Reference Group (FERG) in 2007 (1). The aims of FERG were:

- to estimate the global burden of foodborne diseases according to age, sex and region, for a defined list of hazards present in foods;
- to increase awareness and commitment among Member States for the implementation of food safety standards;
- to strengthen the capacity of countries to conduct burden of foodborne disease assessments, and to increase the number of countries that have undertaken such an assessment;
- to encourage countries to use estimates of the burden of foodborne disease as a basis for formulating food safety regulatory policies and standards, and for cost-effective analyses of prevention, intervention and control measures.

Based on the work supported by FERG, the first-ever WHO estimates of the global burden of foodborne diseases were published in 2015, covering disease caused by 31 hazards, including 11 diarrhoeal disease agents, seven invasive disease agents, ten helminths, and three chemicals and toxins. It was estimated that unsafe foods led to 600 million cases of foodborne illness, 420 000 deaths, and the loss of 33 million years of healthy life globally (1). The burden of disease was estimated using three different metrics: incidence, mortality, and disability-adjusted life years (DALYs).

While these estimates were crucial in highlighting food safety priorities in different parts of the world, they were the product of a massive initiative that faced substantial methodological and data limitations. In conducting global and regional analyses, FERG had to rely on a number of assumptions and data extrapolations, which were reflected in uncertainty in its estimates. Because of the limited availability of some data, FERG presented its estimates on a regional level, which meant that it could not reflect the diversity of risks in different countries in a region, or within countries.

Countries are therefore encouraged to begin working towards preparing their own estimates, with or without simplifications, to the extent that expertise and resources allow. This process will require diverse efforts, depending on the country's current capacity, data availability and general resources. Regardless of the level of development and the efforts needed to conduct a national assessment of burden of foodborne disease, the use of harmonized approaches is essential so that experiences can be shared, estimates compared and food safety policy improved.

PURPOSE OF THIS HANDBOOK

This handbook provides guidance for anyone planning to assess the burden of foodborne diseases, particularly at national level. It gives a complete picture of the requirements, enabling factors, challenges and opportunities of efforts to estimate the burden of foodborne diseases, and of the steps in the process, based on the methodology defined by FERG. It also aims to foster harmonization of methodologies for estimating foodborne disease burden across countries.

BURDEN OF DISEASE

Burden of disease can be expressed using various indicators, such as incidence, mortality, societal costs and summary measures of population health. In this document, the DALY is used as the ultimate summary measure for quantifying the population health impact of foodborne diseases. While estimating DALYs is an aspirational goal, any step towards it is valuable. Estimates of incidence and mortality can also be used to rank and compare the public health impact of foodborne diseases.

SCOPE

This handbook describes the steps involved in estimating the burden of foodborne diseases caused by microbiological agents commonly transmitted through foods. It covers planning, definition of context, data collection, burden of disease estimations,

integration with source attribution estimates, reporting and knowledge translation. The handbook has been organized to reflect as far as possible the sequential steps that need to be followed in carrying out a national burden of foodborne disease study. These steps will need to be adapted to the country's capacity for public health surveillance and data availability.

While chemical hazards, including food allergens, are recognized as important causes of foodborne diseases, they are not included in this handbook. The data requirements and methods for these hazards will be dealt with in a future publication. Nevertheless, Annex 1 provides information on chemical contaminants in foods, describes briefly the methodologies for estimating the burden of disease caused by foodborne chemicals, and gives some examples of national studies.
Most foodborne pathogens are present in a variety of foods, and several can also be transmitted to humans from environmental sources, animal contact, and from other people. As a result, it is essential to attribute infections to foodborne transmission and to specific foods; this is challenging, and requires the application of source attribution methodologies (2). Because such studies are resource-intensive and require specific expertise and capacity, they are not described in detail in this handbook. Annex 2, however, gives an overview of source attribution methods, and outlines their usefulness for different pathogens and public health questions, as well as their strengths and limitations.

TARGET AUDIENCE

The handbook is intended to be used by national governments, academic institutions, and others involved in conducting a study of burden of foodborne disease at national or other level (i.e. regional, subnational).

HOW TO USE THIS HANDBOOK

The activities involved in a study of burden of foodborne disease are described in Chapters 3 to 7. These elements should be adapted to the national context, and may be dynamic and interactive. The steps within each element are best performed in sequence.

Burden of foodborne disease studies are often iterative, with further implementation of new elements as the study evolves. It is therefore wise to take a "step-wise approach", starting with a basic, small-scale study, with the aim of expanding its scope and depth over time. This handbook will guide the reader in this process.

The best way of learning is by doing, and this handbook aims to encourage the initiation of national foodborne disease burden studies. While estimating DALYs should be the aspirational goal for national studies, intermediate steps such as estimating incidence and mortality of foodborne diseases will be valuable. A burden of disease study will also help identify data gaps, engage with food safety stakeholders across the country and align efforts, promoting communication and data-sharing.

A national estimation of the burden of foodborne diseases may require additional technical resources and specific guidance. This will be discussed further in subsequent publications and WHO activities. Keep up to date with developments by consulting the WHO website (https://www.who.int/activities/estimating-the-burden-of-foodborne-diseases).

2

BURDEN OF FOODBORNE DISEASE STUDIES

Goal and objectives
Main elements and steps of a burden of foodborne disease study
Requirements of a burden of foodborne disease study
Enabling factors for burden of foodborne disease studies

BURDEN OF FOODBORNE DISEASE STUDIES

This chapter describes the concept and overall approach of burden of foodborne disease studies, covering: the goal and objectives; the principal elements and steps; and the requirements and enabling factors for its implementation.

The concept of burden of disease was developed in the 1990s by the Harvard School of Public Health, the World Bank and the World Health Organization to describe death and loss of health due to diseases, injuries and risk factors for all regions of the world (3). This study introduced a new metric, the DALY, which combines information on morbidity, mortality and disability caused by diseases. The DALY is a more comprehensive metric than incidence or prevalence rate; it is now the most widely used public health metric for burden of disease studies, and the key measure in the Global Burden of Disease (GBD) study.

The DALY is a health gap metric, measuring the healthy life-years lost due to diseases or risk factors (4) (Figure 1). DALYs are calculated by adding the number of years of life lost due to premature mortality (*YLL*) and the number of years lived with disability (*YLD*), adjusted for severity:

$$DALY=YLL+YLD$$

YLL is the product of the number of deaths (*M*) and the average remaining life expectancy (*RLE*) at the time of death:

$$YLL=M \times RLE$$

YLD is defined as the product of the number of incident cases (*N*), the average duration until remission or death (*D*), and the disability weight (*DW*), which reflects the reduction in health-related quality of life on a scale from 0 (no impact on full health) to 1 (death):

$$YLD_{inc}=N \times D \times DW$$

In this so-called incidence-based approach to calculating disease burden, all health outcomes, including those in future years, are assigned to the initial event. This is considered the most suitable approach for estimating the burden of foodborne disease.

BOX 2.1. The prevalence-based approach to disease burden

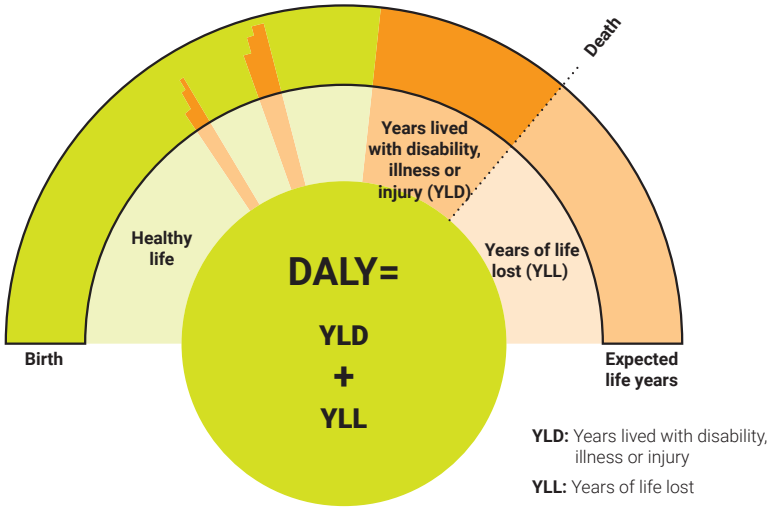
The 2010 GBD study introduced an alternative approach for calculating disease burden – the prevalence-based approach. This approach reflects the current burden of disease resulting from past events. In other words, the health status of a population is assessed at a specific point in time, and prevalent diseases are attributed to initial events that happened in the past. The definition of YLL is the same as in the incidence-based approach, but YLD is defined as the product of the number of prevalent cases (*P*) and the disability weight (*DW*):

$$YLD_{prev}=P \times DW$$

This approach is not deemed the most appropriate for estimating the burden of foodborne diseases. The incidence-based YLD is preferred for several reasons: it is more sensitive to current epidemiological trends; it is more consistent with the hazard-based approach (since the point of infection is the starting-point for the calculations); and it is more consistent with the estimation of YLLs, which by definition follows an incidence-based approach, as mortality can be seen as the incidence of death (5). If the epidemiology of disabilities and the population age structure are constant over time, the two approaches will yield similar overall results. However, burden estimates for specific age groups will always differ, because the prevalence-based approach assigns the burden to the age at which the burden is experienced, while the incidence-based approach assigns the burden to the age of disease onset.

When only prevalence figures are available, incidence can be estimated based on the prevalence and the average duration of the disease.

FIGURE 1. Disability-adjusted life years (DALYs)



*Source: Public Health England (2015). Reproduced under Open Government Licence.

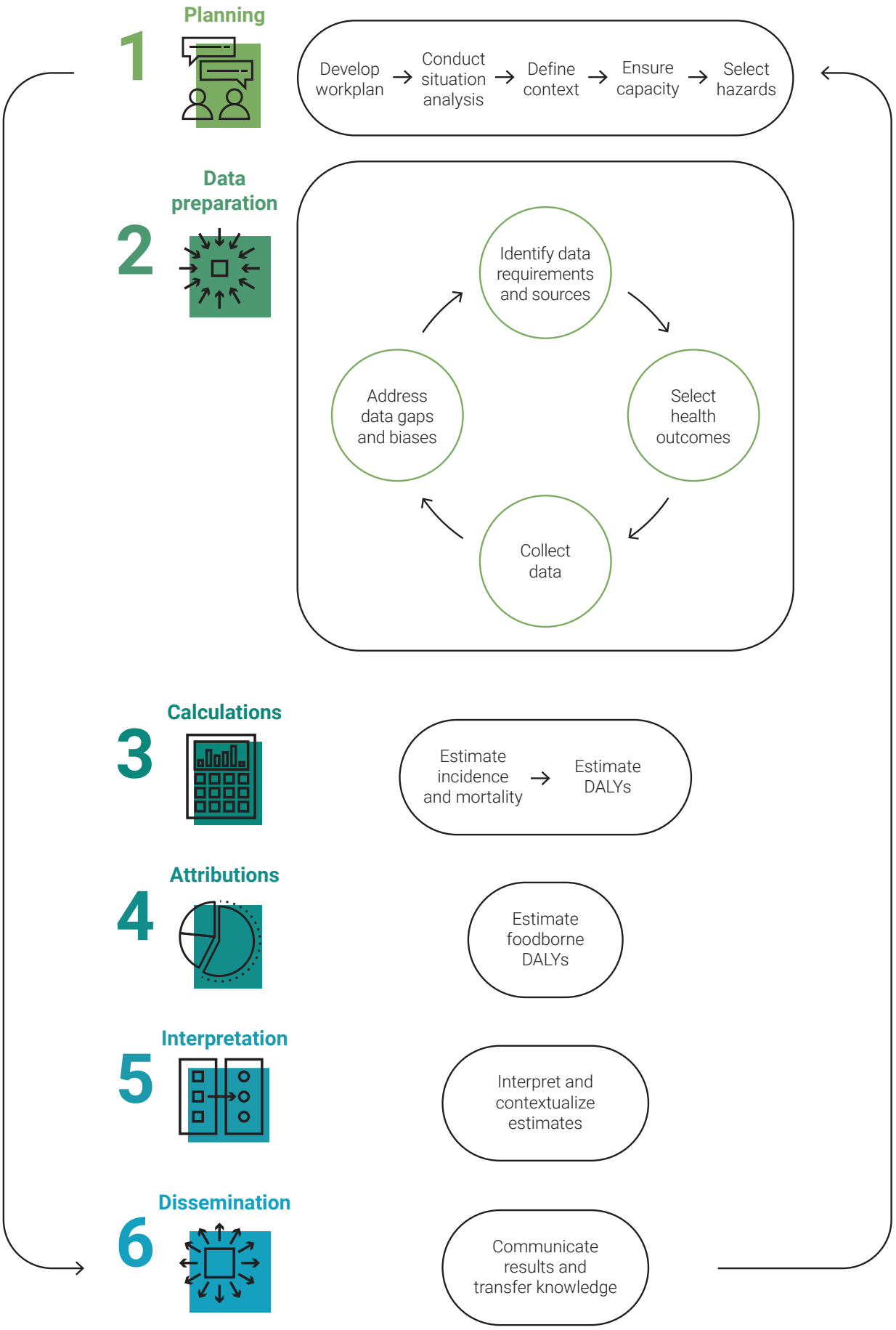
The incidence and hazard-based approach[2] is the gold standard for foodborne hazards, because exposure to most hazards in foods can lead to more than one health outcome.[3] The burden of a specific foodborne hazard is defined as that resulting from all health states that are causally related to the hazard, whatever the time scale or severity (6). These health states may include acute symptoms, chronic sequelae, and death. For example, infection with *Salmonella* spp. causes acute gastrointestinal disease in most cases, and may sometimes also lead to chronic sequelae, such as reactive arthritis and irritable bowel disease (7). Furthermore, acute disease can be mild, moderate or severe, and may also lead to death. The impact of all these health states associated with salmonellosis can be quantified using the DALY.

There are several advantages to using the DALY to quantify the burden of foodborne diseases. It allows an objective comparison across diseases and populations. It delivers comprehensive estimates and uses flexible methods that can be easily updated for new data, new hazards or new diseases. Because it integrates both occurrence and severity in a single metric, the DALY is also suitable for quantifying risk, as defined by the Codex Alimentarius Commission, i.e. "a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food" (8).

[2] Other approaches to estimating burden of disease include the outcome-based approach, which estimates the burden for a specific outcome (for example diabetes, lung cancer, or diarrhoea) without taking the possible etiologies into account; and the risk-factor-based approach, which estimates the burden attributable to risk factors (for example tobacco use, overweight, or air pollution).

[3] The detailed methodology used by FERG can be found in ref 34.

FIGURE 2. Main elements and steps of a burden of foodborne disease study



GOAL AND OBJECTIVES

The goal of a national burden of foodborne disease study is to rank and prioritize foodborne diseases based on their overall public health impact in the population. The objectives of such a study are to:

- estimate the burden of disease for selected foodborne hazards, in terms of incidence, mortality and DALYs by age and sex;
- develop a framework for routine updating of estimates and evaluation of trends; and
- provide a baseline against which food safety interventions can be evaluated.

These objectives can be fulfilled in stages, typically in the order indicated.
Estimates of burden of foodborne diseases can be used to set food safety priorities and allocate resources to national foodborne disease risk management efforts and food safety systems.

MAIN ELEMENTS AND STEPS OF A BURDEN OF FOODBORNE DISEASE STUDY

A foodborne disease study has six main elements: planning; data preparation; calculations; attributions; interpretation; and dissemination (Figure 2). These elements are dynamic; they may follow an order or be interactive, with feedback loops, continuous fine-tuning and updates when needed or possible. For example, new hazards can be added to the study if new data become available or if resources allow. Within each element, different steps will be implemented in sequence, the initiation of one depending on the output of the previous. There may also be a need for feedback loops and fine-tuning within each specific element.

REQUIREMENTS OF A BURDEN OF FOODBORNE DISEASE STUDY

The following should be in place before a burden of disease study is started.

- A minimum set of foodborne disease surveillance data for some pathogens or data on the syndromes frequently associated with these pathogens (e.g. diarrhoea), or the capacity and resources to collect these data. The data should be geographical, age and gender representative of the population in the country in terms of geographical, age and sex distribution.
- Access to national and regional demographic data, either through publicly available databases or through contact with national, regional or local health services and health care providers.
- Capacity to analyse surveillance data, apply methods to adjust for data gaps and biases, and calculate DALYs. This implies having staff with technical knowledge of data management and analysis, epidemiology and modelling.
- Possibility to engage key actors with clinical and contextual knowledge and experts in selected diseases and data, for example clinicians, microbiologists, health data curators, food safety experts.

ENABLING FACTORS FOR BURDEN OF FOODBORNE DISEASE STUDIES

While data collection, calculations and generation of DALYs are often assigned to a specialized agency or group with specific skills, such as statistics or epidemiology of foodborne diseases, it will be important to engage a broader group of actors for particular steps.

The engagement of national stakeholders is crucial to generate interest and recognition of the usefulness of estimates of the burden of foodborne disease for priority-setting in food safety. Stakeholders may include multiple organizations with a role and interest in food safety, such as governmental institutions (e.g. Ministry of Health, Ministry of Agriculture, Ministry of Environment, Food Safety Authorities, and Public Health Agencies), academia, representatives of food business operators and consumer organizations. Their involvement is particularly vital in steps such as situational analysis, knowledge translation and risk communication, to ensure that the burden of disease estimates generated are linked to actions at policy level. Such engagement is also relevant because the DALY can be difficult to comprehend for non-scientific audiences. First, it is a composite metric with no easily understood values. Second,

it requires a substantial amount of data, assumptions and methods that lead to uncertainty. Third, it is used for comparing the impact of potentially very different diseases, risk factors or settings – which is both a strength and a limitation for communication. Engagement will also promote the generation of a common purpose for the study, as well as being crucial for acceptance and use of the results.

Involvement of central or regional public health surveillance units and laboratories will facilitate data collection and sharing.

BOX 2.2. FERG country studies

One of the aims of FERG was to promote burden of disease studies at a national level. This involved capacity-building, and encouragement of the use of information on burden of disease in setting evidence-informed policies. The FERG Country Studies Task Force (CSTF) developed a suite of tools and resources to support national burden of foodborne disease studies. Pilot studies were conducted in four countries: Albania, Japan, Thailand and Uganda. The process used in these pilot studies was largely described in this handbook.

These pilot studies provided important practical lessons. In particular, data gaps prevented DALY calculations in several of the pilot studies. The data gaps included information needed to assign etiology for important syndromes, such as acute gastrointestinal disease and parasitic infections, and data on the incidence of diseases caused by some hazards.

The pilot studies also highlighted the need for engagement of different authorities that can provide access to national data, including public and private data sources. In some countries, private hospitals provide a significant proportion of health care, and may not adhere to the same reporting requirements as public hospitals. Engagement with private hospitals and other facilities may need to be specifically addressed to provide a complete picture of the incidence of diseases caused by foodborne hazards. Data on foodborne hazards can be gathered from primary producers and the food industry, but economic implications, particularly for trade, meaning that such data should be carefully handled.

Social scientists and stakeholders with a role and interest in food safety – such as governmental institutions, academia, and decision-makers (Ministry of Health, Ministry of Agriculture, Ministry of Environment, food safety authorities, and public health agencies) – need to work closely with the study team from the earliest stages to support knowledge translation and the development of science-based policies. They should be involved in developing a situation analysis, and in early and continuous efforts to incorporate knowledge translation and risk communication to the relevant audiences. Engaging these people allows information gathering about their role in food safety within a country, alerts them to the existence of the study so they are prepared for the outputs when they are available, and provides them with the opportunity to shape the study and its outputs (e.g. suggesting additional hazards). Differences in experience and perspectives can make collaboration between social scientists and epidemiological and food safety experts challenging. Barriers to data sharing may be a problem for some studies where multiple agencies have responsibility for food safety. A sponsoring agency, which needs to commit the financial and other resources to the study, provides a mandate for the study team as they engage with stakeholders and collate data. A detailed description of all country studies and support materials developed by the CSTF has been published (9).

3

PLANNING A BURDEN OF FOODBORNE DISEASE STUDY

Develop a workplan
Conduct a situation analysis
Define context
Ensure capacity
Select hazards for estimation

PLANNING A BURDEN OF FOODBORNE DISEASE STUDY

This chapter outlines the activities involved in planning and initiating a national burden of foodborne disease study. It describes: the rationale and steps of a national situation analysis; the variables to be considered when defining the context for the study; the resources and staffing required; and the selection of hazards to include in the study.

One of the first steps in a burden of foodborne disease study is to define a general workplan, identifying the national context in terms of food safety priorities and systems, the parties with an influence, interest and role to play in the study and the use of its results, and ensuring that the capacity and resources needed for the study are in place. It sets the scene for the full undertaking and ensures that the elements of the burden of foodborne disease study are aligned with national interests and capacity.

DEVELOP A WORKPLAN

A team needs to be established to undertake the study. The members of the team should have skills in the areas of epidemiology, public health, surveillance, and food safety. This first step is to draw up a project plan defining the objectives of the study, outlining a protocol, identifying the personnel needed to implement the study, setting tasks, activity leaders and participants, and identifying funding sources. The plan should also establish the timeline, main milestones, and how progress will be monitored and reported.

CONDUCT A SITUATION ANALYSIS

A situation analysis is useful in understanding the context within which the results of the burden of foodborne disease study will be disseminated and used in the country. It analyses the actors, context and dynamics of food safety in the country. It assesses which stakeholders, structures and processes may support or impede changes towards evidence-informed policy and practice in food safety. It also considers the future use of information. While knowledge translation and risk communication can take place only once information on burden of disease is available, consideration of these processes at the start of the study will influence which data are collected and how they are presented.

A situation analysis has three objectives:

- to help define the context of the national burden of foodborne disease study;
- to facilitate knowledge translation of burden estimates into policy;
- to identify and engage with key actors in food safety during the initial information-gathering process, and alert them to the study at its outset, promoting collaboration.

The expected outcomes are a document positioning estimates of foodborne disease burden as input to the national policy-making process, and strengthening of stakeholder collaboration and sharing of data. Situation analyses can draw on stakeholder analyses, analyses of the political context of food and food safety, and assessment of the national policy process (10). These methods are well established, and resources for their implementation are available in other contexts and areas of work (11). Still, even if based on an established framework, the process for an effective situation analysis will vary between countries and needs to

be adapted to the specific context. Context-mapping exercises may be useful; these can be conducted using, for example, interviews with local, regional and national stakeholders, and workshops involving key food safety and policy stakeholders.

COUNTRY EXPERIENCES

ALBANIA

The Albanian study was aimed to plan a national burden of foodborne disease study, involving stakeholders in food safety in the country in several steps of the effort; to collect data; to share results with stakeholders; and to promote efforts to use the information to develop evidence-based policies.

The process began with the creation of a team, the members of which included representatives from government and academic institutions. The team conducted a situation analysis, describing the regulatory status of food safety in the country as well as its structure and connections, identifying actors, policies and practices, and generally providing context for the scientific data and identifying foodborne hazards relevant for Albania. Local scientists collated data and information from human health surveillance sources and food safety agencies on the incidence and nature of foodborne diseases. Data were augmented by searches of scientific literature for information on food safety in Albania.

The stakeholders identified in the situation analysis included agencies responsible for public health and food safety. The Ministry of Agriculture, Food and Rural Development, Food Safety Directorate, includes the National Food Authority, which is responsible for official control, risk assessment, and communication. Official control involves hygiene inspection of food production processes and plants and certification of systems based on hazard analysis critical control point (HACCP). The Food Safety and Veterinary Institute acts as a reference laboratory and is part of the Faculty of Veterinary Medicine at the Agriculture University of Tirana. It conducts testing programmes for hazards in bivalve molluscs, as well as for pesticide residues in food as part of the National Plan of Residues.

Human health surveillance of foodborne diseases in Albania is led by the Public Health Institute within the Ministry of Health and Social Protection, which collates data supplied by regional departments of public health. An early warning surveillance system operates across the country, and the case definitions are the same as for syndromic surveillance under the International Health Regulations. The critical indicator of foodborne disease is the annual rate of reported gastrointestinal illness. Cases are reported on the basis of assessment by physicians in primary health care and hospitals.

This pilot study prompted efforts to develop greater capacity in relation to food safety and foodborne disease in Albania. It was observed that the food safety system in Albania could be strengthened by involving both risk

assessors and risk managers, providing resources for better data collection, and strengthening laboratory capacity for diagnostic testing and more comprehensive monitoring of the food supply.

Several challenges to be addressed after the termination of the study were identified. These included the need to strengthen the capacity of the microbiological and chemical laboratories (food safety and animal health) in the Food Safety and Veterinary Institute, and the foodborne pathogens laboratory (*Salmonella* and *Campylobacter*) in the Public Health Institute.

Stakeholders may be defined as any individual, group, organization, department, structure or network with a stake in food and food safety. Identifying relevant stakeholders must go beyond creating a list of individuals and groups. It should seek to understand the positions, interests, power and dynamics among the global, regional and national stakeholders in food and food safety.

In this process, it is useful to map the role and influence of each stakeholder in food and food safety in the country, and to investigate the dynamics among stakeholders, e.g.:

- How do the interests of different stakeholders converge, overlap or conflict?
- What is the history of interaction among stakeholders (e.g. previous cooperation, relationships and potential conflicts)?
- How might a shift in policy or political context modify these dynamics?

It is important to identify potential barriers to collaboration between stakeholders and data sharing at an early stage, so that these issues can be addressed and overcome. A stakeholder–issue interrelationship diagram, depicting how stakeholders relate to each other and to the major food safety issues, with emphasis on areas of possible cooperation, may be useful.

An overview and analysis of the political context of food and food safety, at the global, regional, and national levels, may also facilitate the planning and implementation of a burden of foodborne disease study. Such an overview may include factors external to the country that affect national policy-making and food safety policy processes, structural elements within the national food industry, and a general understanding of the domestic food safety system, its institutions and management system, operations, capacity, and the resources allocated to food safety.

The situation analysis should be documented in the form of a report that is available to those undertaking the burden estimation study. Suggested headings for the report are:

1. Introduction
2. Methodology
3. Stakeholders (types, description)
4. Stakeholder Responsibilities
5. Political Context
6. National Policy Context (legal and regulatory framework, policy development process, external factors affecting food safety)
7. Food Safety/Control System (institutional framework, existing food safety risk management)
8. Food sector analysis, trade and markets
    - Primary production (crops, livestock, fisheries)
    - Food processing and manufacturing
    - Food services
    - Food exports and imports
9. Country characteristics (location, size, administrative divisions, demographics, urbanization, relevant cultural practices)
10. Sources of information on foodborne diseases (surveillance systems and their coverage, health system reporting)

DEFINE CONTEXT

Defining the context of the burden of foodborne disease study implies setting the population of the study, possible

subpopulations, the levels of analysis, and the period of the study. These choices will determine the data requirements and data sources, as well as methodological considerations throughout the study.

ENSURE CAPACITY

A national burden of foodborne disease study requires a certain level of technical capacity and resources. Participants in the study need a range of skills, including in epidemiology, data management, statistics, modelling, food science, public health and foodborne disease. If the required skills and knowledge are not present in the core team, a network of experts who can provide ad hoc input can be useful. The balance between the core team and the other experts (national and international) will depend on the human resources available in the country and the study timeline (14). The staff running the analysis and coordinating the study need to have technical skills (with a focus on modelling) as well as good coordinating and communication, in view of the multidisciplinary nature of the study, and in order to overcome challenges and gaps in knowledge, and address uncertainties. As suggested in the WHO National Burden of Disease Manual, "creativity and plausibility, courage but not recklessness, precision but not uncertainty-induced paralysis, and good listening skills in contact with experts" are important characteristics (14).

In addition to the requisite staff, an appropriate structure and routes for coordination and collaboration with key partners, e.g. data providers, data collectors and disease experts, need to be in place.

SELECT HAZARDS FOR ESTIMATION

The Codex Alimentarius defines a foodborne hazard as a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (8). In applying a hazard-based approach to burden of disease, the first step is to select the hazards to be included. This selection can be based on pre-identified public health priorities in the population, food contamination evidence, data availability, and resources. The list can be expanded to include other hazards at any time, allowing countries to gradually compile data and build estimates, leading eventually to a comprehensive estimate of the national burden of foodborne diseases. The major causative agents for which burden of foodborne disease estimates could be derived, as compiled by FERG, are listed in Annex 3.

The relevance of the various foodborne hazards will differ between countries. In selecting hazards to include, study teams may consider some or all of the indicators listed in Table 1.

TABLE 1. Factors to consider in selecting hazards for a national burden of foodborne disease study

Indicator	Questions to guide selection
Public health relevance	Is there evidence of cases of illness occurring in the population? Are there data from national public health surveillance, regional studies or ad hoc research studies?
Occurrence of foodborne outbreaks	Have outbreaks of illness caused by the pathogen been identified in the population? Have these outbreaks been investigated, and linked to specific foods?
Food contamination evidence, including food safety events	Is there evidence of foods or animals being contaminated with the hazard in the country? Are data available from national or regional monitoring programmes, ad hoc studies, or food import control programmes? Has there been any trade issue or concern?
Food consumption habits	Are specific food consumption patterns associated with common hazards?
Evidence from other countries	Has the hazard been identified as of public health concern in other countries? Is it a food safety problem in neighbouring countries?
Research, published studies or reports	Are there national or international studies or reports flagging the hazard as a food safety issue at national, regional or global level?

4

DATA PREPARATION FOR A NATIONAL BURDEN OF DISEASE STUDY

DATA PREPARATION

This chapter describes the data requirements for a national burden of disease study, lists potential data sources, and suggests strategies for data collection, and for addressing data gaps encountered throughout the process.

IDENTIFYING DATA REQUIREMENTS AND SOURCES

The data needed for a burden of foodborne disease study can be classified into demographic data, outcome data, hazard data, and disease model data. To the extent possible, data should be stratified by age and sex, as well as other categories defined under context. The reference year(s) should also follow the period defined under the context of the study. As with most models and estimates, there will be limitations and data gaps; these should be documented so that challenges can be overcome, assumptions made, and uncertainties measured.

Demographic data

General demographic data will be relevant to the estimation of burden of disease for all hazards. They include country population and subpopulation size, age distribution, sex distribution, and life expectancy, and may include the numbers of pregnant women, women who have recently given birth, live births, stillbirths and abortions. Table 2 lists the types of demographic data needed for a national burden of foodborne disease study, with examples of data sources and suggestions of indicators for evaluating the quality of such data. As already mentioned, the DALY is a health gap metric that estimates a population's actual

TABLE 2. Demographic data needed for a national burden of foodborne disease study, data sources, and quality assessment indicators

Data requirement	Importance	Data source	Quality assessment
Total population, stratified by age and sex	Required for all diseases	Population census. Demographic surveys (e.g. Demographic and Health Surveys (USAID); WHO World Health Survey; INDEPTH Health and Demographic Surveillance System; National Living Standards Survey; National Household Budget Survey; National Health Survey; standard life tables	Sample size, sampling area and time period
Total number of pregnancies or proportion of pregnant women	Required for some diseases		
Total number or proportion of live births, stillbirths and abortions	Required for some diseases		
Local life expectancy table, stratified by sex	Required for all diseases		
Standard life table	Required for all diseases	WHO global health estimates. Global Burden of Disease Study	

health status in relation to an ideal or reference status. This reference therefore needs to be specified, and will depend on the choice of life expectancy data. Life expectancy represents how long people in good health can expect to live (14), and can be derived from life tables, which show the mortality and survival patterns in a population. Typically, life tables are constructed for men and women separately, because their mortality rates can be very different.

To estimate YLL, the use of a standard life table (see an example in Table 3) is preferred. These reflect ideal life expectancy, based on the lowest possible mortality given current available data. Different standard life tables have been developed for the WHO global health estimates (GHE) (15) and the GBD studies of the Institute for Health Metrics and Evaluation (IHME) (16), and have been updated over time as new data became available. However, countries may prefer to use national data as the reference, particularly if the underlying mortality in the standard life table is not achievable in their situation or not suitable for guiding policy. National data may also be more appropriate when performing subnational studies. This decision should be supported by good evidence and rationale, and should be borne in mind when the resulting estimates are compared with those of other countries. Indeed, using national life expectancy tables precludes international comparisons of foodborne disease burden estimates.

To estimate YLD for lifelong conditions, the use of country-specific life tables is generally recommended and has been endorsed as appropriate by FERG, because only these life tables represent the number of years a person of a given age and sex in the country is expected to live. Country-specific life tables are available on the WHO website (http://apps.who.int/gho/data/node.country) (17).

TABLE 3. WHO standard life table for YLL, used for global burden of disease estimates 2000–2016[a]

Age	SEYLL*	Age	SEYLL*	Age	SEYLL*	Age	SEYLL*	Age	SEYLL*	Age	SEYLL*	Age	SEYLL*
0	91.94	16	76.04	32	60.13	48	44.32	64	28.82	80	14.41	96	4.65
1	91.00	17	75.04	33	59.13	49	43.34	65	27.86	81	13.63	97	4.18
2	90.01	18	74.05	34	58.14	50	42.36	66	26.91	82	12.86	98	3.70
3	89.01	19	73.05	35	57.15	51	41.38	67	25.96	83	12.11	99	3.24
4	88.02	20	72.06	36	56.16	52	40.41	68	25.02	84	11.39	100	2.79
5	87.02	21	71.06	37	55.17	53	39.43	69	24.08	85	10.70	101	2.36
6	86.02	22	70.07	38	54.18	54	38.46	70	23.15	86	10.03	102	1.94
7	85.02	23	69.07	39	53.19	55	37.49	71	22.23	87	9.38	103	1.59
8	84.02	24	68.08	40	52.20	56	36.52	72	21.31	88	8.76	104	1.28
9	83.03	25	67.08	41	51.21	57	35.55	73	20.40	89	8.16	105	1.02
10	82.03	26	66.09	42	50.22	58	34.58	74	19.51	90	7.60		
11	81.03	27	65.09	43	49.24	59	33.62	75	18.62	91	7.06		
12	80.03	28	64.10	44	48.25	60	32.65	76	17.75	92	6.55		
13	79.03	29	63.11	45	47.27	61	31.69	77	16.89	93	6.07		
14	78.04	30	62.11	46	46.28	62	30.73	78	16.05	94	5.60		
15	77.04	31	61.12	47	45.30	63	29.77	79	15.22	95	5.13		

[a] Reproduced from ref. 18.

*SEYLL: standard expected years of life lost.

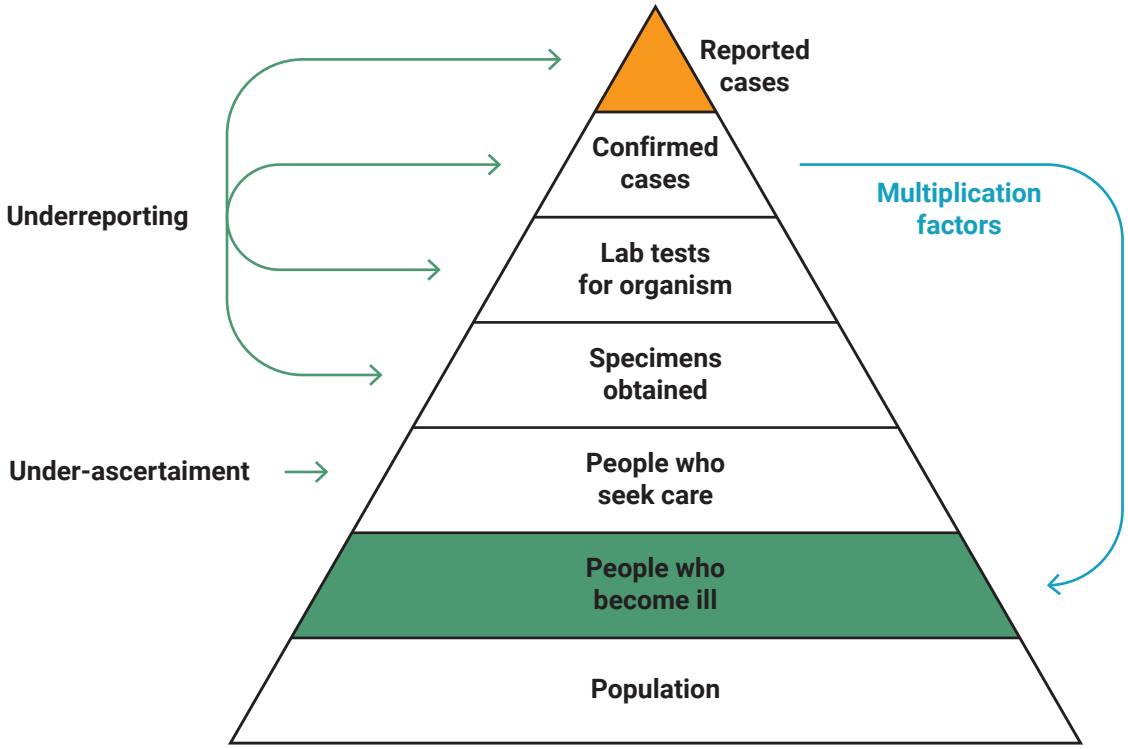
Incidence data

Incidence is the number of new cases of a particular disease or its sequelae in the year of interest. For foodborne diseases, incidence data may be available from public health surveillance systems if the infection is notifiable, from foodborne outbreak surveillance, or from ad hoc studies or research projects.

For most foodborne diseases, some degree of under-reporting is to be expected, even if the disease is notifiable (17, 18). A passive surveillance system inevitably under-represents the true number of ill people, as a consequence of underdiagnosis and under-reporting. This may be because of a failure at any one of the multiple steps by which a case is identified and reported: the ill person may not seek medical care; the physician may not request a stool specimen or submit it to a clinical laboratory for testing; the causative pathogen may not be isolated and identified at the laboratory; and the results may not be reported to the public health surveillance system (19) (Figure 3).

FIGURE 3. The foodborne diseases surveillance pyramid

The green base represents all cases caused by a specific pathogen in the country in a given time period. The tip of the pyramid represents the cases reported to public health surveillance.



Underdiagnosis is the failure of the health care system to capture cases in the community that do not seek medical care, whereas under-reporting is the failure to diagnose or classify cases correctly or to notify the system (19). The degree of underdiagnosis and under-reporting will vary by pathogen and country, reflecting differences in, for example, public health surveillance, severity of disease, health care capacity, laboratory practices and health care-seeking behaviour. For diseases or specific health outcomes that produce severe symptoms or for which there are special surveillance programmes, it may be assumed that all cases are diagnosed and registered. Chapter 5 describes the methods for estimating the true incidence of disease by correcting for underdiagnosis and under-reporting.

BOX 4.1. Underdiagnosis and under-reporting

- *Underdiagnosis* refers to cases in the community that did not seek medical care. Health outcomes caused by foodborne disease vary from mild to very severe, and registered diseases often represent only a small proportion of all disease in a particular region. Diagnoses may be biased towards more severe cases or specific population groups that are more likely to visit the doctor (e.g. children).
- *Under-reporting* refers to cases for which medical advice was sought, but that were not correctly diagnosed, classified, or notified to the surveillance authority. The disease may also not be attributed to the agent, because appropriate laboratory tests are not performed or because the association between exposure and disease is not clear, for instance when there is a time lag between exposure and health effects.

Available incidence data may be collected at different health care levels and reflect different levels of severity of the disease. Registered cases may correspond to physician visits, outpatient attendance, or hospitalization. The data will need to be segregated by source for the burden of disease calculations.

In some countries, registry systems may not have full coverage. Ideally, they will reflect a representative sample of all disease episodes in the country, allowing national incidence rates to be calculated. Knowledge of the catchment populations for the registries is essential for the calculation of population-based data.

To overcome gaps or challenges in gathering valid incidence data, many studies of foodborne agents have used several data sources to estimate the incidence or prevalence of disease. Annex 5 lists the approaches and assumptions adopted by FERG to overcome data gaps. This list is intended as inspiration for defining strategies in national burden of foodborne disease studies and is neither comprehensive nor exhaustive.

COUNTRY EXPERIENCES

CARIBBEAN COUNTRIES

Each year, roughly 1 in 49 people in the Caribbean (approximately 142 000 persons) acquire a foodborne illness as a result of consumption of contaminated food or drink. This incidence increases to 1 in 11 during the frequent mass gathering events, such as Carnival, cricket matches, food festivals and holiday celebrations that the multicultural, tourism-dependent Caribbean is well noted for. Over 40% of the cases are in children aged 1–4 years. The estimated economic cost of gastroenteritis (the most common symptom of foodborne illness) is US$ 21million a year, indicating the huge health and economic burden that gastroenteritis and foodborne diseases pose to the Caribbean.

The Caribbean Burden of Illness Study was conducted from 2008 to 2013 in nine countries and area (Barbados, Belize, Bermuda, Dominica, Guyana, Grenada, Jamaica, St Lucia and Trinidad and Tobago) by the Caribbean Epidemiology Center (CAREC), now part of the Caribbean Public Health Agency (CARPHA), the Pan American Health Organization (PAHO), and the Caribbean Eco Health Program.

This was the first time a burden of illness study had been conducted in the Caribbean to estimate the prevalence and burden of acute gastroenteritis, specific foodborne pathogens, risk factors for infections, economic costs, and data gaps. The findings provided valuable information, which has since guided food safety policy interventions and efforts to reduce foodborne disease in the Caribbean region.

The study confirmed not only that foodborne disease was a common health problem, but that children were at increased risk, and that foodborne disease represented a huge economic burden and potential threat to tourism. Only a small proportion of people who contracted foodborne illness sought medical care. Only a fraction of the cases seen by a health worker were asked for a sample or were associated with a hazard in food, and only a fraction of those were reported to the public health surveillance system. Foodborne disease in the Caribbean was found to be grossly under-reported and underdiagnosed, and there was an urgent need to improve the surveillance of acute gastroenteritis and foodborne diseases and to implement appropriate and targeted food safety measures. However, ensuring food safety in the Caribbean is a complex challenge. The region is characterized by small populations, varying levels of epidemiological and laboratory skills and capacities, and intense movement via trade, labour, and tourism. The Caribbean also imports 55–85% of its food and is the most tourism-dependent region in the world. Foodborne disease affects not only the health of the Caribbean population, but that of its visitors.

The degree of under-reporting for acute gastroenteritis was found to range from 64% to 99% and that for specific foodborne pathogens from 33% to 99.9%. The estimated economic costs of acute gastroenteritis ranged from US$1.3 million to US$40 million. Under-reporting occurred at all levels of the reporting pyramid, with the most significant being at the level of reporting laboratory-confirmed data to the national surveillance unit. There was also significant underdiagnosis of foodborne disease etiology, limiting appropriate prevention measures. The etiology of foodborne diseases in the Caribbean was found to differ from what was being reported. Norovirus was found to be an increasingly important pathogen and in some countries the most common cause of acute gastroenteritis. In contrast, *Salmonella* and *Shigella* infections were the most commonly reported to the surveillance system. Parasitic foodborne diseases, in particular *Giardia spp*., were also a common cause of foodborne diseases. This had not previously been recognized in the Caribbean, since *Giardia spp*. infections were not commonly required to be reported in national or regional surveillance reports.

The findings suggested that national and regional surveillance reports were incomplete, which may have

resulted in ineffective use of resources, surveillance measures and food safety interventions (e.g. a focus on bacterial diagnosis rather than viral), and hence a continued increase in foodborne disease cases and outbreaks. The study provided information for country and region-specific measures and interventions that should be implemented to reduce foodborne disease incidence and outbreaks, improve food safety and strengthen the sustainability of Caribbean tourism-dependent economies. Key recommendations that have been adopted include:

- allocation of additional resources to improve laboratory diagnoses and outbreak investigations;
- improved collection of stool specimens from acute gastroenteritis diarrhoeal cases;
- extended diagnosis of stool specimens from patients with gastroenteritis to include a wider range of bacterial pathogens;
- purchase of norovirus kits and routine testing for this pathogen;
- use of standardized forms to avoid duplication errors in laboratory reporting;
- inclusion of viral and parasitic pathogens on national and regional surveillance reports;
- implementation of country-specific, pathogen-specific, and targeted food safety measures (by age group, parish, practices, locals, tourists);
- multidisciplinary coordination, communication and data-sharing between various disciplines and individuals responsible for food safety, laboratories, environmental health, epidemiology and veterinary public health through inclusion in surveillance meetings and use of integrated databases

This study has thus made a significant contribution to filling the knowledge gap in the Caribbean on the true burden, prevalence, etiology, risk factors and economic cost of acute gastroenteritis and foodborne diseases. It provided valuable evidence to guide both country-specific and Caribbean-wide foodborne disease-reduction efforts and food safety policy. It also provided information for the WHO-led initiative to estimate the global burden of foodborne disease.

Contribution to capacity-building

A major outcome of the study was a number of capacity-building initiatives for improving foodborne disease surveillance in countries, in particular with regard to laboratory testing for a wider range of foodborne pathogens, administration of population surveys and production of issue and policy briefs. Before this study, countries routinely tested specimens mainly for *Salmonella* and sometimes for *Campylobacter*. As a result of this study, a wider range of pathogens has been tested for, isolated, and reported nationally and regionally, beginning in 2008 when the study started in St Lucia. The impact of this laboratory strengthening initiative was reflected by a wider range of pathogens being reported, showing the increasing prevalence of norovirus since 2008.

Contribution to policy change

The study has provided evidence that can be used to guide resource allocation, and country-specific and regional food safety policy interventions. The results were documented in 2-page issue briefs and policy briefs, i.e. the formats that the Ministries of Health use to initiate policy change. The result was policy change in several countries, e.g. Barbados increased laboratory resources to allow norovirus kits to be purchased, and parasitic testing is now routine for cases of acute gastroenteritis in Guyana. Integrated multisectoral teams (incorporating laboratory skills, epidemiology, environmental health and veterinary health) have been created in the countries, and now hold monthly surveillance meetings to promote collaboration for investigation of foodborne diseases.

The Caribbean Burden of Illness Study is described in detail in the following publication:

Etienne CF, ed. Supplement on Caribbean Burden of Illness Study. Journal of Health, Population and Nutrition. 2013; 31(4).

For some foodborne diseases, it may be useful or even necessary to use syndrome-specific data in estimating the burden. Diarrhoea is the dominant feature in many foodborne diseases, and thus incidence and mortality rates of diarrhoeal disease in the population may be required. These data may be available from national health registries, international data banks or estimates, or the scientific literature (Table 4).

TABLE 4. Types of data, data sources, and quality assessment indicators for syndrome-specific data needed for a national burden of foodborne disease study

Data requirement	Importance	Data source	Quality assessment
Incidence of syndrome (e.g. diarrhoea or acute gastroenteritis), stratified by age and sex	Required for burden estimation of enteric diseases when hazard-specific data are not available	National Health Registries. Public health surveillance systems. National health management information systems. Scientific literature. International Data Banks	Covered population and time period
Mortality of syndrome, stratified by age and sex		National Health Registries. Cause of Death Registries. Medical and hospital registers. Scientific literature. International Data Banks (e.g. Demographic and Health Surveys (21) and WHO mortality data (22))	

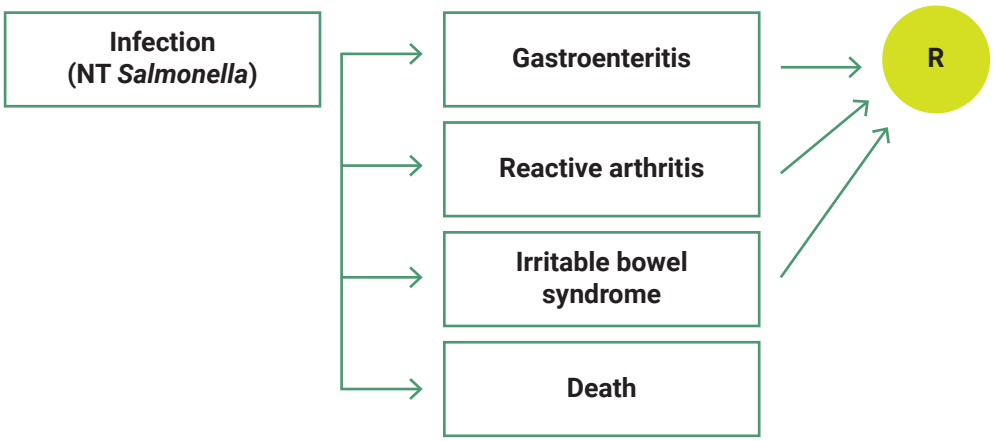
SELECTING HEALTH OUTCOMES

Disease model data

To estimate the disease burden associated with foodborne hazards, the various potential health outcomes of the infection need to be identified. The outcomes of foodborne infections and their probabilities can be described in a disease model. Figure 4 shows an example of a disease model for non-typhoidal (NT) *Salmonella* infection. Health outcomes associated with the hazard may be identified through published epidemiological studies, or by analysis of national clinical data. If country-specific data are not available, the disease models used in other burden of foodborne disease studies, or by FERG (1), may be used. The completeness of the disease models will depend on the available evidence.

FIGURE 4. Example of a disease model for non-typhoidal *Salmonella* infection

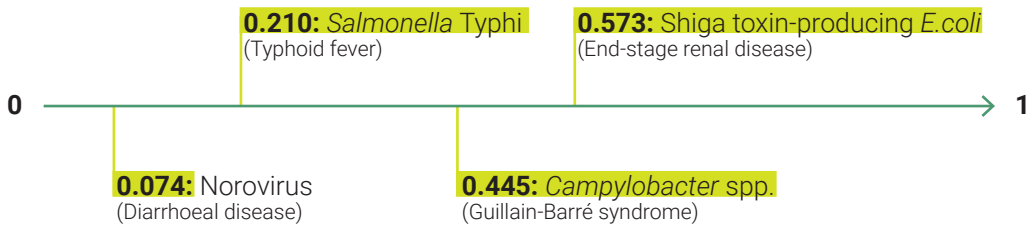
Infection will result in gastroenteritis in all patients, and in some cases may lead to reactive arthritis, irritable bowel syndrome, or death. The non-fatal health outcomes will resolve in recovery (R). This disease model excludes invasive infections.



Disability weights

The severity of each health outcome is translated in the disability weight (23). The value of the DW is between 0 and 1, where 0 represents full health, and 1 represents death (Figure 5). A DW can be interpreted as the proportional reduction in good health due to an adverse health state (24). DWs are estimated in empirical studies that interview a panel of judges who are asked to value their preferences in relation to loss of health associated with causes of disease and injury.

FIGURE 5. Sample disability weights for different diseases (5)



BOX 4.2. Determining disability weights (DWs)

DWs are calculated to overcome the fact that the concepts of health and health loss are subjective and cannot be quantified. Several methods have been proposed to derive DWs from health-related quality of life measures, i.e. measures of the well-being individuals derive from specific health states. As such, they are subject to design choices, which affect the resulting values. The first significant design choice is the panel of judges who are asked about their preferences. This panel may consist of patients, medical experts or members of the community (26–28). Overall, disability weights based on patients' preferences tend to be higher than those derived from the general community (29–31). It has been recommended to use disability weights based on societal preferences because burden of disease studies are primarily used as a tool for guiding decision-making on resource allocation at the population level (32). The second design choice is the valuation method used to measure the preferences of the panel. Available methods include the visual analogue scale (VAS), time trade-off (TTO) and person trade-off (PTO). Each valuation method affects the preference outcomes in a method-specific way, limiting exchange and comparability of preference data from different sources (31, 32). Because of the trade-off feature, the TTO and PTO methods are considered to be more appropriate than the VAS. A third design choice is the description of the health states, which may be disease-specific or generic. Disease-specific health state descriptions indicate the cause, the specific health effects and the treatment of the condition. A generic health description describes functional health without regard to the underlying condition, for instance, by indicating problems with mobility, self-care and usual activities.

Since there is no single best method for eliciting disability weights, available studies and estimates cannot be classified as more or less correct. None the less, it is important to note that disability weight studies that use different elicitation methods and judges are, at least theoretically, not comparable. To the extent possible, DWs from different studies should not be mixed. Given the broadness of its scope, an obvious choice is therefore the most recent set of DWs developed for the WHO global health estimates or GBD study. Alternatively, countries may use country-specific DWs – although it is generally considered that DWs do not vary significantly between countries (35). The default DWs used by FERG were those used for the GHE (5) (see Annex 3). DWs are regularly updated; the latest DWs for GHE can be found on the WHO website.[4]

Duration of disease

Duration is defined as the average observed duration of a health outcome until remission or death, and can vary from a few days to lifelong. Data on the duration of a health outcome can be found in the scientific literature or health registries. If needed, a meta-analysis can be performed to integrate estimates from different sources. When the duration of the health outcome is lifelong, it is recommended to use the life expectancy in the country to calculate the duration of disease, i.e. from onset until expected time of death (36).

Mortality data

Hazard-associated mortality may be available from national health registries, medical records or hospital registers. However, cause of death is often limited to the syndrome (e.g. diarrhoea), and the causative agent may not be registered (e.g. *Campylobacter*). In those cases, as for incidence, mortality associated with a foodborne pathogen often needs to be estimated (see Chapter 5).

COLLECTING DATA

As described, data for the national burden of foodborne disease study will need to be collected from various data sources. While some of these may be easily accessible, others will require close collaboration with public and private stakeholders.

[4] https://www.who.int/healthinfo/global_burden_disease/en/

For example, in some countries, private hospitals provide a significant proportion of health care, and may not have the same reporting requirements as public hospitals. Even within national health registries, clinical data may be reported in a non-harmonized fashion and may be difficult to navigate without the support of agencies' representatives or experts. Clinical experts can often provide useful guidance on collecting relevant epidemiological data. This collaboration will be facilitated by the identification of relevant stakeholders during the planning stages of the study. Annex 4 contains a checklist that countries can use to take stock of the data required for a national burden of foodborne disease study.

ADDRESSING DATA GAPS AND BIASES

It is highly likely that the input data necessary for estimating DALYs at the national level will be incomplete. Data gaps and biases may range from incomplete coverage to a complete absence of data.

Dealing with data gaps and biases is often the most time-consuming part of a foodborne disease burden study. It will be necessary to search for information in other relevant studies, such as burden of foodborne disease studies conducted in other countries, epidemiological studies, international data resources and data banks, and to define approaches for data extrapolation or imputation, which may include collecting data for other years, other populations, or other health outcomes. All assumptions made should be clearly and carefully documents. Thus, the extent to which different data requirements are met will affect some of the methodological components of the burden of disease study (Table 5).

Independent of the strategy adopted, it is crucial that all assumptions, implications and limitations are documented and justified, and that the potential impact of these on the final results of the study are discussed.

Table 5 lists some of the key approaches used to address data gaps and biases in burden of disease studies. In practice, the approach will have to be tailored to the data at hand. These approaches are also inherently linked with the overall methodologies for estimating the burden of foodborne diseases (see Chapter 5). The selection and implementation of the adjustment approach will require a combination of broad epidemiological and statistical knowledge and an in-depth understanding of the quality and characteristics of the locally available data. When representative data are not available, expert opinion may be used as a last resort for filling data gaps.

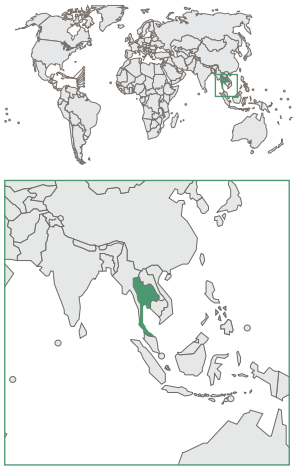
TABLE 5. Examples of data gaps or biases commonly encountered in burden of foodborne disease studies, their causes and possible solutions

Data gap or bias	Causes of the data gap	Possible solutions
Cases of disease not reported to public health surveillance	Disease not notifiable in the country. Laboratory surveillance absent in the country	Apply a disease envelope approach to estimate incidence (see Chapter 5)
Cases reported, but with a degree of underdiagnosis and under-reporting	Failure in any of the steps between onset of illness and reporting to public health surveillance system	Reconstruction of surveillance pyramid to correct for under-reporting (see Chapter 5)
Lack of associated mortality data	Lack of cause of death data in national health statistics. Deaths not linked with infection by pathogen. Lack of data on outcome of cases identified by surveillance	Use of data from epidemiological studies (scientific literature). Apply a disease envelope approach to estimate mortality
Lack of data on health outcomes and sequelae of infections	Occurrence of the health outcome not registered in national health statistics, or not linked with infection by pathogen	Use of data from epidemiological studies (scientific literature) or other clinical data sources
Disability weight for specific health outcomes not available	Health state has not been included in the GBD survey	Use a proxy disability weight that is associated with similar health effects. Choose a disability weight from one of the alternative sets

In estimating the burden of 31 foodborne diseases at global and regional levels, FERG faced numerous data gaps. The approaches used and experience gained can be used as an initial framework for national studies, or as an inspiration for selection of strategies. Annex 5 describes examples of adaptations and assumptions made in the FERG estimations of burden of foodborne disease.

COUNTRY EXPERIENCES

THAILAND



Foodborne illnesses at the community level are poorly understood in Thailand. The National Notifiable Disease Surveillance System has primarily been based on passive syndromic surveillance, which provides limited information on etiology since stools are not routinely collected for laboratory testing (http://www.boe.moph.go.th/boedb/surdata/index.php). Given the large variation in capacities to detect and investigate foodborne disease and the absence of reliable data, it was recognized that more precise information on burden of foodborne disease was needed to assist in allocating resources for effective food safety control efforts, and developing relevant public health policies to prevent and control these illnesses.

The Thai burden of foodborne disease study was led by International Health Policy Program with the Ministry of Public Health. Several data sources, including the National Notifiable Disease Surveillance System, national medical services data, national surveys, and relevant domestic and international literature, were used to obtain information about the occurrence of foodborne illness. A variety of methods were used to ascertain the burden of acute diarrhoea and foodborne disease according to etiological agent. The analysis took into account the fact that public health surveillance systems are subject to under-reporting and underdiagnosis.

The burden of foodborne illness in Thailand was substantial, with an estimated 19 million episodes of acute diarrhoea per year (0.30 episodes per person per year). This estimate was 15 times higher than the values indicated by routine surveillance. The incidence rates of *Salmonella*, *Shigella*, cholera and *Escherichia coli* infections in 2009 were estimated to be 1.74, 0.62, 0.22 and 0.11 per 1000, respectively. Results showed that more than 6 million people were infected with *Opisthorchis viverrini* and there were more than 900 000 cases of rotavirus infection in children.

This study represents the most comprehensive assessment of the incidence of foodborne illness in Thailand. Findings highlighted the significant burden of diarrhoeal diseases in children and the elderly, and indicated that routine surveillance results were much lower than the true values. The model, which used data from national hospital and surveillance databases, national surveys, and community-based studies, had several limitations as a result of assumptions made and

uncertainties. These limitations emphasize the need for a complementary system, such as laboratory-based active surveillance in Thailand, to measure precisely the foodborne diseases burden. While improving capacity in the disease surveillance system is a long-term objective, the Thai Ministry of Public Health has been developing a Smart Surveillance System to increase the functionality of electronic medical records, by using computer algorithms to identify cases that meet surveillance case definitions and automatically report them to public health agencies (https://ehealth.moph.go.th/index.php/resources/draft-ehealth-strategy-ministry-of-public-health-2016-2021?download=7:eng). This new system will increase the detail, timeliness, and completeness of public health surveillance and thereby provide better data to guide public health interventions.

COUNTRY EXPERIENCES

A MULTICOUNTRY PROJECT IN ETHIOPIA, MOZAMBIQUE, NIGERIA, AND THE UNITED REPUBLIC OF TANZANIA

Low- and middle-income countries, particularly in Africa, bear the highest burden of foodborne disease. However, because research and disease surveillance data from this region are limited, previous burden estimates are unreliable.[a] The main challenge to estimating the burden of foodborne diseases in Africa is a lack of data, since factors ranging from lack of capacity to lack of political commitment, and a focus on priority diseases, limit existing surveillance systems.

Foodborne Disease Epidemiology, Surveillance and Control in African LMIC (FOCAL) is a project funded by the Bill and Melinda Gates Foundation and the United Kingdom's Department for International Development between November 2019 and October 2022. It will estimate the burden of foodborne diseases in four African countries: Ethiopia, Mozambique, Nigeria, and the United Republic of Tanzania. FOCAL is a consortium of eight academic partner institutions from these four countries and Canada, Denmark, and South Africa, working together to establish best practices for estimating the burden and provide the best evidence of the health impact, and the relative contribution, of different sources of foodborne infections in the target countries.

FOCAL is taking a stepwise and multimethod approach. To estimate incidence and distribution of diarrhoea in the community, population surveys are being conducted using a combination of face-to-face and online questionnaires. While the online questionnaires are focused on urban populations, where penetration and usage of smart phones and computer services are expected to be higher, face-to-face interviews are being conducted in both rural and urban settings.

To estimate proportions of diarrhoeal disease caused by different agents, FOCAL is conducting a systematic literature review using the same method as the WHO initiative to estimate the global burden of foodborne diseases 2007–2015.[b] To complement these two methods and estimate the extent of under-reporting in existing surveillance, local partners are also conducting an active review of available reports on foodborne disease.

Perspectives and lessons learned so far

Lessons from this large-scale project can be extrapolated to other countries and regions where the burden is high but data are scarce. The consortium has focused on investing in studies and methods for data collection, and ensuring good leadership, including delegation of duties, setting milestones, regular meetings, transparency, and risk mitigation plans. The leading role of experts in this project has helped to reduce hurdles, and local community involvement, e.g. through health extension workers, is central. Furthermore, coordination of processes for study approval and data transfer agreements among partners may be time-consuming and should be started early. FOCAL has adapted existing data collection tools for use across the diverse study populations. The data collection tool used is compatible with different operating systems, can accommodate different languages, can collect data both off and online, and stores data securely in a common database. The consortium is engaging stakeholders who will use the research outputs, by involving them at all stages of the project.

[a] Kirk MD, Pires SM, Black RE, Caipo M, Crump JA, Devleesschauwer B et al. World Health Organization estimates of the global and regional disease burden of 22 foodborne bacterial, protozoal, and viral diseases, 2010: a data synthesis. PLoS Med. 2015;12(12):1–21.

[b] Pires SM, Fischer-Walker CL, Lanata CF, Devleesschauwer B, Hall AJ, Kirk MD et al. Aetiology-specific estimates of the global and regional incidence and mortality of diarrhoeal diseases commonly transmitted through food. PLoS One. 2015;10(12):1–17.

5

ESTIMATING INCIDENCE, MORTALITY AND DALYS

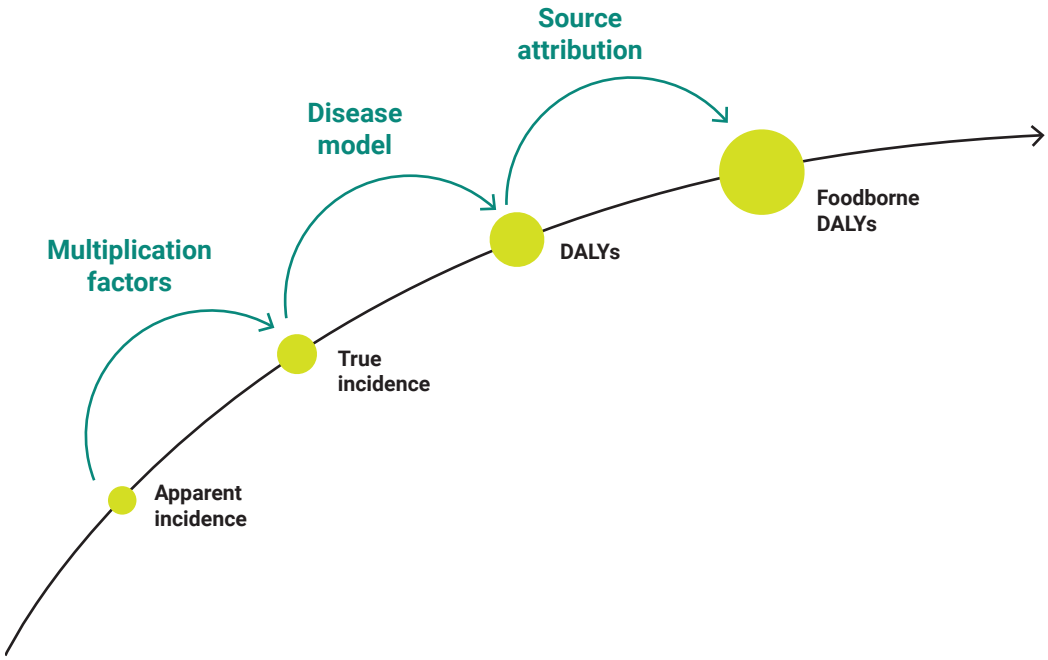
Incidence and mortality
Incidence of other health outcomes and sequelae
Calculating DALYs
Uncertainty
Software

ESTIMATING INCIDENCE, MORTALITY AND DALYS

This chapter describes all steps involved in calculating the burden of foodborne diseases in a country. It describes how to calculate incidence, mortality and DALYs, how to estimate and address the potential associated uncertainties, and considers software that can be used in this element.

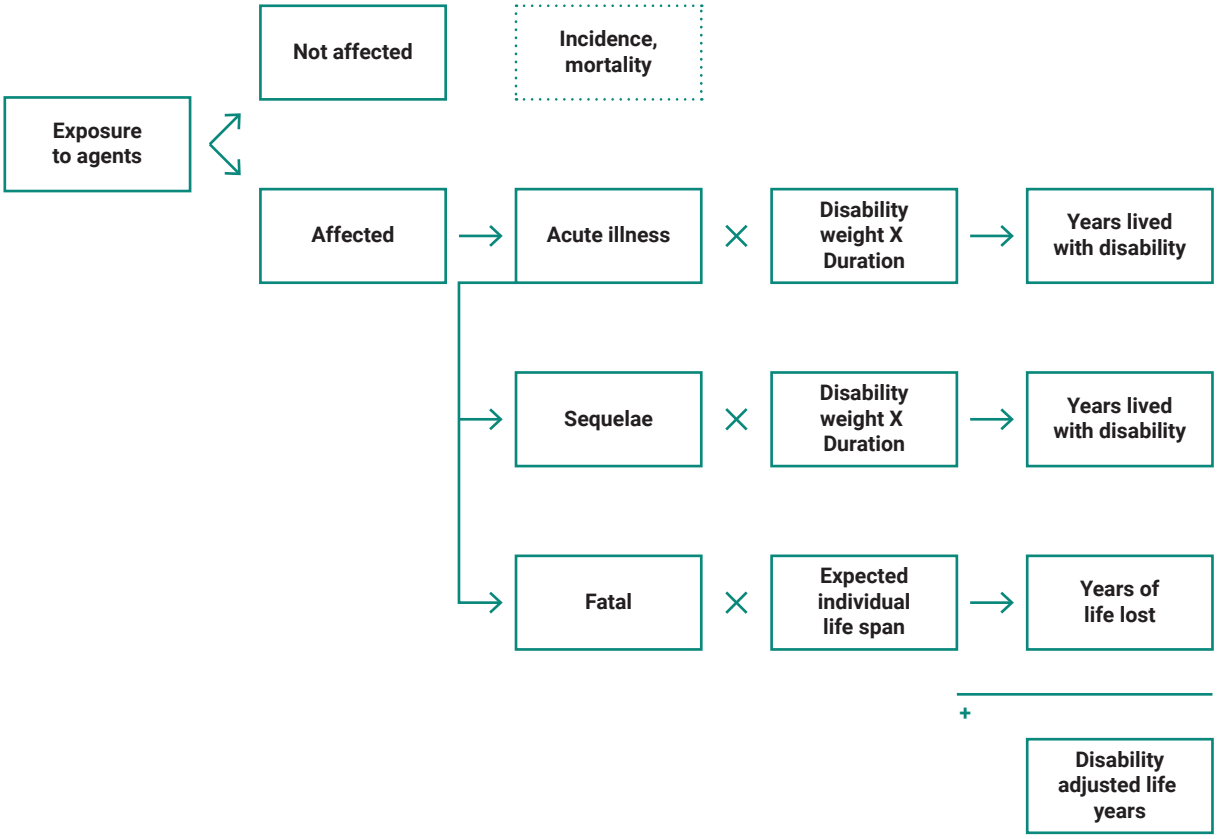
Figure 6 outlines the steps involved in estimating the burden of foodborne diseases. The first step is to estimate the true incidence of the disease and of all its health outcomes, including mortality. DALYs for the disease can then be estimated. (The final step – attributing the appropriate proportion of burden of disease to foodborne transmission – is described in Chapter 6.)

FIGURE 6. Main steps of the burden of foodborne disease calculation



The backbone of the burden of disease calculation is the disease model developed for each disease. In order to calculate DALYs, all the data boxes defined in this model need to be filled and integrated in consecutive steps (Figure 7).

FIGURE 7. Template for a disease model for the calculation of the burden of foodborne hazards



INCIDENCE AND MORTALITY

The number of cases of disease caused by foodborne hazards, and the number of resulting deaths, may be collected directly from available data, if it can be assumed that there is no under-reporting or underdiagnosis in the population, i.e. that the reported incidence is the true incidence in the population. For example, if symptoms of a disease are always severe, it may be assumed that all cases of that disease are captured by public health surveillance.

For diseases that are known not to be fully captured by public health surveillance, the true incidence of disease can be calculated using three approaches.

1. Reconstruct the surveillance pyramid. This approach starts with the number of reported cases of a pathogen (e.g. *Salmonella* infections) and corrects it for underdiagnosis and under-reporting by applying multiplication factors accounting for each level of the surveillance pyramid between occurrence and reporting of an illness.
2. Use a disease-envelope approach. Start with the total number of cases of a syndrome (e.g. diarrhoea) and multiply by the proportion attributable to the hazard under study (e.g. *Salmonella*) to obtain the incidence of hazard-associated diarrhoea.
3. Use a risk assessment approach. This estimates exposure to a hazard via all potential transmission routes and combines this with dose–response models to predict the consequent incidence of the disease.

The choice of approach will depend on the data available and the hazard in question. Reconstructing the surveillance pyramid (Approach I) is the preferred choice when etiology-specific incidence data are available from public health registries or other sources, and medical care-seeking behaviour, testing and diagnostic practices have been investigated in the population. Information on care-seeking and sample submission is typically collected through cross-sectional surveys of a subset of individuals in the target population. These surveys are conducted during an established period, using questionnaires

that include standard questions, such as experience of foodborne disease in the previous 2–4 weeks, duration of illness, health-care seeking behaviour, laboratory tests done, and demographics. The questionnaires may be administered through telephone interviews, face-to-face interviews, or web and smart phone surveys. Studies throughout the world often use standard questions, which ensures comparability between target areas and with other studies (37–39). Data on laboratory testing and reporting practices may be collected from national or regional health laboratories and registries, scientific studies and reports, or through direct contact with relevant national experts.

The responses from the population surveys are then analysed to estimate the proportions of ill individuals who seek care, from whom samples are collected, and for whom the samples are tested in a laboratory and the results reported. These proportions are combined with data on the sensitivity of the laboratory methods to generate country-, gender- and age-specific under-reporting pyramids. If the surveillance data are adequate, the derived multipliers representing the degree of under-reporting are applied to the number of notified cases of the pathogen to estimate the true incidence of each disease. This method for reconstructing the surveillance pyramid relies on a model that consists of a set of non-pathogen-specific parameters and a set of pathogen-specific parameters. All parameters can be described by probability distributions, defined on the basis of the data available.

The disease envelope approach (Approach II) is useful when hazard-specific data are not available from public health surveillance or other databases. This may be because pathogens are not notifiable in a country, or because laboratory surveillance is less established and etiology-specific data are generally absent (39, 40). This approach is also particularly useful for estimation of mortality associated with foodborne pathogens, because foodborne infection is seldom registered as cause of death in health registries (40, 41). It involves collecting data on the total incidence and mortality, as well as the gender- and age-specific incidence of diarrhoea (the diarrhoea envelope) in the population, and multiplying these numbers by the proportion associated with a particular etiology typically estimated on the basis of a systematic review of peer-reviewed inpatient, outpatient and community studies (40, 41). Approaches I and II were both applied by FERG to estimate the burden of foodborne diseases due to enteric agents (43).

Exposure or risk assessment (Approach III) is the gold standard for estimating the burden of disease caused by foodborne chemicals (see Annex 1). It is not recommended for microbiological agents, mainly because it is requires considerable data and is associated with higher uncertainty (44).

INCIDENCE OF OTHER HEALTH OUTCOMES AND SEQUELAE

To calculate the incidence of health outcomes that may be associated with the disease but are not always present in a case of illness, the estimate of total incidence is combined with the probability of occurrence of each of these health outcomes. This step builds on the disease model illustrated in Figure 7, using probabilities taken typically from scientific literature or relevant burden of disease studies.

Continuing with the example of *Salmonella* infection, it is well established that most symptomatic cases of infection will develop diarrhoea. Several studies have also reported that infection with *Salmonella* spp. may lead to development of reactive arthritis (44, 45), and irritable bowel syndrome (8, 45). Furthermore, severe cases of salmonellosis may result in death (47). To estimate the incidence of each of these health outcomes, the probability of their occurrence is combined with the incidence of diarrhoea (see Figure 4 in Chapter 4).

CALCULATING DALYS

Once all data have been collected and organized, the DALY calculation is a relatively simple step. It follows the formula that we presented in Chapter 2.

$$DALY=YLL+YLD$$

BOX 5.1. Example calculation of DALYs

The starting-point for calculating YLD is the number of cases, or incidence, of each health outcome, and the duration of these health outcomes. The DW of each health outcome translates morbidity into healthy life-years lost, thus enabling comparison of different outcomes that lead to morbidity or death. Living 10 years with a health outcome that has a DW of 0.1 is equivalent to 5 years with one that has a DW of 0.2, and both correspond to losing one full year of healthy life.

DALYs are in essence population health metrics, but for illustration purposes, let us picture the DALY for an individual. Consider a female patient who lives in a perfect state of health until she develops mild rheumatoid arthritis at age 40. This condition has a DW of 0.58 (25), and is thus assumed to cause a 58% reduction in health, which corresponds to a loss of approximately 58% of the potential healthy life-years. She lives with this condition for another 20 years. The YLD for this patient is calculated as:

$$YLD = N \times D \times DW, \text{ i.e.}$$

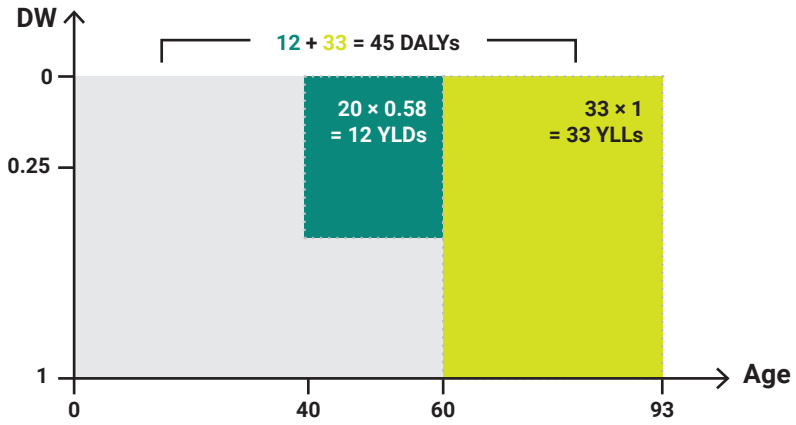
$$YLD = 1 \times (60 - 40) \times 0.58 = 12$$

After these 20 years, the patient dies from this condition. This death is premature in comparison with the life expectancy in the population. YLL, the mortality component of the DALYs, is calculated as follows:

$$YLL = M \times RLE$$

The remaining life expectancy of a 60-year-old female is 32.65 years (18). Dying at the age of 60 thus causes a loss of 33 life-years potentially lived in optimal health (Figure 8).

FIGURE 8. Graphical representation of the health gap quantified by the DALY metric



For our patient, this would mean 12 (YLD) + 33 (YLL) = 45 (DALYs), which can be interpreted as a loss of 45 healthy life-years (Figure 8).

In population-based burden studies, average DALYs are calculated for specific age and sex strata, based on the total number of cases and deaths in each stratum, and the average duration, age at onset and age at death in each stratum. Population totals are then obtained by summing these stratum-specific DALYs.

UNCERTAINTY

It is important to identify and address uncertainties in DALY calculations in order to demonstrate the strength of the evidence generated and allow valid comparisons between studies. The uncertainties in burden of foodborne disease estimates can be linked to the quality and representativeness of the data, and to the specifications and assumptions of the disease model used. Transparency in relation to uncertainties and how they have been addressed will reinforce the validity of the estimates and facilitate knowledge translation. It will also help to identify knowledge gaps, and underline the need for further data collection and research. To the extent possible, sources of uncertainty in DALY calculations should be identified, quantified and analysed, and reported in order of importance.

The most useful method for quantifying and analysing uncertainty is probabilistic sensitivity analysis, also called uncertainty analysis or uncertainty propagation. Probabilistic analysis represents the uncertain parameters by uncertainty distributions. It uses Monte Carlo simulations to sample random values from the specified uncertainty distributions (48). Further information about uncertainty propagation is given elsewhere (34, 49).

BOX 5.2. Variability and uncertainty

Variability is an expression of the heterogeneity in a defined population. For example, food consumption, duration of exposure, and expected lifetime are inherently variable and cannot be represented by a single value. We can only determine their moments (e.g. mean, variance, skewness, etc.) with precision (50). While we cannot reduce variability, we can characterize it.

Uncertainty refers to the lack of knowledge we have about a parameter. Each parameter has a single value, but this cannot be known with precision because of measurement or estimation error. Uncertainty can be reduced by collecting more and more precise data.

SOFTWARE

A variety of software packages are available for performing calculations and modelling, including burden of disease models. These may be general software tools, such as Microsoft Excel or R (51), or tools that have been specifically designed for burden of disease calculations, such as DisMod, DisModII (52) and the DALY calculator.[5]

DisMod and DisModII were developed for the WHO GBD study, to help model the parameters needed for YLD calculations, to incorporate expert knowledge, and to check the consistency of different epidemiological estimates and ensure that the estimates used are internally consistent (52). These are freely available but require training.

The DALY calculator is a free-to-download graphical user Interface (GUI) for stochastic DALY calculations and was developed in the R environment for statistical computing. The DALY calculator is supported by a manual that includes a stepwise explanation of the tool and has examples derived from the literature on foodborne disease. It is intuitive, easy to use and requires no training. The R-based DALY calculator is available online and requires installation of R.

[5] https://cran.r-project.org/web/packages/DALY/index.html

6

ESTIMATING FOODBORNE DALYS

ESTIMATING FOODBORNE DALYS

This chapter suggests an approach for estimating the proportion of the total disease burden that is due to foodborne transmission.

Once the DALYs have been estimated for a particular pathogen, the proportion of the total disease burden that is due to foodborne transmission needs to be attributed. Some foodborne pathogens may be considered as being transmitted to humans only through consumption of contaminated foods (e.g. *Listeria monocytogenes*, *Taenia solium*). However, many foodborne pathogens can also be transmitted through other routes – environmental transmission, direct contact with live animals, or person-to-person transmission. Furthermore, pathogens can enter the food chain at several points, and can contaminate a variety of foods. The process of partitioning the burden of disease to the various sources is called source attribution (2). For most foodborne hazards, this is a challenging process because of the many possible transmission routes, data requirements and data gaps. In recent years, a variety of methods to estimate the relative contribution of different sources and routes of transmission for human infections have been developed, including data from outbreak surveillance, molecular subtyping, and systematic reviews of case–control studies (2).

The first step in the source attribution process is to estimate the proportions of the burden of disease that can be attributed to foodborne transmission and other routes. A review of available methods and data for a number of foodborne pathogens concluded that, for most foodborne hazards, data-driven methods (for example based on surveillance and monitoring data) are not feasible, because they would require an exhaustive review and inclusion of all potential sources and pathways within the main routes (52, 53). Depending on the hazard, it is preferable to use analysis of epidemiological data, expert elicitations or intervention studies. In the absence of data, researchers often have to rely on the opinions of panels of foodborne disease experts, with modelling of uncertainty around the resulting proportions (55).

Under the WHO initiative to estimate the global burden of foodborne diseases, a structured expert elicitation was conducted to estimate foodborne attribution proportions for the hazards included in the global burden of foodborne diseases (1). The experts were selected for their knowledge of the groups of diseases and regions, and experience, including of work at international level (56). This study derived attribution proportions for different transmission pathways for eleven diarrhoeal diseases, seven other infectious diseases and one chemical (lead) in 14 subregions. For some pathogens, the proportions of the foodborne disease burden that could be attributed to specific foods were also estimated (57).

Some countries have conducted expert elicitations at national level to estimate foodborne attribution proportions for pathogens commonly transmitted through foods (52, 57–59). Other countries are in the process of conducting or updating national elicitations. Numerous source attribution studies for a variety

of foodborne pathogens have applied different methodologies to estimate the contribution of specific sources and routes of transmission, most of them in a restricted number of high-income countries. Countries with national estimates should use these to estimate the proportion of the estimated DALYs for each pathogen that is foodborne. Countries without such estimates are encouraged to use the FERG estimates for their subregion as a proxy. Detailed estimates can be found in the literature (56,57).

For a complete overview of source attribution approaches, their applicability to different public health questions, and general data requirements, see Annex 2.

COUNTRY EXPERIENCES

JAPAN

In relation to food safety in Japan, risk assessment, risk management and risk communication are assigned to several independent agencies. The Food Safety Commission is an independent body assigned to conduct risk assessments under the Food Safety Basic Act. Risk management is covered by the Ministry of Health, Labour and Welfare, Ministry of Agriculture, Forestry and Fisheries, Ministry of Environment and Consumer Affairs Agency. They are responsible for developing necessary measures and regulations based on the results of risk assessment. These agencies are also responsible for risk communication with stakeholders, including consumers. Using the above framework, risk-based controls are formulated according to current knowledge about the human health risks associated with each foodborne hazard, whether expressed quantitatively or qualitatively.

Estimating the burden of foodborne diseases

As part of the FERG project, national estimates of incidence, deaths, and disease burden due to *Campylobacter* spp., non-typhoid *Salmonella* spp. and enterohaemorrhagic *E. coli* (EHEC) were calculated in 2011. First, the annual incidence was estimated from reported surveillance data, adjusted for the proportions of cases confirmed or seen by a physician. The estimated annual incidence was significantly higher than that reported in the routine surveillance data compiled using information collected by local governments, suggesting a marked underestimation of foodborne diseases. A series of systematic reviews were done of the disabling sequelae of the three priority diseases. Subsequently, the estimated incidence was adjusted for food-attributable proportions, estimated by an expert elicitation process. Using this together with the cause-of-death data from vital registration, the disease burden in terms of DALYs was estimated. It was found that foodborne disease caused by *Campylobacter* spp., non-typhoid *Salmonella* spp. and EHEC led to an estimated 6099, 3145 and 463 DALYs in Japan, respectively. The burden due to disabling sequelae was consistently higher than that due to gastroenteritis. Building on the FERG framework, a situation analysis was carried out of the food safety policies and systems in Japan.

Japan is currently conducting research on the following topics: 1) to estimate foodborne illness, using active laboratory-based surveillance to fill data gaps, 2) to estimate the proportions of foodborne diseases caused by seven major pathogens (*Campylobacter* spp., *Salmonella* spp., EHEC, *V. parahaemolyticus*, *Clostridium perfringens*, *Staphylococcus aureus*, and norovirus) that are attributable to foods, using outbreak surveillance data.

COUNTRY EXPERIENCES

NEW ZEALAND

Food safety regulatory authorities in New Zealand have used burden of foodborne disease estimates to rank the risks from various enteric microbial pathogens in a series of studies dating back to 2004. A series of reports on this topic have been published on a dedicated New Zealand food safety webpage: https://www.mpi.govt.nz/food-safety/food-safety-and-suitability-research/food-risk-assessment/food-risk-ranking/ (accessed 28 May 2020).

The hazards include bacterial, viral and parasitic enteric pathogens. The burden estimates are calculated in terms of DALYs and include calculations of community incidence and estimates of foodborne transmission attribution. The attribution estimates are obtained from structured expert elicitation studies, two rounds of which have been conducted.

Two other studies related to this work have also been published.

Cressey PJ, Lake RJ, Thornley C, Campbell D. Expert elicitation for estimation of the proportion foodborne for selected microbial pathogens in New Zealand. Foodborne Pathogens and Disease. 2019; 16(8) DOI: 10.1089/fpd.2018.2576.
Lake RJ, Cressey PJ, Campbell DM, Oakley E. Risk ranking for microbiological hazards in New Zealand: burden of disease estimates. Risk Analysis. 2010;30: 743–752.

7

INTERPRETING NATIONAL BURDEN OF FOODBORNE DISEASE RESULTS

INTERPRETING NATIONAL BURDEN OF FOODBORNE DISEASE RESULTS

This chapter outlines important considerations when describing and interpreting the results of a burden of foodborne disease study. It includes suggestions for presenting the outputs of a national study and discussing assumptions and limitations, and gives an example to illustrate discussion points.

National burden of foodborne disease studies may generate a large number of estimates, and it is crucial to provide detailed results. To the extent possible, these should be interpreted by experts in the fields of clinical medicine, public health, epidemiology, food science and food safety, and other relevant areas.

In describing and interpreting the results, there are important points to consider.

- The burden of foodborne disease study will produce various metrics, e.g. incidence, mortality, DALYs, YLL and YLD. It is important to present all these results for all diseases, to allow interpretation and comparison of results between diseases.
- All population groups considered in the analysis should be reflected in the results, e.g. age groups, male and female, geographical regions, and risk groups.
- Results of the overall burden of disease estimates, and of foodborne burden of disease estimates, should be presented and compared. This parallel presentation will be important to guide the priority given to particular foodborne diseases, since the ranking of pathogens may change when the overall burden of disease or of foodborne disease is considered.
- If possible, the uncertainty in the estimates should be described. This can be done in qualitative terms or by presenting uncertainty intervals. It is important to interpret all results in the light of these uncertainties.

Other considerations may be important in different contexts, situations or for specific diseases.

When interpreting and discussing burden of foodborne disease estimates, it may also be useful to draw comparisons with the burden of non-foodborne diseases in the same population. Such comparisons should consider potential differences in burden of disease approaches applied, and discuss the impact of such differences in the results.

BOX 7.1. Example of presentation and interpretation of burden of foodborne disease results

The table below presents the burden of disease estimates for four pathogens in Denmark in 2017. These results illustrate the points to consider when interpreting estimates of burden of foodborne disease. In this example, the pathogen causing the highest number of DALYs is *Campylobacter*. Driven by a high incidence and relatively high mortality, it leads to the highest number of DALYs, YLL and YLD. The pathogen that produces the highest number of cases in the population is norovirus. However, because most cases are mild and of short duration, the YLD estimate for this pathogen is low. The overall burden of the other two diseases (listeriosis and congenital toxoplasmosis) is lower than for Campylobacter and norovirus, and is borne by a very low number of cases. This may mean that the health outcomes are very severe, lifelong, or borne from an early age, or that the disease is often fatal.

TABLE 6. Burden of foodborne disease results, Denmark, 2017[a]

Pathogen	Reported cases	Estimated cases	Estimated deaths	YLD	YLL	DALY	DALYs per 100 000 population	Proportion foodborne (%)	Foodborne DALYs
Campylobacter	4231	58 141 (49 617 – 71 781)	56	1013 (969–1060)	696	1709 (1665–1755)	29.7 (29.0–30.5)	76	1299
Norovirus	-	185 060 (156 506 – 212 627)	25.9 (20.4–31.7)	128.6 (106.3–153.4)	356.3 (280.4–435.8)	485 (398–573.1)	8.6 (7.0–10.1)	18	86
Listeriosis	58	58	12	14.2 (11.4–16.9)	186.4	196 (193.5–198.5)	3.4 (3.4–3.5)	100	196
Congenital toxoplasmosis	-	10 (8–12)	1 (1–2)	53 (32–77)	112 (81–153)	165 (126–222)	-	61	100

[a] Adapted from ref. 40.

When the estimates of overall burden of disease (i.e. total DALYs) are compared with the burden of disease that can be attributed to foods (i.e. foodborne DALY), it is evident that the ranking may be different. While *Campylobacter* keeps its place at the top of the ranking, norovirus moves to the last position. This is because only 18% of the burden of norovirus is attributable to foodborne transmission. In contrast, because *Listeria monocytogenes* is transmitted to humans almost exclusively through foods, for practical purposes the burden of disease remains unchanged.

In this example, uncertainty intervals are presented for some estimates and not for others. The reader is unable to evaluate if the absence of an uncertainty interval means that there was no associated uncertainty, or if the uncertainty was not quantified. This should be clarified in the text supporting the interpretation of the burden of disease results.

Inclusion of the details of the national study in the report is crucial to support all other presentation formats, and to ensure that everything is documented – each step, all methodologies, data availability and gaps, and any uncertainties and limitations. The report can also describe the team's experiences, which may help efforts in other countries and regions.

8

KNOWLEDGE TRANSLATION AND RISK COMMUNICATION

KNOWLEDGE TRANSLATION AND RISK COMMUNICATION

This chapter suggests formats for presentation and communication of the results of burden of disease studies for different target audiences, and outlines the tools available for communicating risk and translating scientific knowledge into policy.

The presentation and communication of the results of a burden of foodborne disease study are essential elements. The findings should be delivered in a way that captures the interest of policy-makers, stakeholders and the community at large, highlights priorities and motivates action for disease prevention. Experience in global and national studies has shown that estimates of the burden of foodborne disease command media attention and put food safety on the agenda of decision-makers, industry and citizens. These are very different target audiences, and a recognition of how each group will respond to different messages needs to be part of the communication process.

Good reporting, knowledge transfer and communication are critical if the estimates are to be used to their full potential. Ideally, a strategy of dissemination of results will be established at the start of the study and embedded in the defined objectives. For example, the best way to communicate results will depend on whether the messages are intended for policy-makers, the scientific community, or the general population. Table 6 gives some examples of the areas of interest of different stakeholders, and possible ways of communicating with them (61).

TABLE 7. Stakeholders' interests and communication of burden of foodborne disease results[a]

Stakeholder	Area of interest	Communication of results
Policy-makers	Ranking of foodborne diseases according to public health impact. Prioritization of food safety problems. Allocation of resources. Development of new food safety standards. Identification of risk groups in the population. Implementation or improvement of food safety interventions in the food production chain	Study report. Summary of the study and its main results. Graphs, tables. Policy briefs
Food business operators	Awareness of food safety priorities and practices	Summary of the study and its main results. Graphs, tables. Policy briefs
Media	Communicating information to the general public	Press releases
Community, general public, consumers	Recognizing public health problems. Learn about risk behaviour and how to modify these to prevent disease	Simple messages on risks and preventive behaviour. Infographics. Campaigns
Scientific community	Methods, innovations, particular findings. Identification of data and knowledge gaps	Scientific publications, books and reports. Dissemination in scientific conferences and meetings

[a] Adapted from ref. 60.

Different levels of reporting can be used to address these different audiences.

- Concise summary of results and key findings through, for example, policy briefs and infographics.
- Detailed presentation of results, for example through an online visualization platform or a set of tables and graphs.
- Technical document describing the methods, data sources, assumptions and limitations. This document should include all data gaps encountered, the approaches used to address them, and a consideration of how the study should be evaluated in the context of data and methodological limitations. The team should plan to make available all calculations and data for public scrutiny.

A variety of tools are available for communicating risk and translating scientific knowledge to policy-making. These range from press releases to priority-setting exercises. Again, the approach chosen will depend on the target audience and the purpose of the message. Independent of their level of complexity, all approaches will need to ensure that scientific methods illuminate problems, suggest solutions, influence policies and actions and, ultimately, improve the health of a population. Depending on the resources available and the dimension of the burden of foodborne disease study, it may be useful to involve a specialist in publishing and disseminating the findings of the study.

BOX 8.1. Using DALYs to estimate the economic burden of foodborne diseases

DALYs represent years lost to illness, disability or death. These losses can be expressed as costs to an economy. Reducing these costs will be beneficial for countries, but interventions to reduce the incidence or severity of foodborne illnesses may also involve direct or indirect costs. The magnitude of the potential benefits needs to be weighed against the potential costs, to government or the private sector, of the proposed investments or regulatory measures.

DALYs combine YLL and YLD, which reflect respectively lives lost (mortality) and illness (morbidity). Loss of life can be valued in two ways: (i) the forgone output from the life lost: what a person would have produced if the premature death had not occurred; and (ii) the value of a statistical life (VSL), which is derived from the "willingness to pay" (WTP) to avoid death. Of the two, the WTP approach typically yields much higher estimates, since the WTP to avoid death is typically higher than income. However, WTP estimates are not available for many countries.

Illness or morbidity costs include the direct costs of care and treatment, the forgone productivity due to days or years of work lost, and the cost of suffering. Because most illnesses have multiple outcomes depending on individual characteristics, tracing these various costs is a considerable challenge. For example, for any given disease, the number of hospitalizations, days lost from work, etc. needs to be derived for both mild and more serious infections.

Given the difficulty of making detailed estimates for the value of either YLL or YLD, a frequently used shortcut is to use a country's per capita gross national income (GNI) as a measure of lost productivity. Intuitively, for each year lost to illness, disability or premature death, the country loses the economic output associated with that year. Foodborne disease is therefore represented as a drain on a country's productivity.

The calculation is straightforward and represented by: $VP_i = B_i \times Y_i$
where VP_i is the value of the productivity losses associated with foodborne illness in country i; B_i is the total DALY burden from foodborne illness in country i; and Y_i is the per capita GNI for country i. This value can be expressed in local currency or in US$ to allow for comparisons among countries.

Such estimates of productivity loss have been made by Jaffee et al.[a] for all low- and middle-income countries, drawing on foodborne disease estimates by FERG, but using more recent (2016) population and GNI estimates. The aggregate for developing countries came to US$95 billion for 2016, with 28 countries having an estimated productivity loss from FBD exceeding US$500 million.

To interpret the significance of the estimated productivity loss due to foodborne diseases, it can be compared with the country's agricultural gross domestic product (GDP), the turnover of its food manufacturing industry, or the total food expenditures. Jaffee et al.[a] used the last indicator, and found that FBD-related productivity losses in many developing countries were equivalent to between 3% and 5% of total food spending, compared with around 1% in most high-income countries. Significant variations were found in developing countries, reflecting differences in their demographic and dietary characteristics and their capacities to manage emerging food safety risks. More refined foodborne disease DALY estimates, as done by Li et al.[b] for animal-source foods, can be used to make more specific analyses in relation to the economic size, performance, and regulatory capacities associated with subsectors in a country's agriculture or food sector.

[a] Jaffee S, Henson S, Unnevehr L, Grace D, Cassou E. The safe food imperative: accelerating progress in low- and middle-Income countries. Washington, DC: World Bank; 2019.
[b] Li M, Havelaar AH, Hoffmann S, Hald T, Kirk MD, Torgerson PR, et al. (2019) Global disease burden of pathogens in animal source foods, 2010.PLoS ONE. 2019; 14(6): e0216545 (https://doi.org/10.1371/journal.pone.0216545).

COUNTRY EXPERIENCES

THE NETHERLANDS

In the Netherlands, the Ministry of Health, Welfare and Sport mandates the National Institute for Public Health and the Environment (RIVM) to provide annual updates for the number of incident cases, associated burden of disease and cost of illness caused by an agreed-upon panel of 14 enteric pathogens. These pathogens are mainly zoonotic pathogens transmitted via food, but also via direct contact with animals, the environment and person-to-person transmission routes. For risk management purposes, including control, prevention and surveillance activities, quantitative assessments of the public health relevance of foodborne infections are needed.
The burden of disease is expressed in DALYs, while the cost of illness is expressed in euros. The estimates of cost of illness include health care costs, the costs for the patients, their family and caregivers (e.g. travel and external care expenses), and productivity losses. The methodology for the estimations is standard and has been described in detail by Havelaar et al.[a] and in the 2015 report.[b] Data on the size and age distribution of the Dutch population, as well as mortality risks and the number of live births and stillbirths, are obtained from Statistics Netherlands, while the incidence of cases by pathogen for which medical help was sought is obtained from various RIVM-coordinated surveillance systems. For instance, data on the notifiable pathogens *Listeria monocytogenes*, Shiga-toxin producing *Escherichia coli* O157 (STEC O157) and hepatitis A

virus are obtained from both case notifications and the laboratory surveillance system, which has national coverage. For other pathogens, such as *Campylobacter*, *Salmonella*, *Cryptosporidium*, norovirus and rotavirus, which are not notifiable, data are obtained from either case notifications or laboratory surveillance based on networks of sentinel diagnostic laboratories participating voluntarily in surveillance activities. The collected data are corrected for geographical coverage of the surveillance system and for under-reporting, to obtain an estimate of the incidence. Should the incidence for a given pathogen in a given year be missing or unreliable (for whatever reason), prediction estimates based on observations in previous years are applied.
Since 2008, the RIVM has regularly published the burden and cost estimates on its Web site and since 2010 in publicly available reports.[c, d] Moreover, using the structured expert elicitation described by Havelaar et al.,[e] these estimates are attributed to five major transmission pathways (i.e. food, environment, direct animal contact, human–human transmission, and travel) and 11 food groups (e.g. eggs, pork, dairy, etc.) within the foodborne pathway. The most recent estimates, for 2018, show that the 14 pathogens in question are cumulatively responsible for about 11 000 DALYs and €426 million cost. The share apportioned to foodborne transmission is estimated at 4300 DALYs and €171 million, which is comparable to previous years. These estimates provide crucial insights for policy-makers concerned with guiding public health actions (e.g. establishing a process hygiene criterion for *Campylobacter* on broiler meat) and particularly resource allocation (e.g. funding for research and other activities on specific pathogens or other conditions that appear to have a higher burden or cost) in the Netherlands. The burden and cost estimates also enable policy-makers and the scientific community to monitor trends and generate scientific hypotheses.

[a] Havelaar AH, Haagsma JA, Mangen MJJ, Kemmeren JM, Verhoef LP, Vijgen SM et al. Disease burden of foodborne pathogens in the Netherlands, 2009. Int J Food Microbiol. 2012;156(3):231-8.
[b] Mangen MJJ. Disease burden of food-related pathogens in the Netherlands, 2015. Bilthoven: National Institute for Public Health and the Environment; 2017.
[c] Mangen MJJ. Disease burden of food-related pathogens in the Netherlands, 2017. Bilthoven: National Institute for Public Health and the Environment; 2018. Contract No.: 2018-0037.
[d] Pijnacker R. Disease burden of food-related pathogens in the Netherlands, 2018. Bilthoven: National Institute for Public Health and the Environment; 2019. Contract No.: 2019-0086.
[e] Havelaar AH, Galindo AV, Kurowicka D, Cooke RM. Attribution of foodborne pathogens using structured expert elicitation. Foodborne Pathog Dis. 2008;5(5):649-59.

9

FINAL CONSIDERATIONS

FINAL CONSIDERATIONS

Burden of foodborne disease estimates are essential to inform food safety policy and help establish priorities for interventions to reduce the burden. National studies are critical to fill in data gaps identified in global and regional efforts, focus efforts on the national context, and deliver estimates that are as accurate as possible and build on local data. They can also flag needs and data gaps in food safety systems, and promote cooperation and communication among stakeholders in food safety.

While the ability of countries to undertake large-scale studies will vary, all countries are encouraged to start working towards implementation of studies to the extent that expertise and resources allow. This may mean starting at a basic level, and working towards continuous improvement and expansion as resources allow. For example, more hazards can be included, data can be added as they become available, and methodologies can be adapted to changing circumstances. The process itself may be beneficial, by demonstrating the usefulness of burden of disease estimates and encouraging further investments. The data gaps and needs identified in a national study may also promote further development of national foodborne disease surveillance programmes.

The methods described in this manual will usually be implemented by a team of technical and scientific staff. Nevertheless, a range of stakeholders, decision-makers and social scientists should be engaged by the study team from the earliest stages. Inclusion of all interested parties will support knowledge translation and the development of science-based policies.

In the longer term, information on burden of foodborne disease should be a fundamental component of a systematic approach to food safety, such as the risk management framework advocated by the Codex Alimentarius Commission (62). Such an approach can improve both public health and trade.

REFERENCES & ANNEXES

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REFERENCES

1. WHO estimates of the global burden of foodborne diseases. Geneva: World Health Organization; 2015.
2. Pires SM, Evers EG, van Pelt W, Ayers T, Scallan E, Angulo FJ, et al. Attributing the human disease burden of foodborne infections to specific sources. Foodborne Pathog Dis. 2009;6(4):417–24.
3. Murray CJL. Quantifying the burden of disease: The technical basis for disability-adjusted life years. Bull World Health Organ. 1994;72(3):429–45.
4. Devleesschauwer B, Havelaar AH, Maertens C. DALY calculation in practice: a stepwise approach. Int J Public Health. 2014;59:571–4.
5. Devleesschauwer B, Haagsma JA, Angulo FJ, Bellinger DC, Cole D, Döpfer D et al. Methodological framework for World Health Organization estimates of the global burden of foodborne disease. Kretzschmar MEE, ed. PLoS One. 2015;10(12):e0142498 (http://dx.plos.org/10.1371/journal.pone.0142498; accessed 7 September 2018).
6. Mangen MJJ, Plass D, Havelaar AH, Gibbons CL, Cassini A, Mühlberger N, et al. The pathogen- and incidence-based DALY approach: an appropriate methodology for estimating the burden of infectious diseases. PLoS One. 2013;8(11).
7. Helms M, Simonsen J, Molbak K. Foodborne bacterial infection and hospitalization: a registry-based study. Clin Infect Dis. 2006; 42(4):498–506 (http://www.ncbi.nlm.nih.gov/pubmed/16421794; accessed 28 May 2019).
8. Codex Alimentarius Commission procedural manual, twenty-sixth edition. Rome: Food and Agriculture Organization of the UNited Nations; 2018 (http://www.fao.org/documents/card/en/c/I8608EN/; accessed 7 July 2020).
9. Lake RJ, Devleesschauwer B, Nasinyama G, Havelaar AH, Kuchenmüller T, Haagsma JA et al. National studies as a component of the World Health Organization initiative to estimate the global and regional burden of foodborne disease. PLoS One. 2015;10(12):1–10.
10. Schmeer K. Stakeholder analysis guidelines, Section 2. Washington, DC: Pan American Health Organization; 2000 (https://www.who.int/workforcealliance/knowledge/toolkit/33.pdf; accessed 29 July 2020)
11. Varvasovszky Z, Brugha R. A stakeholder analysis. Health Policy Plan. 2000;15(3):338–45.
12. Food control system assessment tool: introduction and glossary. Rome: Food and Agriculture Organization of the United Nations, World Health Organization; 2019 (https://www.who.int/publications/i/item/9789241515719, accessed 29 July 2020)
13. Gilmour S, Miyagawa S, Kasuga F, Shibuya K. Current measures on radioactive contamination in Japan: a policy situation analysis. PLoS One. 2016;11(3):e0152040 (https://dx.plos.org/10.1371/journal.pone.0152040; accessed 28 July 2020).
14. Mathers CD, Vos T, Lopez AD, Salomon JEM, ed. National burden of disease studies: a practical guide. Edition 2.0. Geneva: World Health Organization; 2001 (https://www.who.int/healthinfo/nationalburdenofdiseasemanual.pdf; accessed 29 July 2020).
15. Global health estimates. Geneva; World Health Organization (https://www.who.int/healthinfo/global_burden_disease/en/; accessed 22 June 2020).
16. Global Burden of Disease (GBD). Seattle: Institute for Health Metrics and Evaluation (http://www.healthdata.org/gbd; accessed 22 June 2020).
17. Global Health Observatory country views. Geneva: World Health Organization (https://apps.who.int/gho/data/node.country; accessed 11 May 2020).
18. WHO methods and data sources for global burden of disease estimates 2000-2016. Geneva: World Health Organization; 2018 (Global Health Estimates Technical Paper, WHO/HIS/IER/GHE/2018.4) (https://www.who.int/healthinfo/global_burden_disease/GlobalDALY_method_2000_2016.pdf?ua=1; accessed 29 July 2020).

19. Haagsma JA, Geenen PL, Ethelberg S, Fetsch A, Hansdotter F, Jansen A et al. Community incidence of pathogen-specific gastroenteritis: reconstructing the surveillance pyramid for seven pathogens in seven European Union member states. Epidemiol Infect. 2012;141(8):1–15 (http://www.ncbi.nlm.nih.gov/pubmed/23013659).
20. Scallan E, Hoekstra RM, Angulo FJ, Tauxe R V., Widdowson MA, Roy SL et al. Foodborne illness acquired in the United States. Major pathogens. Emerg Infect Dis. 2011;17(1):7–15.
21. The DHS Program. Demographic and Health Survey (DHS). (https://dhsprogram.com/what-we-do/survey-Types/dHs.cfm; accessed 20 June 2020).
22. Global Health Observatory (GHO) [Internet]. Geneva: World Health Organization; (https://www.who.int/data/gho; accessed 20 June 2020).
23. Anand S, Hanson K. Disability-adjusted life years: a critical review. Journal of Health Economics. 1997;16:685–702.
24. Devleesschauwer B, Havelaar AH, Maertens de Noordhout C, Haagsma JA, Praet N, Dorny P et al. Calculating disability-adjusted life years to quantify burden of disease. Int J Public Health. 2014; 59(3):565-9.
25. Salomon JA, Haagsma JA, Davis A, de Noordhout CM, Polinder S, Havelaar AH et al. Disability weights for the Global Burden of Disease 2013 study. Lancet Glob Heal. 2015;3(11):e712–23.
26. De Wit GA, Busschbach JJ, De Charro FT. Sensitivity and perspective in the valuation of health status: whose values count? Health Econ. 2000;9(2):109-26.
27. Dolan P, Olsen JA, Menzel P, Richardson J. An inquiry into the different perspectives that can be used when eliciting preferences in health. Health Econ. 2003;12(7):545–51.
28. Brazier J, Deverill M, Green C. A review of the use of health status measures in economic evaluation. Journal of Health Services Research and Policy. 1999;4:174–84.
29. Torrance GW, Thomas WH, Sackett DL. A utility maximization model for evaluation of health care programs. Health Serv Res. 1972; 7(2):118–33 (http://www.ncbi.nlm.nih.gov/pubmed/5044699; accessed 29 May 2020).
30. Boyd NF, Sutherland HJ, Heasman KZ, Tritchler DL, Cummings BJ. Whose utilities for decision analysis? Med Decis Mak. 1990;10(1):58–67.
31. McNamee P, Seymour J. Comparing generic preference-based health-related quality-of-life measures: advancing the research agenda. Expert Rev Pharmacoecon Outcomes Res. 2005;5:567–81.
32. Field MJ, Gold MR, ed. Summarizing population health. Washington, DC: National Academies Press; 1998.
33. Green C, Brazier J, Deverill M. Valuing health-related quality of life: a review of health state valuation techniques. PharmacoEconomics. 2000;17:151–65.
34. Krabbe PFM, Essink-Bot ML, Bonsel GJ. The comparability and reliability of five health-state valuation methods. Soc Sci Med. 1997;45(11):1641–52.
35. Maertens De Noordhout C, Devleesschauwer B, Salomon JA, Turner H, Cassini A, Colzani E et al. Disability weights for infectious diseases in four European countries: comparison between countries and across respondent characteristics. Eur J Public Health. 2017;28(1):124–33 (https://academic.oup.com/eurpub/article-abstract/28/1/124/4111224; accessed 18 June 2020).
36. Life expectancy. Geneva: World Health Organization (https://www.who.int/gho/mortality_burden_disease/life_tables/en/; accessed 20 June 2020).
37. Müller L, Korsgaard H, Ethelberg S. Burden of acute gastrointestinal illness in Denmark 2009: a population-based telephone survey. Epidemiol Infect. 2012;140(02):290–8.
38. Thomas MK, Majowicz SE, MacDougall L, Sockett PN, Kovacs SJ, Fyfe M et al. Population distribution and burden of acute gastrointestinal illness in British Columbia, Canada. BMC Public Health. 2006; 19:307 (https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-6-307; accessed 3 June 2020).
39. Thomas MK, Perez E, Majowicz SE, Reid-Smith R, Albil S, Monteverde M et al. Burden of acute gastrointestinal illness in Galvez, Argentina, 2007. J Heal Popul Nutr. 2010;28(2):149–58.
40. Pires SM, Jakobsen LS, Ellis-Iversen J, Pessoa J, Ethelberg S. Burden of disease estimates of seven pathogens commonly transmitted through foods in Denmark, 2017. Foodborne Pathog Dis. 2019;17(5):322-339. (https://www.liebertpub.com/doi/10.1089/fpd.2019.2705; accessed 6 January 2020).
41. Pires SM, Fischer-Walker CL, Lanata CF, Devleesschauwer B, Hall AJ, Kirk MD et al. Aetiology-specific estimates of the global and regional incidence and mortality of diarrhoeal diseases commonly transmitted through food. PLoS One. 2015;10(12).
42. Lanata CF, Fischer-Walker CL, Olascoaga AC, Torres CX, Aryee MJ, Black RE et al. Global causes of diarrheal disease mortality in children <5 years of age: a systematic review. PLoS One. 2013;8(9):e72788 (http://dx.plos.org/10.1371/journal.pone.0072788; accessed 14 December 2017).
43. Kirk MD, Pires SM, Black RE, Caipo M, Crump JA, Devleesschauwer B et al. World Health Organization estimates of the global and regional disease burden of 22 foodborne bacterial, protozoal, and viral diseases, 2010: a data synthesis. PLoS Med. 2015;12(12):e1001940.

44. Bouwknegt M, Knol AB, van der Sluijs JP, Evers EG. Uncertainty of population risk estimates for pathogens based on qmra or epidemiology: a case study of campylobacter in the Netherlands. Risk Anal. 2014;34(5):847–64.
45. Raybourne RB, Roberts T, Williams KM. Food poisoning: economic implications. In: Caballero B, Trugo LC, Finglas PM, eds. Encyclopedia of food sciences and nutrition. London: Elsevier Science; 2003.
46. Havelaar AH, Haagsma JA, Mangen MJJ, Kemmeren JM, Verhoef LPB, Vijgen SMC et al. Disease burden of foodborne pathogens in the Netherlands, 2009. Int J Food Microbiol. 2012;156(3):231–8 (http://dx.doi.org/10.1016/j.ijfoodmicro.2012.03.029).
47. Helms M, Vastrup P, Gerner-Smidt P, Mølbak K. Short and long term mortality associated with foodborne bacterial gastrointestinal infections: registry based study. BMJ. 2003;326(7385):357 (http://www.ncbi.nlm.nih.gov/pubmed/12586666; accessed 4 December 2018).
48. Food safety risk analysis. Part I. An overview and framework manual, provisional edition. Rome: Food and Agriculture Organization of the United Nations; 2005.
49. Bilcke J, Beutels P, Brisson M, Jit M. Accounting for methodological, structural, and parameter uncertainty in decision-analytic models: a practical guide. Med Decis Making. 2011;31(4):675–92 (http://www.ncbi.nlm.nih.gov/pubmed/21653805; accessed 28 July 2020).
50. Application of risk analysis to food standards issues. Rome: Food and Agriculture Organization of the United Nations; 1995 (http://www.fao.org/3/ae922e/ae922e00.htm#Contents; accessed 4 June 2020).
51. R Core Team. R: a language and environment for statistical computing. 2018 (https://www.gbif.org/tool/81287/r-a-language-and-environment-for-statistical-computing; accessed 15 October 2018).
52. Barendregt JJ, van Oortmarssen GJ, Vos T, Murray CJL. A generic model for the assessment of disease epidemiology: the computational basis of DisMod II. Popul Health Metr. 2003;1:4.
53. Havelaar AH, Galindo AV, Kurowicka D, Cooke RM. Attribution of foodborne pathogens using structured expert elicitation. Foodborne Pathog Dis. 2008;5(5):649–59 (http://repository.tudelft.nl/assets/uuid:0f1a31fe-6c37-4b4f-83a5-28bf781a38a3/Cooke_2008.pdf).
54. Batz MB, Hoffmann S, Morris JG. Ranking the disease burden of 14 pathogens in food sources in the United States using attribution data from outbreak investigations and expert elicitation. J Food Prot. 2012;75(7):1278–91 (http://www.ncbi.nlm.nih.gov/pubmed/22980012).
55. Aspinall WP, Cooke RM, Havelaar AH, Hoffmann S, Hald T. Evaluation of a performance-based expert elicitation: WHO global attribution of foodborne diseases. PLoS One. 2016;11(3): e0149817.
56. Hald T, Aspinall W, Devleesschauwer B, Cooke R, Corrigan T, Havelaar AH et al. World Health Organization estimates of the relative contributions of food to the burden of disease due to selected foodborne hazards: a structured expert elicitation. PLoS One. 2016;11(1):1–35.
57. Hoffmann S, Devleesschauwer B, Aspinall W, Cooke R, Corrigan T, Havelaar A et al. Attribution of global foodborne disease to specific foods: findings from a World Health Organization structured expert elicitation. PLoS One. 2017;12(9):e0183641 (https://dx.plos.org/10.1371/journal.pone.0183641; accessed 15 January 2020).
58. Hoffmann S, Fischbeck P, Krupnick A, McWilliams M. Using expert elicitation to link foodborne illnesses in the United States to foods. J Food Prot. 2007;70(5):1220–9 (http://www.ncbi.nlm.nih.gov/pubmed/17536683; accessed 7 November 2018).
59. Butler AJ, Pintar KDM, Thomas MK. Estimating the relative role of various subcategories of food, water, and animal contact in transmission of 28 enteric diseases in Canada. Foodborne Pathog Dis. 2016;13(2):57–64. (http://online.liebertpub.com/doi/10.1089/fpd.2015.1957).
60. Ravel A, Davidson VJ, Ruzante JM, Fazil A. Foodborne proportion of gastrointestinal illness: estimates from a Canadian expert elicitation survey. Foodborne Pathog Dis. 2010;7(12):1463–72.
61. Mathers C, Stevens G. WHO methods and data sources for global burden of disease estimates 2000-2011. Geneva; World Health Organization; 2013 (https://www.who.int/healthinfo/statistics/GlobalDALYmethods_2000_2011.pdf).
62. Codex Alimentarius Commission. Principles and guidelines for the conduct of microbiological risk management (MRM). Vol. CAC/ GL 63. Rome: Food and Agriculture Organization of the United Nations; 2007 (http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/, accessed 29 July 2020).

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ANNEX 1:
ESTIMATING THE BURDEN OF DISEASE DUE TO CHEMICAL HAZARDS IN FOODS

Estimation of the burden of disease caused by chemical hazards requires different data and methods than microbial hazards. These differences are linked, for example, to the type of health outcomes to which exposure leads (i.e. chronic), to the availability of surveillance and epidemiological evidence, and to knowledge of the presence and effects of hazards in foods.

Estimating the burden of disease caused by chemicals is challenging for various reasons. First, it is difficult to establish the link between exposure to a chemical hazard and the development of disease, because of the often multicausal nature of the health outcomes, and because symptoms may only appear some time following exposure. Consequently, human data linking exposure to effect (i.e. dose-response) are often lacking or have to be extrapolated from in vitro or in vivo studies. In addition, adverse effects identified in a toxicological risk assessment may not manifest themselves as clinical human cases. Assessments also need to account for long-term exposure through foods and other sources and link this with the probability of adverse health effects. Consumers are continually exposed to multiple chemical hazards, which may potentially lead to synergistic effects. And finally, one chemical can exert a spectrum of health effects.

BURDEN OF DISEASE APPROACH

The incidence and hazard-based approach is the gold standard for estimating the burden of foodborne hazards, including foodborne chemicals. The burden of a specific foodborne hazard is defined as that resulting from all health states that are causally related to the hazard concerned, whatever the time scale or severity. These health states may include acute symptoms, chronic sequelae, and death.

To estimate the incidence of disease due to exposure to a chemical through foods, a risk assessment approach is applied, in which disease incidence is calculated from the combination of a dose–response relationship and exposure data. The approach has three steps.

1. Estimate exposure to the hazard in the population.
2. Estimate the probability of occurrence of the selected health outcomes following exposure to the hazard based on dose–response models, to derive incidence.
3. Integrate the estimated incidence of the health outcomes with disease duration and disability weights to calculate DALYs.

Exposure assessment

Estimating exposure via foods requires data on the consumption of foods by individuals in the population, and on the concentration of the hazard in the individual foods. The first steps should be to identify the foods in which the hazard has been found and for which data are available. Table A1.1 shows the data required for this step.

The general equation for calculating dietary exposure to foodborne chemicals is the same for chronic and acute effects:

$$\text{dietary exposure} = \frac{\sum C_i \times I_i}{\text{bodyweight (kg)}}$$

where *C* is the concentration of the chemical in the food *i*, and *I* is the amount of food *i* consumed. The exposure is given per kg of bodyweight of the consumer, and is summed over all foods containing the chemical. For chronic exposures, the exposure over a long time is estimated and expressed as usual exposure per day over a given time period, e.g. a lifetime. For acute exposure, the exposure over a short period of time, e.g. 24 hours, or even per meal, is estimated. If a validated biomarker is available for a chemical, the exposure assessment may be performed using biomarker data on collected body fluid or tissue; in that case, intake and concentration data are not needed. The biomarker may be the chemical itself or a metabolite and is a direct indicator of the individual's internal exposure. The usability of biomarkers may be limited by a possible short half-life, if assessment of chronic exposure is needed. Also, it may not be possible to distinguish between sources of exposure (i.e. food vs smoking vs occupational exposure). If dose–response relationships require information on exposure via food, this may be estimated by back-calculation of biomarker levels via toxicodynamic–toxicokinetic models to the corresponding intake of food.

Identification and selection of health outcomes

A crucial step is to identify the potential health effects associated with exposure. This is typically done through a review of the scientific literature, ideally of epidemiological studies that have established an association. Alternatively, published reviews of the literature, risk assessment studies and scientific opinions from international organizations or burden of disease studies may be used. The final list of health outcomes to be included in the study will be based on the level of evidence of association between exposure and disease, and the availability of dose–response data. If the level of exposure estimated for the given population is lower than what is expected to have an adverse effect, the health outcome in question may not be accounted for despite a confirmed cause–effect relationship and available dose–response evidence.

BOX A1.1. The dose–response relationship

Dose–response models for estimating the risk of a health outcome on exposure to a chemical via the diet may be derived from human observational studies or from animal studies; if these are not available, other test systems used in toxicology may be applied. Common to all types of data is that a dose–response relationship should be modelled to establish: (i) for threshold effects, the dose above which the health outcome in question occurs, or (ii) for non-threshold effects, the relationship between exposure and risk of health outcome at all relevant dose ranges. Where risk assessments have been conducted for chemical hazards, dose–response relationships have generally been modelled and published. As a precaution, risk assessments apply extrapolation factors to dose–response relationships when establishing health-based guidance values (i.e. exposure levels that are sufficiently low to protect a population and at which risk of disease is negligible). In estimating burden of disease of foodborne chemicals, dose–response relationships should provide evidence to estimate the current burden, i.e. estimates of the proportion of a population with the health outcome in question at a given exposure.

TABLE A1.1. Overview of data requirements, possible data sources and quality assessment criteria for estimation of burden of disease due to foodborne chemicals

Data requirement	Data source	Quality assessment
Consumption of foods in the population, in grams per day. Data can be at individual level or aggregated by age group and sex	National dietary survey in the population. International databases such as FAOSTAT, FAO/WHO GIFT (Global Individual Food Consumption Data Tool)	Sample size. Representativeness of the population
Concentration of chemical hazard in foods	National food monitoring. International databases. Scientific literature	Sample size. Testing method used. Level of detection
Dose–response models	Scientific literature	Grading evidence based on peer review, reviews or other scientific reports from international organizations
Disability weights	Scientific literature. WHO Global Burden of Disease Reports	NA
Duration of disease	National health registries or statistics	NA

NA: not applicable.

Estimating incidence and mortality of health outcomes

Estimated exposure for each population group is integrated with the dose–response evidence to estimate the incidence of each health outcome given current exposure in the population. This incidence is then linked with the probability of death from the given disease to estimate the overall mortality due to the hazard.

DALYs

To calculate DALYs, the estimated incidence and mortality of each health outcome are combined with the corresponding disability weights and duration of disease. See Chapter 5 for more details.

ANNEX 2:
SOURCE ATTRIBUTION METHODS

A variety of methods are available to attribute foodborne diseases to specific sources, including approaches based on analysis of data from occurrence and epidemiological studies, intervention studies, and expert elicitations (1). Each of these methods has advantages and limitations, and the usefulness of each depends on the public health questions being addressed. In addition, the different methods have different data requirements and attribute human illness at different points of the farm-to-consumption chain (i.e. production, processing or exposure). Their usefulness will therefore vary depending on the hazard and the country or region in question.

This annex reviews the available source attribution methods, assessing their applicability in attributing illness caused by foodborne hazards of each hazard group (enteric pathogens, parasites and chemicals) to the responsible sources. Pires (2) published a detailed review of source attribution methods, as well as recommendations on the most appropriate methods for attributing human disease caused by each hazard considered by FERG.

MAIN CONCEPTS

Human illness source attribution is the partitioning of the human disease burden caused by one or more foodborne diseases to specific sources, where the term source includes reservoirs and vehicles (1). The term reservoir refers to an animal species or non-animal substance on which a pathogen depends for its survival or from which a chemical compound originates. Many foodborne hazards have more than one reservoir.

A vehicle is a carrier of a hazard from its original reservoir until final exposure. The pathway from reservoir to exposure may involve multiple vehicles; vehicles of foodborne hazards are traditionally food items, but other sources, e.g. contaminated drinking-water, recreational water and live animals, can also be vehicles.

Harmonized categorization of sources is necessary to compare and integrate results from various databases, source attribution models, approaches and hazards. We consider four main types of transmission route from the main reservoirs to humans: foodborne, environmental, contact with animals, and person-to-person transmission. For the purpose of source attribution, person-to-person transmission may not be relevant, because the aim is to estimate the relative importance of the original sources of the pathogen (to which the index case would have been exposed) and to use this information to define control measures in the food chain. There are several ways to categorize food commodities (3). When relevant, environmental transmission routes (e.g. contaminated water or air emissions of industrial pollutants) and transmission through direct contact with animals are considered.

Human illness source attribution can take place at different points along the food chain (points of attribution), but it is most often done at the reservoir (e.g. animal production stage, environmental emissions) or the point of exposure (end of the transmission chain). The point of attribution depends on the method chosen, which in turn depends on the risk management question being addressed and on the availability of data. Source

attribution estimates obtained through the application of different methods are not necessarily comparable. When possible, they can be combined with the results of other studies.

SOURCE ATTRIBUTION APPROACHES

Approaches to source attribution can be grouped broadly into four categories: microbiological, epidemiological, expert elicitation, and intervention studies (1,4). Methods in all categories have been used to estimate the sources of several pathogens in different subpopulations (e.g. *Salmonella*, *Campylobacter*, *Listeria monocytogenes*). Table A2.1 presents an overview of the strengths and limitations of each method.

Microbiological approaches for source attribution include subtyping and assessment of comparative exposure. Both involve the use of data on the occurrence of foodborne hazards in animals, food and the environment. Ideally, these data will be available from surveillance or monitoring programmes in the country, but they may also be obtained from, for example, targeted projects or a literature review. The subtyping approach attributes human cases to the reservoir level, i.e. as close as possible to the origin of the pathogen, and gives no information on the relative contributions of different exposure routes to humans. On the other hand, the comparative exposure assessment approach estimates the relative importance of different routes of exposure, which may include several routes from the same reservoir.

Epidemiological approaches include analysis of data from case–control studies and outbreak investigations. Case-control studies are useful in identifying sources and risk factors for a disease, as well as the fraction of human cases than can be attributable to these (by estimating population attributable fractions). Even if few case–control studies have been conducted and are insufficient to allow extrapolation of source attribution estimates at national level, a meta-analysis of several case–control studies from different countries can be used to estimate the number of illnesses attributable to each exposure at regional and global level.

In contrast, data on foodborne disease outbreaks are widely available in most parts of the world. Many outbreak investigations are successful in identifying the specific contaminated source or ingredient that transmitted the causative agent, and an analysis of these data can show the relative contributions of the most important sources of disease. These analyses can be done at national, regional and global levels and, within the limitations of assuming that outbreak data are representative of all cases in the population (i.e. also of sporadic cases of disease), outbreak attribution analyses provide useful evidence for source prioritization.

Expert elicitations may also be used to fill data gaps, to combine data from different studies and scientific approaches into a single estimate. Small-scale intervention studies are useful if the number of exposure pathways is limited for a particular hazard and each pathway is well characterized from source to exposure. However, they are not often conducted because they are expensive and difficult to implement.

TABLE A2.1. Strengths and limitations of source attribution methods

Approach	Strengths	Limitations
Microbiological approaches		
Subtyping	Identifies the most important reservoirs of the hazard. Useful to prioritize interventions at production level. Reduces uncertainty due to cross-contamination or spread to accidental sources	Limited to hazards heterogeneously distributed among the reservoirs. No information on transmission pathways from reservoirs to humans. Data-intensive, requiring collection of representative isolates from all (major) sources

Approach	Strengths	Limitations
Comparative exposure assessment	Accounts for different transmission routes from the same reservoir. Easily updated	Often limited by lack of data, resulting in large uncertainties
Epidemiological studies		
Case–control studies (including systematic review)	Able to identify variety of risk factors, including exposure routes, predisposing, behavioural or seasonal factors. Systematic reviews can be useful for regional analysis and may detect temporal and geographical variations. Can identify a wide range of known and unknown risk factors	Misclassification because of immunity may reduce attributable risk or suggest protection. Most studies only explain a small fraction of all cases. Cases may reflect a mixture of possible sources of exposure. Misclassification due to recall bias may lead to an underestimation of the attribution proportion
Analysis of data from outbreaks	Documentation that a hazard was transmitted to humans via a specific food item may be available. Data may capture the effect of contamination at multiple points in the production-to-consumption chain Wide variety of foods represented, including uncommon foods. Most readily available information for source attribution in some countries or regions	Quality of evidence varies. Large or severe outbreaks, those associated with point sources, and those with short incubation periods are more likely to be investigated. Investigated cases may not be representative of all foodborne illnesses. Certain pathogens and foods are more likely to be associated with reported outbreaks, which can lead to an overestimation of the attribution proportion
Intervention studies	Allow direct measurement of the impact of a source on the number of infections, avoiding accounting for the effect of external factors	Interpretation of data from large-scale interventions is difficult, since usually several interventions are implemented at the same time. Complex and resource-demanding
Expert elicitations	Allow attribution to main transmission routes. Useful when data are lacking. May be the only available method for source attribution	Conclusions are based on the individual experts' judgement, which may be misinformed or biased

APPLICABILITY OF SOURCE ATTRIBUTION METHODS TO FOODBORNE PATHOGENS

Attribution to main types of transmission

The first step in the source attribution process is to estimate the overall proportion of the burden of disease that can be attributed to the four main transmission routes, i.e. foodborne, environmental, direct contact with animals, and person-to-person. For most foodborne hazards, data-driven methods, based for example on surveillance and monitoring, would require an exhaustive review and inclusion of all potential sources and pathways within these main routes. Consequently, these are not the most appropriate tool for this initial step when applied individually. A combination of epidemiological methods – for example, an analysis of outbreak data combined with studies of sporadic cases – could provide a more adequate picture of the relative importance of the different types of transmission. For hazards that are transmitted through a limited number of routes (e.g. Brucella spp.), the application of one epidemiological approach may be sufficient for source attribution. If epidemiological data are not available, two methods are currently available to attribute disease to these main routes: expert elicitations and intervention studies.

Attribution of foodborne disease to food and other transmission routes may be undertaken for individual foodborne hazards or for syndromic groups, e.g. diarrhoeal disease. In both cases, expert elicitations can be conducted at country or regional level. Interventions, however, are best done as small-scale population-based studies, which can be expensive and difficult to apply.

FERG undertook a large-scale expert elicitation to attribute disease due to 19 foodborne hazards to the main transmission groups at global, regional and subregional level (5). The study applied structured expert judgement using Cooke's classical model (6)to obtain estimates for the relative contributions of different transmission pathways for eleven diarrhoeal diseases, seven other infectious diseases and one chemical (lead). Experts were selected based on their experience, including of work at international level, and worked in 10 global panels and nine subregional panels. This study presented the first worldwide estimates of the proportion of specific diseases attributable to food and other major transmission routes. Other similar expert elicitations have been conducted at a national level, specifically in the Netherlands and Canada (7,8). Further country-specific initiatives will be useful to improve estimates and reduce uncertainties.

Attribution to specific foods and exposure routes

The risk management question, the characteristics of the hazard causing the disease, and the data available influence the usefulness of source attribution methods. When more than one method proves useful, the final choice will be determined by the question that needs answering, and will be influenced by the analytical capacity in the country and the level of data-sharing between agencies.

The type of reservoir of the hazard will influence the applicability of some source attribution methods, particularly the subtyping approach. This approach can be used for hazards with one or more animal reservoirs, to which disease can be traced back, and where the hazard can potentially be controlled. All other approaches are in principle applicable regardless of the origin of the hazard, since they focus on routes of transmission or the point of exposure.

There may also be differences in the usefulness of methods at regional or national level. In general, epidemiological approaches, specifically analysis of outbreak data and systematic review and meta-analysis of case–control studies of sporadic infections, are useful for source attribution at a regional level when data are not available at country level.

The applicability and usefulness of the source attribution methods varies for enteric, parasitic and chemical hazards. If an enteric pathogen has mainly an animal reservoir, can be subtyped by appropriate discriminatory methods, and subtyping data are available, the subtyping approach is appropriate to attribute human disease caused by that pathogen. For the majority of enteric hazards, source attribution by an analysis of data from outbreak investigations is appropriate. The comparative exposure assessment has proved useful in attributing infections by pathogens that are mostly transmitted by a limited number of food routes. A systematic review of epidemiological studies of sporadic infections can be useful for enteric hazards that have been extensively studied throughout the world.

REFERENCE

1. Pires SM, Evers EG, van Pelt W, Ayers T, Scallan E, Angulo FJ et al. Attributing the human disease burden of foodborne infections to specific sources. Foodborne Pathog Dis. 2009;6(4):417–24.
2. Pires SM. Assessing the applicability of currently available methods for attributing foodborne disease to sources, including food and food commodities. Foodborne Pathog Dis. 2013;10(3).
3. Richardson LC, Bazaco MC, Parker CC, Dewey-Mattia D, Golden N, Jones K et al. An updated scheme for categorizing foods implicated in foodborne disease outbreaks: a tri-agency collaboration. Foodborne Pathog Dis. 2017;14(12):701–10 (http://www.liebertpub.com/doi/10.1089/fpd.2017.2324; accessed 7 November 2018).
4. Batz MB, Doyle MP, Morris JG, Painter J, Singh R, Tauxe R V et al. Attributing illness to food. Emerg Infect Dis. 2005;11(7):993–9.
5. Hald T, Aspinall W, Devleesschauwer B, Cooke R, Corrigan T, Havelaar AH et al. World Health Organization estimates of the relative contributions of food to the burden of disease due to selected foodborne hazards: a structured expert elicitation. PLoS One. 2016;11(1):1–35.
6. Cooke R. Experts in uncertainty : opinion and subjective probability in science. Oxford: Oxford University Press; 1991 (https://books.google.dk/books/about/Experts_in_Uncertainty.html?id=4taZBr_nvBgC&redir_esc=y; accessed 22 April 2018).
7. Havelaar AH, Galindo AV, Kurowicka D, Cooke RM. Attribution of foodborne pathogens using structured expert elicitation. Foodborne Pathog Dis. 2008;5(5):649–59 (Available from: http://repository.tudelft.nl/assets/uuid:0f1a31fe-6c37-4b4f-83a5-28bf781a38a3/Cooke_2008.pdf).
8. Davidson VJ, Ravel A, Nguyen TN, Fazil A, Ruzante JM. Food-specific attribution of selected gastrointestinal illnesses: estimates from a Canadian expert elicitation survey. Foodborne Pathog Dis. 2011;8(9):983–95.

ANNEX 3:
LIST OF FOODBORNE HAZARDS COMPILED BY FERG

As part of the initiative to estimate the global burden of foodborne diseases, in 2007 a list of major foodborne hazards of global public health significance was produced (1). Some hazards were classified as global hazards (considered to be of relevance in all regions), while others were local (considered to have different relevance in different countries). Because of data gaps and methodological limitations encountered during the initiative, the final list of hazards included in the 2015 report contained only 31 hazards (2).

TABLE A3.1. Extensive list of major causative agents of foodborne disease, initially compiled by FERG 2007-2015[a]

Parasites	Enteric pathogen	Chemicals and Toxins
Ancylostoma duodenale *Angiostrongylus cantonensis* *Angiostrongylus costaricensis* *Anisakis simplex* *Ascaris lumbricoides* *Blastocystis hominis* *Capillaria philippinensis* *Clonorchis sinensis* *Cryptosporidium spp.* *Cyclospora spp.* *Dicrocoelium dendriticum* *Dientamoeba fragilis* *Diphyllobothrium latum* *Echinococcus spp.* *Echinostoma spp.* *Entamoeba histolytica* *Fasciola spp.* *Fasciolopsis buski* *Gastrodiscoides hominis* *Giardia intestinalis* *Gnathostoma spinigerum* *Heterophyes heterophyes* *Hymenolepis nana* *Isospora belli* *Linguatula serata* *Metagonimus yokogawai* *Nanophytes salmincola* *Opisthorchis felineus* *Opisthorchis viverrini* *Paragonimus spp.* *Sarcocystis hominis* *Taenia saginata* *Taenia solium* *Toxocara spp.* *Toxoplasma gondii* *Trinchinella spp.* *Trichostrongylus spp.* *Trichuris trichiura*	Adenovirus *Aeromanas spp.* Astrovirus Bacterial toxins (*B. cerus*) Bacterial toxins (*C. perfringens*) Bacterial toxins (*S. aureus*) *Brucella* sp. *Campylobacter sp.* *Clostridium botulinum* Enteroaggerative *E. coli* (EAggEC) Entero-pathogenic *E. coli* (EPEC) Entero-toxigenic *E.coli* (ETEC) Enterovirus *Helicobacter pylori* Hepatitis A virus Hepatitis E virus *Leptospira sp.* *Listeria monocytogenes* *Mycrobacterium bovis* Non cholera Vibrios Norovirus Prions Rotavirus *Salmonella* (non-typhoidal) *sp.* *Salmonella* (typhoidal) *sp.* Shiga-toxin producing *E. coli* (STEC) *Shigella sp.* *Vibrio cholerae 01/0139* *Yersinia sp.*	**Elementals contaminants** Lead, mercury, cadmium, manganese, arsenic **Mycotoxins** Aflatoxins, ochratoxin, fumonisin, trichothocenes **Food additives** Sulphites, nitrites/nitrates, benzoic acid **Pesticides** Organophosphates, carbamates, DDT, pyrethrins **Organic industrial contaminants** Persistent organic pollutants **Veterinary drugs/residues** Antibiotics, hormones - but not antimicrobial residues **Seafood toxins** Tetrodotoxi, ciguatera, shellfish toxins, DSPs, PSPs, histamines **Process contaminants** Acrylamide, PAHs, choropropanol **Allergens** Peanuts **Natural toxicants** Cyanide in cassava, aminoglycosides **Radionuclides and depleted uranium**

[a] Reproduced from ref. 1.

TABLE A3.2. List of hazards for which burden of foodborne disease estimates were derived by FERG 2007-2015[a]

Parasites	Enteric pathogen	Chemicals and Toxins
Ascaris spp.	*Brucella* spp.	Aflatoxin
Clonorchis sinensis	*Campylobacter* spp.	Cassava cyanide
Cryptosporidium spp.	Enteropathogenic *E. coli* (EPEC)	Dioxin
Echinococcus granulosus	Enterotoxigenic *E. coli* (ETEC)	
Echinococcus multilocularis	Hepatitis A virus	
Entamoeba histolytica	*Listeria monocytogenes*	
Fasciola spp.	*Mycobacterium bovis*	
Giardia spp.	Norovirus	
Intestinal flukes	Non-typhoidal *S. enterica*	
Opisthorchis spp.	*Salmonella paratyphi*	
Paragonimus spp.	*Salmonella typhi*	
Taenia solium	Shiga toxin-producing *E.coli* (STEC)	
Toxoplasma gondii	*Shigella* spp.	
Trichinella spp.	*Vibrio cholerae*	

[a] Reproduced from ref. 2.

TABLE A3.3. Foodborne hazards, causally related health states and corresponding disability weights[a]

Hazard	Health state	DW
Diarrhoeal disease agents		
Norovirus	Diarrhoeal disease [a]	0.074
Campylobacter spp.	Diarrhoeal disease [a]	0.101
	Guillain-Barré syndrome	0.445
Enteropathogenic *E. coli*	Diarrhoeal disease [a]	0.074
Enterotoxigenic *E. coli*	Diarrhoeal disease [a]	0.074
Shiga toxin-producing *E.coli*	Diarrhoeal disease [a]	0.091
	Hemolytic uremic syndrome	0.210
	End-stage renal disease	0.573
Non-typhoidal *S. enterica*	Diarrhoeal disease [a]	0.101
	Invasive salmonellosis	0.210
Shigella spp.	Diarrhoeal disease [a]	0.101
Vibrio cholerae	Diarrhoeal disease [a]	0.194
Cryptosporidium spp.	Diarrhoeal disease [a]	0.074
Entamoeba histolytica	Diarrhoeal disease [a]	0.074

Hazard	Health state	DW
Giardia spp.	Diarrhoeal disease [a]	0.074
Invasive infectious disease agents		
Hepatitis A Virus	Hepatitis	0.108
Brucella spp.	Acute brucellosis	0.108
	Chronic brucellosis	0.079
	Orchitis	0.097
Listeria monocytogenes, perinatal	Sepsis	0.210
	Central nervous system infection	0.426
	Neurological sequelae	0.292
Listeria monocytogenes, acquired	Sepsis	0.210
	Central nervous system infection	0.426
	Neurological sequelae	0.292
Mycobacterium bovis	Tuberculosis	0.331
Salmonella Paratyphi	Paratyphid fever	0.210
	Liver abscesses and cysts	0.254
Salmonella Typhi	Typhoid fever	0.210
	Liver abscesses and cysts	0.254
Toxoplasma gondii, congenital	Intracranial calcification	0.010
	Hydrocephalus	0.360
	Chorioretinitis, early in life	0.033
	Chorioretinitis, later in life	0.033
	Central nervous system abnormalities	0.360
Toxoplasma gondii, acquired	Chorioretinitis, mild	0.004
	Chorioretinitis, moderate	0.033
	Chorioretinitis, severe	0.191
	Acute illness	0.053
	Post-acute illness	0.254
Enteric intoxications		
Bacillus cereus [b]	Acute intoxication	0.061
Clostridium botulinum [b]	Moderate/Mild botulism	0.198
	Severe botulism	0.445
Clostridium perfringens [b]	Acute intoxication	0.061
Staphylococcus aureus [b]	Acute intoxication	0.061

Hazard	Health state	DW
Cestodes		
Echinococcus granulosus, cases seeking treatment	Pulmonary cystic echinococcosis	0.192
	Hepatic cystic echinococcosis	0.123
	Central nervous system cystic echinococcosis	0.221
Echinococcus granulosus, cases not seeking treatment	Pulmonary cystic echinococcosis	0.015
	Hepatic cystic echinococcosis	0.012
	Central nervous system cystic echinococcosis	0.054
Echinococcus multilocularis	Alveolar echinococcosis	0.123
Taenia solium	Epilepsy: treated, seizure free	0.072
	Epilepsy: treated, with recent seizures	0.319
	Epilepsy: severe	0.657
	Epilepsy: untreated	0.420
Nematodes		
Ascaris spp.	Ascariasis infestation	0.030
	Mild abdominopelvic problems due to ascariasis	0.012
	Severe wasting due to ascariasis	0.127
Trichinella spp.	Acute clinical trichinellosis	0.637
Trematodes		
Clonorchis sinensis	Abdominopelvic problems due to heavy clonorchiosis	0.123
Fasciola spp.	Abdominopelvic problems due to heavy fascicolosis	0.123
Intestinal flukes[c]	Abdominopelvic problems due to heavy intestinal fluke inffections	0.123
Opisthorchis spp.	Abdominopelvic problems due to heavy opisthorchiosis	0.123
Paragonimus spp.	Central nervous system problems due to heavy paragonimosis	0.420
	Pulmonary problems due to heavy paragonimosis	0.132
Organic pollutants		
Dioxin	Infertility	0.056
	Hypothyroidy due to prenatal exposure	0.019
	Hypothyroidy due postnatal exposure	0.019
Toxins and allergens		
Aflatoxin	Hepatocellular carcinoma: diagnosis and primary therapy	0.294
	Hepatocellular carcinoma: metastatic	0.484

Hazard	Health state	DW
	Hepatocellular carcinoma: terminal phase with medication	0.508
	Hepatocellular carcinama: terminal phase without medication	0.519
Cyanide in cassava	Konzo	0.065
Peanut allergens [b]	Living with peanut-induced allergy	0.012

[a] Reproduced from ref. 3.

[a] The disability weights for Diarrhoeal disease were defined as a weighted average of the disability weights for mild, moderate and severe Diarrhoeal, with different relative contributions of these severity levels leading to different weighted averages for different Diarrhoeal disease agents.
[b] Excluded from global burden assessments
[c] Includes *Echinostoma* spp., *Fasciolopsis buski*, *Heterophyes* spp., *Metagonimus* spp., and other foodborne intestinal species.

REFERENCE

1. First formal meeting of the Foodborne Disease Burden Epidemiology Reference Group (FERG): implementing strategy, setting priorities and assigning the tasks. Geneva: World Health Organization; 2008 (https://www.who.int/foodsafety/publications/burden_nov07/en/).
2. WHO estimates of the global burden of foodborne diseases. Geneva: World Health Organization; 2015.
3. Devleesschauwer B, Haagsma JA, Angulo FJ, Bellinger DC, Cole D, Döpfer D et al. Methodological framework for World Health Organization estimates of the global burden of foodborne disease. PLoS ONE. 2015;10(12): e0142498.

ANNEX 4:
DATA COLLECTION CHECKLIST

This annex contains a checklist that countries can use to take stock of the data required for a national burden of foodborne disease study. It is intended as an aid to data-gathering and is neither comprehensive nor exhaustive.

1. DEMOGRAPHIC BASELINE

- Total population for the selected time period, stratified by age and sex.
- Total number of pregnant women and total number of live births, stillbirths and abortions for the selected time period.
- Local life expectancy table for the selected time period, stratified by sex.

TABLE A4.1. A list of demographic data sources, expected information and quality assessments

Data source	Expected information	Quality assessments
Population census	Total population, stratified by age and sex Total number of pregnancies; total number of live births, stillbirths and abortions Local life expectancy table, stratified by sex	Sample size, sampling area and time period
Demographic surveys • Demographic and Health Surveys (USAID) • WHO World Health Survey • INDEPTH Health and Demographic Surveillance System • National Living Standards Survey • National Household Budget Survey • National Health Survey	Population stratification by age and sex Proportion of pregnant women and postpartum women Proportion of live births, stillbirths and abortions	Sample size, sampling area and time period
Government statistics • Bureau of Statistics • Ministry of Population • Ministry of Health	Total population, stratified by age and sex Total number of pregnancies Total number of live births, stillbirths and abortions Local life expectancy table, stratified by sex	Sample size, sampling area and time period

2. EPIDEMIOLOGICAL DATA

- Disease incidence and disease duration, stratified by age and sex.
- Disease mortality, stratified by age and sex.

TABLE A4.2. A list of epidemiological data sources, expected information and quality assessments

Data source	Expected information	Quality assessments
Burden of disease studies • National (general) burden of disease • Specific FBD burden studies	Burden estimates, stratified by age and sex YLD and YLL, stratified by age and sex	Sample size, sampling area and time period Confidence or credibility intervals
Health surveillance	YLD and YLL, stratified by age and sex	Sample size, sampling area and time period Description of reporting system Case definitions
• Laboratory-based active surveillance	Incidence estimates, by age and sex	
• Laboratory-based passive surveillance	Incidence estimates, by age and sex	
• FBD outbreak surveillance	Number of outbreaks per causal hazard Number of cases per outbreak; involved (food) source per outbreak, if known	
• Mortality register with cause of death information	Mortality estimates, by age and sex	
Data collection networks	YLD and YLL, stratified by age and sex	Sample size, sampling area and time period
• Demographic and Health Survey	Overall mortality estimates, by age and sex Causes of death in children under 5 years, by age and sex; Prevalence of diarrhoea in children under 5 years, by age and sex; Immunization coverage, by age and sex	
• WHO World Health Survey	Overall mortality estimates, by age and sex Causes of death in children and adults, by age and sex Prevalence of diarrhoea in children under 5 years, by age and sex Immunization coverage, by age and sex	
• INDEPTH Health and Demographic Surveillance System	Socio-demographic and health indicators including birth, death, migration, marriage, maternal health, education and employment; cause specific mortality	
• Global Foodborne Infections Network	Number of *Salmonella* isolates identified Number of *Salmonella* isolates serotyped Sources of *Salmonella* isolates	

Data source	Expected information	Quality assessments
• Acute gastrointestinal Illness survey	Incidence of acute gastrointestinal illness Symptoms and duration of symptoms Quantification of under-reporting in surveillance systems	
• National (general) health survey	Overall mortality estimates, by age and sex; causes of death in children < 5y, by age and sex; prevalence of diarrhea in children < 5y, by age and sex; immunization coverage, by age and sex	
Community-based studies (national/regional) • Government: assessment studies and publications • International organizations: assessment studies and publications • Local NGOs: assessment studies and publications • Academia: dissertations • Scientific journals: peer-reviewed articles	YLD and YLL, stratified by age and sex	Sample size, sampling area and time period

Existing burden of disease studies, official data sources and national surveys are the preferred sources. If specific information is not available through these data sources, local or regional community-based studies may be used. A detailed description of how incidence data may be derived from different data sources is given in Chapter 5.

For every data source, it is important to assess the level of uncertainty associated with the respective estimates. For most data sources, information on the type of study, the sample size and the area and time period of sampling should be collected along with the actual data.

ANNEX 5:
APPROACHES AND ASSUMPTIONS USED BY FERG TO OVERCOME DATA GAPS

In estimating the global and regional burden of disease for 31 foodborne hazards, FERG had to deal with variations in data availability across regions and countries (1). Challenges included sparseness or unavailability of information on disease incidence, hazard-specific or epidemiological data for some diseases, and disability weights. This annex describes the strategies adopted by FERG to overcome the data gaps encountered. These strategies may provide useful ideas for national burden of foodborne disease studies.

INCIDENCE AND MORTALITY DATA OF ENTERIC DISEASES

Different strategies were adopted to address lack of incidence data for different foodborne diseases. It is acknowledged that public health surveillance of enteric diseases covers only a fraction of the true number of cases in the population. Because FERG was not able to estimate the level of under-reporting for individual countries or regions, it searched for national etiology-specific incidence and mortality estimates. Such estimates were available only for a limited number of countries. Therefore, FERG used two approaches to estimate the incidence and mortality of the diseases (2). Countries for which one or the other approach was applied were grouped according to overall child and adult mortality rates, as defined by WHO (http://www.who.int/choice/demography/mortality_strata/en/) (2, 3).

Countries with very low child and adult mortality rates

In the first approach, a literature review of published national estimates (with associated uncertainty intervals) of foodborne diseases was conducted. Such estimates were derived from studies that corrected national surveillance data to account for underdiagnosis and under-reporting. Estimates from each study were presented or transformed into foodborne incidence and mortality rates per 100 000 population. These estimates, with the associated uncertainty intervals, were applied to the country for which they were estimated; the median incidence and mortality of all the studies, with the associated uncertainty intervals estimates, were then applied to each country in the European Region. They were also applied to parts of other Regions that did not have national foodborne incidence or mortality estimates but were known to have low child and adult mortality rates. These included countries in the Americas and the Western Pacific. This approach produced foodborne incidence and mortality estimates, with uncertainty intervals, for 61 countries.

Other countries

A different approach was applied to another 133 countries worldwide. First, the overall incidence of diarrhoea from all causes (i.e. the "envelope" of diarrhoeal incidence) for 2010 was estimated by combining estimates of diarrhoeal incidence in those under and over 5 years of age, based on published systematic reviews (4, 5). WHO estimates of diarrhoeal mortality in 2010 (i.e. the envelope for diarrhoeal deaths) were used.The etiological proportions for the various diseases by region were estimated from systematic reviews of stool sample isolation or detection proportions from inpatient, outpatient and community-based studies of people with diarrhoea. It was assumed that the distribution of pathogens

observed among patients hospitalized with severe diarrhoea represented the pathogen prevalence among diarrhoeal deaths. To derive etiological proportions for children under 5 years of age, it was assumed that the distribution of pathogens in outpatient and community studies represented the pathogen prevalence among diarrhoeal episodes for those who did not die. The same assumption was made for persons 5 years of age and over, but due to sparseness of data, inpatient studies were also included.

INCIDENCE AND MORTALITY DATA OF NON-ENTERIC DISEASES

The Computational Task Force of FERG developed, tested and evaluated several possible approaches to impute missing incidence data at the country level (1). These models estimated parameters based on data of neighbouring regions or other time periods. A log-normal random effects model was the default model for imputing missing country-level incidence data (6). In brief, this model assumes that the log-transformed incidence rate in a country belonging to a specific subregion arises from a normal distribution with subregion-specific mean and a within-region (between-country) variance. The parameters were defined differently depending on the number of countries within a specific subregion for which data were available. More details of this approach are described elsewhere (6).

DISABILITY WEIGHTS

The DWs used by FERG were based on those estimated for the 2010 GBD study (7). When DWs were missing for specific health outcomes, alternative values were assumed or collected. These were defined as proxy health states. Furthermore, FERG opted for an alternative value for primary infertility (i.e. 0.056 instead of the 0.011 defined in the GBD) (7). This revision was motivated by an analysis showing that the 2010 GBD weights undervalued the health states associated with fertility (8). When there were no DWs of health outcomes of foodborne diseases, proxy health states were selected. These selections were made by a medical expert and a DW expert.

REFERENCE

1. Devleesschauwer B, Haagsma JA, Angulo FJ, Bellinger DC, Cole D, Döpfer D et al. Methodological framework for World Health Organization estimates of the global burden of foodborne disease. PLoS One. 2015;10(12):1–20.
2. Pires SM, Fischer-Walker CL, Lanata CF, Devleesschauwer B, Hall AJ, Kirk MD et al. Aetiology-specific estimates of the global and regional incidence and mortality of diarrhoeal diseases commonly transmitted through food. PLoS One. 2015;10(12):1–17.
3. Kirk MD, Pires SM, Black RE, Caipo M, Crump JA, Devleesschauwer B et al. World Health Organization estimates of the global and regional disease burden of 22 foodborne bacterial, protozoal, and viral diseases, 2010: a data synthesis. PLoS Med. 2015;12(12):1–21.
4. Walker CLF, Rudan I, Liu L, Nair H, Theodoratou E, Bhutta ZA et al. Global burden of childhood pneumonia and diarrhoea. Lancet. 2013;381(9875):1405–16 (http://www.ncbi.nlm.nih.gov/pubmed/23582727; accessed 14 December 2017).
5. Fischer Walker CL, Sack D, Black RE. Etiology of diarrhea in older children, adolescents and adults: a systematic review. PLoS Negl Trop Dis. 2010;4(8):e768 (http://dx.plos.org/10.1371/journal.pntd.0000768; accessed 17 January 2019).
6. Mcdonald SA, Devleesschauwer B, Speybroeck N, Hens N, Praet N, Torgerson PR et al. Data-driven methods for imputing national-level incidence in global burden of disease studies. Bull World Heal Organ. 2015;93:228–36 (http://dx.doi.org/10.2471/BLT.14.139972; accessed 16 June 2020).
7. Salomon JA, Vos T, Hogan DR, Gagnon M, Naghavi M, Mokdad A et al. Common values in assessing health outcomes from disease and injury: disability weights measurement study for the Global Burden of Disease Study 2010. Lancet. 2012;380(9859):2129–43.
8. Mathers, C, Stevens G. WHO methods and data sources for global burden of disease estimates 2000-2011. Geneva: World Health Organization; 2013 (https://www.who.int/healthinfo/statistics/GlobalDALYmethods_2000_2011.pdf).


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