Food safety metrics relevant to low and middle income countries

Working paper

Agriculture, Nutrition & Health Academy
Food Safety Working Group

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Abbreviations and acronyms

ALOP	Appropriate Level of Protection
A4NH	CGIAR Research Program on Agriculture for Nutrition and Health
ANH	Agriculture, Nutrition and Health
CAC	Codex Alimentarius Commission
CDC	Centres for Disease Control and Prevention
DALY	Disability Adjusted Life Year
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
FBD	foodborne disease
FERG	Foodborne Disease Epidemiology Reference Group
FSO	Food Safety Objective
GHP	Good Hygienic Practice
HACCP	Hazard Analysis and Critical Control Points
HIC	High Income Countries
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
IFPRI	International Food Policy Research Institute
ILRI	International Livestock Research Institute
IMMANA	Innovative Methods and Metrics for Agriculture and Nutrition Actions
LCIRAH	Leverhulme Centre for Integrative Research on Agriculture and Health
LMICs	Low and middle income countries
LSHTM	London School of Hygiene and Tropical Medicine
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
PDS	participatory disease surveillance
PE	participatory epidemiology
PO	performance objective
PC	performance criterion
RVC	Royal Veterinary College
SDG	Sustainable Development Goal
SPS	Sanitary and Phytosanitary
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

Working group on food safety metrics

Working group objectives

The Agriculture, Nutrition and Health (ANH) Academy is a global network for research into improving nutrition and health through agriculture and food systems, serving as a platform for learning and sharing. It is jointly founded by the Leverhulme Centre for Integrative Research on Agriculture and Health (LCIRAH), the project on Innovative Methods and Metrics for Agriculture and Nutrition Actions (IMMANA) and the CGIAR Research Program on Agriculture for Nutrition and Health (A4NH).

The ANH Academy constituted a number of working groups to advance knowledge among the global research community regarding methods and metrics relating to different aspects of nutrition and health. The working group on food safety was tasked as follows:

- To review the metrics, tools, definitions and software platforms currently used in food safety research, with application to low and middle income countries (LMICs).
- To produce a summary of current gaps and challenges related to the use of these metrics.
- To suggest additional metrics and refinements to existing methods that would help make research in the area of food safety in LMICs more robust and/or replicable.
- To identify needs and opportunities for extending research on food safety in LMICs.

Working group members

The working group on food safety metrics was led by Delia Grace, International Livestock Research Institute (ILRI), Kenya. Members are:

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Advisory committee members

An advisory committee was also constituted of senior experts in agri-food systems. Members are:

- Hoang Van Minh, Hanoi University of Public Health, Vietnam
- Bassirou Bonfoh, Centre Suisse de Recherches Scientifiques, Côte d'Ivoire
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1 Background: Foodborne disease, its management and measurement

1.1 Paper objectives and outline

Mounting evidence on the high health and economic burden of foodborne disease (FBD), rapid transformation of agri-food systems and increasing concerns about the safety of what we consume are powerful motivations for better understanding food safety in low and middle income countries (LMICs). Because it is positioned at the intersection of agri-food systems and health, there are many ways of understanding it and no discrete set of research tools. This paper aims to bring together and discuss approaches, measures and methods to provide a synthesis about measuring food safety in the context of generating actionable evidence and to identify needs and opportunities for food safety research in LMICs.

We start by summarizing the importance of food safety in LMICs and then discuss concepts and definitions related to food safety. Next, we discuss measures and metrics for food safety, their application to LMICs and research needs. Generally, principles and caveats are considered and recommendations are made for core food safety metrics.

1.2 Foodborne disease in low and middle income countries

Evidence on the extent and burden of FBD in LMICs is still limited, but important studies in recent years have broadened our understanding. Especially relevant is the recently released first global study on the burden of FBD by the Foodborne Disease Epidemiology Reference Group (FERG) under the aegis of the World Health Organization (WHO) (Havelaar et al. 2015). The FERG finds the global burden of FBD is comparable to that of malaria, HIV/AIDS or tuberculosis; around 98% of this burden falls on LMICs. The study covered 31 foodborne hazards, for which there was sufficient data to develop global estimates. Together, these caused an estimated 600 million foodborne illnesses and 420,000 deaths in 2010. The combined burden of death and disability was estimated at 33 million Disability Adjusted Life Years (DALYs)[1]; children under five years old bore 40% of this burden, a disproportionate share as they represent 9% of the global population. The greatest per capita burden fell on the subregions in Africa, followed by the subregions in Asia and the eastern Mediterranean subregion. However, the region with the highest total burden was Asia. The most frequent causes of foodborne illness were diarrhoeal disease agents, led by norovirus and *Campylobacter* spp.; however, the most important in terms of death were non-typhoidal *Salmonella enterica*, *S. typhi* and enteropathogenic *Escherichia coli*. The report considers that estimates are conservative and the true burden is likely higher.

A summary of evidence on FBD specific to LMICs is set out in Grace (2015a) and Grace (2015b). These reviews find there is reasonable evidence that most of the (known) burden of FBD is caused by biological hazards (defined in Box 1). There is also good evidence that FBD are a concern for many consumers and policymakers in LMICs but not yet a concern for most food producers. Moreover, we have good evidence that in high income countries (HIC) most FBD results from the consumption of fresh, perishable foods and that these foods are probably also responsible for the majority of FBD in LMICs. (As we do not have good evidence on attributing FBD to specific foods in LMICs, this claim is based on the limited studies available as well as biological plausibility and ecological studies.) Evidence is also strong that most of this risky food is sold in informal (traditional or wet) markets and there is moderate quality evidence that the informal sector will continue to be the most important source of fresh food for decades in Africa, South Asia and poorer countries in southeast Asia. There is solid evidence that there are often high levels of hazards in food produced in LMICs and that there is little systematic, effective food safety assurance. There is much less evidence on the health risk associated with given hazards in food value chains, but it is clear that practices along the value chain and in the household have a major influence in mitigating or augmenting health risks.

FBD may be likely to increase in LMICs. Exacerbating factors include massive increases in the consumption of the riskiest foods (livestock/fish products and produce), rapid lengthening and increased complexity of value chains and slow or absent improvements in food safety governance (Roesel and Grace 2014; Grace 2015a; Auler et al. 2017). The reviews also find that although intensification and sophistication of agricultural production and transformation of supply chains is a strong trend in many LMICs, there is no good evidence that intensive, agro-industrial production and modern retail have clear advantages in food safety or in more general control of animal and human disease (e.g. emerging diseases, occupational hazards and livestock diseases). Some aspects of these systems

[1] DALYs are a summary measure of health developed by the Global Burden of Disease study. One DALY represents a lost year of healthy life.

appear to reduce risk (e.g. greater capacity to apply some good practices such as vaccination or easier monitoring) while other aspects appear to increase risk (e.g. longer chains with more bulking of food offer more opportunities for bacterial growth and cross-contamination), so the overall effect is difficult to predict (Roesel and Grace 2014). Importantly, there is overall limited evidence on the existence of effective, sustainable and scalable interventions to improve food safety in domestic markets of LMICs, but encouragingly, there are some promising approaches (such as improving infrastructure and training food handlers).

FBD in LMICs is also a concern because of a broad range of economic costs (from cost of illness to industry recalls) and its impacts on market access (both export and high-value domestic markets) (Unnevehr and Ronchi 2014; Humphrey 2017). More recently, concern is emerging about the interaction of food safety with other development goals such as improving equity and access to nutritious foods or livelihoods for women and the poor (Grace 2015a). In this context, FBD in LMICs should be viewed in the context of Sustainable Development Goals (SDGs). Building on the success of the Millennium Development Goals, the SDGs set an unprecedentedly ambitious, broad and integrated set of goals for improving the well-being of people and the planet. While FBD receives little specific attention in

Box 1: Definitions related to food safety and foodborne disease

Food safety has been defined as “a reasonable certainty that no harm will result from intended uses under the anticipated conditions of consumption” (OECD 1993).

There are various definitions of **FBD**. The WHO FERG report defines FBD as “a disease commonly transmitted through ingested food. FBDs comprise a broad group of illnesses, and may be caused by microbial pathogens, parasites, chemical contaminants and biotoxins” (WHO 2015). FERG follows the Codex Alimentarius Commission (CAC) definition of **food** as “any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of food but does not include cosmetics or tobacco or substances used only as drugs”. According to the CAC, bottled and packaged water, as well as other drinks, are foods.

The agents responsible for FBD are called **hazards**. CAC defines a hazard as “a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect” (CAC 2001). Hazards are divided into three categories: biological, chemical and physical. Biological hazards are living organisms, including viruses, bacteria, protozoa, moulds and parasites, which have the ability to infect people or produce toxins injurious to health. Chemical hazards are substances intentionally produced by industry (such as pesticides) and natural chemicals (e.g. those produced by volcanic emissions or toxic metals) which are injurious to health. Physical hazards include fragments of different materials such as stones, metal or glass. Physical hazards, except nanomaterials and radionuclides, do not transfer to human tissues, so impacts on human health are the result of physical trauma.

Biological hazards as broadly defined include agents causing food **allergies** and food **intolerances** (Taylor and Hefle 2005). Food allergies are abnormal immunological responses to a particular food or food component, usually a naturally occurring protein. They include antibody-mediated allergies (e.g. acute reactions to milk or peanuts) and cell-mediated conditions (e.g. coeliac disease in response to gluten). Food intolerances, on the other hand, do not involve abnormal responses of the immune system. Important in LMICs is lactose intolerance, which results from genetically inherited inability to metabolize milk sugar (lactose) due to lack of a specific enzyme (lactase).

The CAC defines a **contaminant** as any substance not intentionally added to food but present as part of the production-to-consumption pathway (e.g. Salmonella or aflatoxins); **adulterants** are not defined by the CAC but are commonly held to be substances deliberately added to food for deceptive purposes (e.g. water added to milk). Most hazards can be categorized as contaminants or adulterants.

Some confusion can result when definitions do not reflect common use of words, for example, the CAC definition of ‘food’ includes beverages and the CAC definition of ‘contaminant’ does not include rodent hairs or insect fragments in food. Mycotoxins (chemical compounds produced by moulds) and phycotoxins (chemical compounds produced by algae and accumulated in marine organisms) are sometimes considered to be biological hazards and sometimes to be chemical hazards.

Other food issues may have health implications but are not necessarily diseases transmitted by food. Food **fraud** is probably common in developing countries, especially for high-value foods. It may have health impacts if the adulterant is harmful (e.g. addition of melamine to milk) or if adulteration lowers the nutritional quality of food (e.g. addition of water to milk). Food **spoilage** is caused by microbes, but these are mostly different from the microbes causing FBD so spoiled food may not be unsafe and vice versa. However, good hygienic practices can reduce both types of microbes. **Antimicrobial residues** very rarely cause adverse reactions in people consuming them. A more important human health impact is if the use of antimicrobials in agriculture leads or contributes to **antimicrobial resistance** in pathogens, which can then infect people resulting in diseases that do not respond to antibiotics.

In the context of food safety, **risk** is the probability of harm resulting from a given exposure to a hazard. Risk, by definition, has two elements: probability, which captures the likelihood of occurrence, and harm, which refers to the nature and extent of ill effects.

Finally, the WHO defines a **health system** as “all the activities whose primary purpose is to promote, restore or maintain health” (WHO 2000). By extrapolation, a **food safety system** can be considered as those activities whose primary purpose is to ensure food is safe to eat. As such, the food safety system includes actors whose main mandate is assuring food safety (e.g. food safety authorities) and actors who are concerned with food safety as one aspect of food (e.g. local government authorities, institutional providers of food, and workers at all stages of the ‘farm to fork’ food production-to-consumption pathway).

the SDGs, probably because the first global assessment was not published until after the goals were signed off, food safety is integral to attaining the goal of ‘Good health and well-being’ and relevant to all 17 goals (Grace forthcoming). However, there is also potential antagonism between actions intended to improve food safety and the attainment of SDGs and vice versa (Box 2).

Box 2. Concerns over public health motivate efforts to control zoonotic pandemics such as highly pathogenic avian influenza.

Control efforts in LMICs often involved mass killing of poultry and restrictions on how poultry were kept. A study in Egypt found that control impacts resulted in a significant decrease in consumption of poultry and eggs and this in turn led to increased stunting: the health burden of which was likely greater than the health burden directly attributable to avian influenza in people (Kavle et al., 2015).

1.3 Measuring foodborne disease: definitions

The terms ‘measure’, ‘indicator’, ‘target’ and ‘metric’ are often used imprecisely or interchangeably. For the purposes of this report, we will use the following definitions:

- A **measure** is the act of measuring something (e.g. taking the temperature of meat), or the data that results from measuring something (e.g. a thermometer reading, the cost of running a hospital or the number of bacteria per gram of meat).
- An **indicator** is a measure that corresponds to an outcome of interest (e.g. the number of patients treated per month is an indicator of patient volume; low milk pH is an indicator of spoilage; child and maternal mortality ratio are impact indicators of health status).
- A **target** is the explicit statement of desired results for a specific indicator (e.g. 100 patients to be treated a month; 99% of milk sampled to comply with the pH standard).
- An **index** is a set of related indicators that allows systematic comparisons of performance across programs that are similar in content and/or with the same goals and objectives (e.g. the Women’s Empowerment in Agriculture Index).
- A **standard** is an agreed way of doing something. It provides rules, guidelines or characteristics for activities or for their results. Standards may apply to food products, test methods, codes of practice or ways of managing.
- An **instrument** or tool is a testing device for measuring a phenomenon. It includes anything used to collect data such as questionnaires, guidelines for observation, thermometers etc.
- The term **metric** originally referred to a scale or standard against which something was measured (e.g. a measuring rod). This use has been extended to methods of measuring (e.g. patient admission sheets) and to measures (that is, the results of measuring something) themselves (e.g. number of patients treated per month). Metric is less commonly used to specifically refer to a derivative of two or more measures (e.g. cost per patient). In this paper, we will restrict its use to methods for measuring as opposed to measures or indicators.

1.4 Measuring foodborne disease in research and practice

Health measures and metrics have been mainly developed for use in health implementation, that is, in the delivery of health services. They are also important in the implementation of development projects, especially while donor and national government investment is directed at improving health. Health businesses employ business-related measures (e.g. those related to productivity and profitability). Most health-related measures and metrics have been developed and most widely used in HIC. While few measures and metrics are specific to research, most can and have been applied to the conduct of research into different aspects of health in HIC and LMICs. Measures and metrics can also be applied to the act of research itself rather than the questions researched. The most important of these are bibliometrics, or statistical analyses of written publications. Related methods for understanding research evaluation and measurement of scientific productivity include informetrics, scientometrics, webometrics/cybermetrics, patentometrics and altmetrics (UNESCO 2015). This paper, however, focuses on measures and metrics related to conducting health research and not those for analysing research products.

Some broad principles for understanding food safety include:

- Food safety has different aspects that are measured in different ways using different metrics. Some of these aspects include food itself (e.g. use-by date as an indicator of when food is safe to consume; bacterial counts), FBD health burden (e.g. campylobacteriosis incidence), FBD management (e.g. number and cost of recalls; number of food inspectors), the health system (e.g. cost of hospitalization from FBD) and the agri-food system (e.g. coverage of vaccination against salmonellosis in poultry).
- In discussing FBD health burden, one important distinction is between measures related to health outcomes (e.g. mortality; cases of illness) and measures related to health determinants or influencers of health (e.g. access to safe food; awareness of FBD; facilities able to diagnose FBD).
- Measures of FBD may be direct, that is, they capture aspects of FBD itself (e.g. illness caused by a specific foodborne pathogen; pathogen content in food) or indirect (also called proxy measures). Proxies are indirect measures, which are not themselves directly relevant to the measure of interest but are strongly correlated to it, and can be used when the measure of interest is difficult to obtain (e.g. diarrhoea from all causes, including foodborne pathogens, is a proxy for diarrhoea due to FBD; sales of over-the-counter medication for specific symptoms are a proxy for cases of FBD; or counts of total faecal bacteria are a proxy for presence of FBD-causing pathogens).
- It is also important to distinguish between food safety and food quality. Food safety ensures that food is fit for human consumption and not injurious to human health and is most often under the competence of veterinary, health or agricultural inspectors while food quality is a market category which is usually the responsibility of food or market inspectors (World Bank 2014).

2 Use of metrics and measures in health and food safety

This section reviews the measures, metrics, tools, definitions and platforms currently used in or applicable to food safety research in LMICs, as well as current gaps and challenges and research opportunities.

2.1 Information on foodborne disease burden in LMICs

While there is abundant literature on health measures, associated metrics and the information they generate, and many are used in research, literature which specifically refers to some or all FBD is scarcer (Table 1). See Annex 1 for general health information sources, relevant but not specific to FBD.

Information relating to LMICs is found in global burden of disease estimates. However, the only FBD-specific estimate, which was developed by the FERG, is acknowledged to be conservative. Moreover, FERG estimates were developed at regional level, relying on available data and expert opinion, and those related to LMICs are likely less accurate. In addition, there are no plans to regularly repeat this assessment. The global burden of disease reports of the WHO and the Institute for Health Metrics and Evaluation have been better funded and are likely more robust. However, they do not systematically cover FBD as they are organized by disease rather than transmission route.

Table 1: Examples of measures of foodborne disease health outcomes

Thing measured	Measures	Metrics	Research application	Reference
Global burden of FBD	Burden of FBD in terms of cases, deaths and DALYs for the year 2011	• Systematic literature review • Algorithms • Expert opinion	• How is the burden of FBD distributed across men and women? • Which countries are FBD hotspots?	WHO (2015)
Regional burden of FBD	Burden of FBD and waterborne disease in DALYs in 2009–13	Reports to the European Surveillance System	What is the burden of FBD and waterborne disease in Europe?	• Cassini et al. (2016a) • EFSA (n.d.)
Global burden of disease studies	Repeated estimates of burden of many important diseases, including some that are foodborne, using a range of mortality, morbidity and health adjusted life year indicators	• Surveys • Registries • Hospital data • Surveillance systems • Systematic literature review • Statistical models • Expert opinion	• What are the trends in FBD? • Which diseases are responsible for most health burden?	• WHO (2008) • Murray et al. (2012)
National burden of FBD	Annual reports from government bodies One-off or irregularly repeated studies on different aspects of burden	Various	As above	http://www.foodsafety.govt.nz https://www.cdc.gov • Gkogka et al. (2011) • Tam et al. (2014) • Kirk et al. (2014) • Mangen et al. (2014)
Disease burden specific to a single FBD	One-off academic studies on different aspects of burden Summary data regularly or intermittently reported	Mainly systematic literature review	Pathogen-specific As above	• Torgerson et al. (2015) • Schelling et al. (2007) Cystinet, Trichinet

Table 2: Surveys of gastrointestinal disease with estimates of burden attributable to food

Region	Number of acute gastrointestinal illness cases per year (self-reported)	Proportion of cases attributed to food	Reference
China (representative)	0.6	36%	Chen et al. (2013)
Hong Kong	0.9	45%	Ho et al. (2010)
China (Gansu)	1.2	86%	Sang et al. (2014)
Bermuda (population)	1	29%	Government of Bermuda (2012)
India (28 states)	At least 3.2	N/A	Vemula et al. (2016)

We could not find any examples of publicly available information on FBD published annually by LMICs. There are compilations of FBD data from national statistics in grey and published literature (Ombui et al. 2001). However, these suffer from major under-reporting bias, which is often not acknowledged or discussed in the report; typically, official sources report hundreds or thousands of cases of FBD per year although it is almost certain that millions occur. A few studies have attempted to estimate the possible extent of under-estimation. For example, in Gansu in China, there were an estimated 30 million cases of acute gastrointestinal disease but only 400 cases reported to the official system, and in Malaysia, less than 0.1% of FBD cases are officially reported (Gurpreet et al. 2011; Sang et al. 2014). When notification data are scarce or unavailable, as is the case in most LMICs, alternative methods can be useful, such as capture-recapture studies, returning traveller studies, analysis of attack rates and serological studies (See Annex 3).

There are few comprehensive, systematic research studies of FBD at national level from LMICs, and those which do attempt to estimate FBD at national level often rely on heroic extrapolations or on expert opinion (ILRI 2011). Surveys on self-reported gastrointestinal disease are much more common, although most are specific to a study site and many are not probabilistically sampled, making it difficult to generalize to national level. A minority of studies include questions on attribution or perceived cause of the illness (Table 2); these can serve as a proxy for FBD. However, it is not possible for people to reliably indicate the source of their illness.

What cannot be measured will not be well managed and studies on burden are essential for prioritization and appropriate investment. Some general lessons from the literature on assessing the health burden in LMICs are:

- Prioritization of diseases by burden has proven to be a powerful tool for influencing investment.
- Health burden by itself is not a justification for investment and additional information is needed on the costs and benefits of interventions to prioritize investments.
- Estimating FBD burden is complex and expensive and there are relatively few studies.
- Official reports nearly greatly under-estimate disease burden and need to include a multiplication factor to account for this.
- Single disease studies are prone to over-estimate disease burden and burden estimates should ideally be made across multiple diseases.
- Especially in LMICs, there are few systematic longitudinal (or repeated) studies that allow monitoring of trends over time.

2.2 Metrics and measures for food safety

Given the growing evidence for an enormous burden of FBD in LMICs, yet the extreme scarcity and unreliability of information about the extent of the burden, its consequences and how it can be best managed, it seems safe to conclude that metrics and measures for better understanding FBD are important. However, while our review found abundant literature on health indicators and their measurement, we did not find any reviews specific to food safety measures and metrics, nor did we find any widely accepted consensus on which health metrics should be used for understanding food safety. In making suggestions and recommendations, we consider metrics and measures under three rubrics:

1. Food safety in terms of hazards present and risk entailed
2. FBD outcomes, especially health and economic burden
3. Food safety system performance

Much of this information is drawn from HICs, where understanding food safety has been a greater priority and is more advanced. Therefore, we discuss in light of its applicability to food safety and food safety research in LMICs as well as the implications for food safety research.

2.2.1. Food safety standards, measures and metrics

Recapitulating from the first section, food safety measures are concerned with those aspects of food which lead or contribute to it being more or less safe for human consumption. Metrics are the methods used to measure these aspects. Food safety measures and metrics are discussed under three headings: relating to public food safety, private food safety and export food safety.

Public food safety standards, measures and metrics

Public food safety standards are enacted to protect consumers' health by assuring safe food as well as to eliminate fraudulent practices. Food legislation has typically been designed to set a minimum standard (or agreed level) of safety and quality that society finds acceptable. Historically, many food standards were hazard-based, specifying that a hazard should be absent according to a specified testing method or below a certain maximum permitted level. A variety of microbiological, chemical and physical methods are used to identify and quantify hazards in food, and the field is rapidly advancing due to research innovations. Table 3 gives examples of hazard-based standards along with the indicators and metrics.

Hazard-based approaches are still used for some food safety problems. For example, because very small amounts of allergens can trigger reactions, a hazard-based approach is often suitable for allergens, with many countries requiring mandatory labelling (Barlow et al. 2015). However, as analytical methods have become more sensitive, and as realization has grown that many hazards have a threshold level below which no effect was detectable (or even beneficial effects may result), it is increasingly realized that risk-based approaches are more useful for managing most hazards. As a result, food safety risk analysis has formalized and emerged as the best way to assess links between hazards in food and actual risks to human health. Risk analysis is a structured decision-making system comprised of three highly interrelated components: risk management, risk assessment and risk communication. A listing of some commonly used risk measures, metrics and indicators is given in Annex 2.

Recent decades have seen a growing convergence of official national standards. Varying standards may raise concerns that some consumers are not optimally protected as regards to health and standards can be an unnecessary barrier to trade (because countries could refuse to trade with other countries which had different standards, even if the health implications of the standards were not different). As a result of these concerns, the Food and Agriculture Organization of the United Nations (FAO) and WHO established the CAC jointly in 1962. Its mandate was to address safety and nutritional quality of foods and develop international standards to promote trade (CAC 2006). Its role was set to establish a broad range of international food safety and quality standards, codes of practice and guidelines for use by member countries, which are either taken up in national legislation or referred to in setting national food laws. The CAC establishes standards for maximum levels of food additives, maximum limits for contaminants and toxins, and maximum residue limits for pesticides and veterinary drugs.

At national level, government food safety systems monitor compliance with official standards through food inspections. This can involve inspecting premises, evaluating Hazard Analysis and Critical Control Points (HACCP) plans and their implementation, sampling food, and identifying food products unfit for consumption and removing them (FAO/WHO 2006). These activities generate data which may be made publicly available, be made available in an aggregated form or not released. Laboratory systems are needed to support sampling and analysis.

Traceability is generally defined as the ease with which a product can be traced throughout the supply chain, from farm or point of production to the end user. Good traceability is necessary for product recall but it also supports verification of food authenticity and integrity as well as responding to consumer desires to know more about food origin and processing. Traceability aids risk-based targeting of surveillance and improves understanding of the agri-food system. Conventionally, traceability relies on record-keeping and documentation but new metrics include DNA analysis, protein analysis, enzyme-based methods, mass spectrometry, spectroscopy, isotopic analysis, microbial ecology and chromatography. These can identify geographical origin, composition, species and strain (Cifuentes 2012).

Public food safety standards in the context of LMICs

Where 5% of food does not meet the standards, there is a problem with food; where 95% does not comply, there may be a problem with standards (Blackmore et al. 2015). Surveys from LMICs typically find that significant amounts of food do not meet the standards. For example, pork in Nagaland state in India was tested for common hazards and only 6% of samples complied with standards; only 2% of meat samples tested in Ibadan city in Nigeria complied with standards; milk in Assam state in India was tested and none of samples complied with standards (Grace 2015a; Grace 2015b).

The issue of food standards in LMICs is complicated and some of the aspects to consider include:

- LMICs often adopt standards from HICs with little adaptation to local context. The growth in standard harmonization and exports and donor investments encourages this arguably premature adoption of standards.

Table 3: Examples of hazard-based food safety standards, indicators and metrics

Standard	Indicator	Metric	Authority
Coliforms (a type of bacteria) in milk	No more than 10 colony forming units in 100 ml	Microbiological culture	East African Community
Chloramphenicol (an antibiotic) residues	0.3 micrograms per kilogram	Enzyme-linked immunosorbent assay or gas chromatography	European Union

- Standards can act as a barrier to participation in both export and high-value domestic markets, tending to exclude women, small-scale farmers and other less privileged groups. However, these barriers can often be overcome with appropriate policies and investments (Humphrey 2017).
- Standard setting in LMICs typically does not consider feasibility of standards; it is commonplace to acknowledge a huge gap between policy and implementation.
- LMICs typically have little capacity to enforce standards especially in informal, domestic markets and make little use of other approaches to improve compliance (e.g. approaches based on incentives or behaviour change communication).
- Standard setting in LMICs typically does not consider trade-offs between meeting standards and other goals (e.g. if all food not meeting standards was destroyed then food and nutrition security would suffer).
- Standards can also have unintended governance consequences, such as being used by formal firms to discourage competition from the informal sector, being used as income generation for poorly funded authorities (e.g. municipal authorities who require payments for licences but do not provide adequate services) or encouraging extortion and rent-seeking from enforcement agents (e.g. police who confiscate equipment of traders and only release it after an unofficial payment is made).
- In general, traceability is not a feature of food sold in the informal markets of LMICs. The logistical problems of traceability are far higher in LMICs, given the large number of actors, the relatively small volume of goods handled per business, the lack of formal organization, the typically low-trust environment, the presence of disincentives for traceability (e.g. traceability is often linked to paying fees) and the absence of incentives for traceability (e.g. price premiums).
- A recent study using a tool to assess traceability assessed 21 Organisation for Economic Co-operation and Development (OECD) countries (Charlebois et al. 2014). European countries ranked highest; Australia, New Zealand, the United States of America (USA), Canada, Japan and Brazil ranked average; and China ranked poor.

How research can help optimize issues related to public food safety standards

Risk analysis has been officially adopted by most LMICs but their ability to implement it is very limited. Conventional risk analysis is often expensive and time consuming and requires considerable amounts of data (e.g. attribution data for exposure assessment) and quantitative analysis. In most LMICs, risk analysis is not used in setting standards or regulations for food sold in domestic markets. Most development, LMICs government and private sector efforts to build capacity in risk analysis have focused on the export sector or formal private sector. Research has played a role in better adapting risk analysis methods, measures and metrics to LMICs. Over the past 10 years, the International Livestock Research Institute (ILRI) has led a program to build capacity in risk analysis for academics and food safety implementers in LMICs. Activities have included short trainings, postgraduate scholarships in risk analysis, producing guidelines and manuals, publishing case studies and introducing risk analysis into curricula. In addition, an approach has been developed which builds on the core concepts of risk analysis and combines them with proven development analytic methods such as participatory rural appraisal and gender analysis, which has been called ‘participatory risk analysis’ (Grace et al. 2008).

Given that national official standards are often not aligned to the reality of LMICs, economists have suggested that LMICs should create more adapted domestic and regional standards and that there should not be a single official standard but a range of options, which would provide an upgrading pathway for food producers and handlers (Humphrey 2017). Research is needed to address concerns that these approaches would have unacceptable health or equity consequences and efforts for improving LMICs capacity for standard meeting would help make better use of these strategic options.

In practice, official standards are often less important than private standards. Generating a pluralistic understanding of standards could help address the discrepancy between standards and reality, prominent in many LMICs. This would be supported by measures and metrics, which support more holistic measures related to food safety, which include associated spillover benefits and costs.

Private food safety standards, measures and metrics

Private standards are playing an increasingly important role in domestic formal markets and ‘informal private standards’, i.e. non-codified norms, are the de facto way that much informal food is marketed (e.g. there is a societal expectation that milk vendors will not excessively adulterate products and that customers will continue to patronize sellers who provide good products). The main drivers for the proliferation of private food safety schemes have been the assignment of legal responsibility to food chain operators for ensuring food safety, increasingly global and complex supply chains and increasing consumer concerns about food safety (Clarke 2010). As a result, the formal large-scale agriculture and food processing industry (sometimes called ‘Big Ag’ and ‘Big Food’, respectively) has an elaborate, well conceptualized and generally well managed set of methods, tools and metrics.

Historically, food safety assurance by private firms was mainly hazard- and process-based; HACCP is a keystone to these methods. Recent years have seen these essential measures and metrics complemented by the development of a strong interface with risk-based approaches, aligning well with the international trade community. There is little doubt that food sector innovations have been extraordinarily successful in feeding large numbers of people with relatively safe and nutritious foods at low cost, and that private measures, metrics and standards have contributed to this. At the same time, there are many concerns over the possible health, social and environmental impacts of modern agri-food systems (Fox et al. 2018).

Private food safety standards in the context of LMICs

Multi-national companies operating in LMICs and (to a lesser extent) the domestic formal sector apply similar private standards to those prevailing in HICs. However, there are typically fewer checks and balances that help assure the relatively high safety standards of food sold in HICs. For example, in many LMICs, it is hard to identify the source of a FBD outbreak and legal systems are not suited to obtaining redress for victims of FBD. At the same time, the challenges of attaining food safety presented by poor infrastructure and production practices are more acute. It is not surprising that food sold by the formal sector is not always or necessarily safe.

Moreover, most food continues to be sold in informal, traditional or wet markets. There have been few attempts to implement systematic, comprehensive FBD assessment or management in the informal sector and hence there is little information on the use of measures and metrics outside of case studies and research projects.

How research can contribute to optimizing issues associated with private food safety standards

Even in HICs, small and medium firms find it difficult to comply with complex and technocratic rules, measures and metrics that are characteristic of HACCP and risk-based approaches and these methods are hardly applicable to the great majority of enterprises in LMICs (Taylor 2001; Taylor 2008). The same applies for traceability, which, despite many efforts to promote it, appears only attainable in niche, high-value markets in LMICs. There have been research efforts to adapt HACCP for small firms in the United Kingdom (UK); these types of approaches would be even more useful in LMICs (Taylor 2008).

Research can help develop measures and metrics to systematically capture the negative externalities of the formal and informal food sectors. Some hold that modern agri-food systems undermine rural communities, are anti-poor and contribute to poor nutritional outcomes by promoting consumption of highly processed food with excessive sugars and oils (Fox et al. 2018). Interest in local foods, organic foods, non-genetically modified and antimicrobial-free foods may reflect a lack of trust in modern agri-food systems as well as a poor understanding of risk. While often motivated, at least partly, by safety concerns, there is little evidence that these are safer, and the lack of good measures of food system externalities may lead to decisions that are less than optimal.

Risk communication has been under-researched in LMICs. In general, members of the public, and even decision-makers, do not distinguish well between risk and hazard, and their perception of risk is prone to many biases, making it difficult to convey objective, science-based evidence. Although there has been considerable research on the psychology of risk perception, there is much less on how to correct misperceptions.

Export-orientated food safety standards, measures and metrics

Overall, international trade in food is trending strongly upwards and economists consider that while there are winners and losers, trade is generally beneficial to net global welfare. Official international trade in food is governed by a clear and agreed array of rules, standards, guidelines and authorities under the World Trade Organization, established by the Uruguay Round of Multilateral Trade Negotiations in 1994. Under this, the CAC has a major role in the formulation and standardization of international standards.

Food safety has implications for trade and vice versa. Increased food trade may introduce new food safety hazards, revive previously controlled risks and spread contaminated food widely. On the positive side (at least from a health perspective), food that is legally imported from HICs into LMICs is usually of high safety levels and may indeed be safer than food sold on the domestic markets (Hawkes et al. 2015).

Information from food importers and exporters is a good indicator of the safety of products traded and an indirect indication of the safety systems and performance in exporting countries. Examples of trade metrics include import rejections, records of administrative actions in importing countries (e.g. bans) and reports from exporting countries of problems related to food safety.

Rejection data are the most comprehensive indicators available for the safety of food exported from LMICs. The Rapid Alert System for Food and Feed shares information among European food safety authorities. Information from Japan (www.mhlw.go.jp/english/topics/importedfoods/) and the USA (www.accessdata.fda.gov/scripts/importrefusals/) is also available. The latter is operated by the Food and Drugs Administration, which is responsible for controls on food products (except for poultry and meat, which are the responsibility of the Food Safety Inspection Service of the United States Department of Agriculture).

Export trade, metrics and measures in the context of LMICs

Exports of high-value and more risky foods from LMICs are growing faster than exports of traditional agricultural products. At the same time, export is dominated by a small number of countries and the poorest countries tend to export little and be net food importers. Increasing populations, especially in Africa (the United Nations estimates that the population of Africa will be 4 billion by 2100), may aggravate this trend.

- Substantial and increasing food exports from some LMICs indicate standards with associated metrics and measures have not been an insurmountable barrier. However, compliance and verification have costs and trade-related standards and the measures and metrics they require generally appear to have adversely affected exports from LMICs (Unnevehr and Ronchi 2014).
- Some countries are consistently better compliers (Argentina, Chile, Ecuador and South Africa) and some are consistently worse (China, India, Thailand and Vietnam) (Henson and Olale 2011).
- Although smallholder farms can have higher productivity than large farms and be part of high-standard export chains without support, this is not always the case; moreover, these chains at best involve only a small number of smallholders (Humphrey 2017).

- There is general agreement that the complex architecture of international trade favours exporting HICs and the minority of LMICs with substantial food exports (e.g. Brazil, China and India). Many LMICs are not able to fully participate in rule making for international trade.
- There are also cases where detection of hazards in exports alerted authorities and researchers to previously unknown hazards present in domestic markets. For example, high levels of toxic chemicals were discovered in smoked fish exported from Côte d'Ivoire to France, leading to improvements in local production (Roesel and Grace 2014).

How research can help optimize food safety issues for international trade

While the benefits of global trade are well captured by economic and food security measures, data on the health risks are less available. However, trade is linked to an increase in non-communicable diseases associated with increased consumption of soft drinks and fast foods (Hawkes et al. 2015). This has been documented in cases studies such as the obesity crisis in Tonga (linked to consumption of high-fat imports) and the nutritional transition in Central America (Thow and Hawkes 2009). Better understanding of the nutritional risks of trade requires research into trade flows as well as behaviour around food consumption.

Although, as mentioned, good data exists on import rejections, there is less information on the value of products rejected or their destination after rejection. There is concern that foods rejected from more fastidious countries may end up in other markets, and there is some evidence this happens; for example, milk powder contaminated with melamine in China appears to have reached other markets (Schoder 2010).

Research can also provide more insight into barriers to participating in trade and the importance of standards. Although there are estimates of the cost of trade barriers, the methods are not always standardized, and the approaches have been questioned for not considering other barriers to accessing high-quality markets (such as endemic disease, management capacity or competitiveness) (Rich et al. 2009). For example, an influential prospective study that argued new European Union legislation on aflatoxins would seriously impact African exports while having little benefit on the health of Europeans (Otsuki et al. 2001). Subsequent research, however, found that changes in standards were not decisive in influencing exports (Diaz Rios and Jaffee 2008; Xiong and Beghin 2012).

In response to concerns over trade equity, 'Fair Trade' initiatives have grown rapidly in recent decades. These initiatives design and monitor voluntary standards that aim to improve the wellbeing of producers and offer some assurances that products are safe and ethical. There is some evidence that these provide benefits to producers and consumers, although there are some concerns over the distribution of benefits and the effects of market distortions (Dragusanu et al. 2014; Krasnozhon and Levendis 2015). A separate concern is that certifying bodies stand to lose business in the case of a negative finding, and so are not truly independent. A recent systematic review found mixed, but overall limited, evidence for substantial impacts and the need for further research with better use of methods (Oya et al. 2017).

There is interest, but little conclusive evidence, in the possibility that complying with export standards could have spillover benefits to domestic markets by improving capacity of regulators and value chain actors. Further research is needed to clarify actual benefits as well as options for implementing export standards, measures and metrics in ways that might have more spillover benefits.

2.2.2. Foodborne disease outcome measures

Burden measures are concerned with the outcomes of unsafe food in terms of human health burden, economic cost or other considerations.

Public health outcomes

In HICs, most public health systems have developed surveillance systems to detect and monitor health outcomes from FBD. Public health measures and metrics are given in Annex 3. Information can be collected at different levels: health service institution, community or national population. Because these systems commonly rely on people seeking treatment in the health service, there is widespread under-reporting of FBD, the so-called 'tip of the iceberg' or 'eyes of the hippo' effect. As discussed previously, under-reporting is much more of a problem in LMICs. Misdiagnosis is also a major problem and studies find evidence for both under- and over-diagnosis of FBD (see Thakur et al. [2002] for the former and de Glanville et al. [2017] for the latter in the case of brucellosis, which is commonly transmitted through consumption of milk or cheese). Systems for FBD surveillance include

- Pathogen-specific passive or enhanced passive surveillance: for example, in the USA, healthcare facilities and laboratories report individual cases of disease when selected notifiable pathogens, such as Salmonella enterica or Escherichia coli O157:H7, are identified in specimens from patients. Further testing can provide information on origin and spread.
- Complaint systems: Healthcare providers or the public identify and report suspected disease clusters (group notifications) or individual complaints. Exposure information is acquired by interviews with cases.
- Outbreak management refers to the measures taken to protect public health by identifying the source of infection and implementing control measures to prevent further spread or recurrence.
- Syndromic surveillance: systematic (usually automated) gathering of data on non-specific health indicators that might reflect increased disease occurrence, such as purchase of

antidiarrhoeal agents, visits to emergency departments for diarrhoeal complaints, search behaviour on internet search engines etc.
- Active surveillance: for example, FoodNet conducts telephone surveys (https://www.cdc.gov/foodnet/surveys/index.html)

Information technology, such as the internet, mobile phones and satellite data, is giving rise to novel approaches for detection and surveillance of disease outbreaks, sometimes called 'infodemiology'. In general, these methods have good congruence with traditional approaches and combining information from multiple data sources can result in better estimates (Santillana et al. 2015). They are especially suitable for seasonal diseases (including many FBD) and diseases with short incubation periods. Ways of gathering information through infodemiology, some of which have been applied to food safety, have included search query data (including for gastroenteritis) (Pelat et al. 2009); clinicians' search engines; crowd-sourced participatory disease surveillance; online news reports; microblogs (Twitter); social media data (Facebook); reduction in online restaurant reservations (Nsoesie et al. 2014); hospital parking lot traffic data extracted from high-resolution satellite imagery (Nsoesie et al. 2015) and over-the-counter medicine sales (Magruder 2003).

Public health measures and metrics in the context of LMICs

A major challenge in LMICs is that only a small and unknowable fraction of FBDs is reported. Many victims go untreated or get treatments from unqualified people. Even if treated at a hospital or clinic, there is often no collection of a stool sample for laboratory examination. When laboratory tests are required, they may not cover all potential causes. In many (sometimes most) cases, no pathogen is identified. Even if a pathogen is identified, it is not possible to know where the pathogen came from without further investigations (e.g. finding a genetically identical pathogen in food) or evidence (e.g. multiple people reporting eating the same food before becoming ill). Another challenge is assessing the burden of FBD due to manifestations other than gastrointestinal illness (especially chronic manifestations, e.g. acquired epilepsy, meningitis, ocular syndromes etc.). In HICs, this is responsible for about half the overall burden. In LMICs, there is little information or ability to collect evidence on this.

Although DALYs provide an extremely useful tool for comparing disparate diseases, prioritization and monitoring, they are not immediately intuitive and the various refinements added at different times (discounting etc.) are a further barrier to understanding. The most problematic aspect of the DALYs is the subjective weight assigned to the disutility of being ill; especially for diseases which are very common, small changes in weighting can have large effects on the overall burden and this is not transparent to the users of DALYs. Weights have been assigned by experts and assessed by surveys of people with and without the condition being weighted but all these methods have some problems. A benefit of the DALY, in that it 'makes all diseases equal', can also be a disadvantage. There is an economic argument for distinguishing between contagious diseases for which state intervention often delivers benefits many times the cost of intervention and benefits are captured by others than the victim (e.g. vaccination, stopping a pandemic) and non-contagious diseases where the intervention may only benefit the victim (e.g. treatment for diabetes). There is also an argument that when resources are scarce, contagious diseases should be prioritized for public investment. Likewise, diseases are increasingly due to risky behaviours that are at least partly driven by choice and from which people may derive enjoyment or utility (e.g. diseases linked to consuming excessive amounts of food or alcohol). Some might argue that public investments should prioritize those DALYs that are not lifestyle-related but are the result of something which did not bring any offsetting benefit (e.g. infectious disease). Similarly, the public and policymakers often prefer to prioritize less common diseases with high mortality over more common diseases with lower mortality, even though the burden in DALYs may be the same.

The FERG study depended on algorithms and expert judgement where empirical data were lacking, resulting in uncertainty. Moreover, a conservative approach was taken to estimates. In addition, only a limited number of hazards were considered and FBD of unknown aetiology was not included. Comparing FERG estimates with those from countries with good health data, we see that while FERG estimates were 9.2 million cases of FBD in the USA, Canada and Cuba in 2010, official figures suggest 52 million annual cases in the USA and Canada around the same time (Scallan et al. 2011; Thomas et al. 2013). On the other hand, a regional burden of disease study for Europe, based on relatively good reporting, found a slightly lower burden to all comparable FBD (19 DALYs per 100,000 population in the European study versus 27 in the FERG study) (Cassini et al. 2016). There is also a disconnect between inductive risk-based approaches that predict illness from exposure and deductive public health-based approaches that measure illness and then look back to predict cause. Anecdotally, risk-based predictive methods seem to generate higher estimates than retrospective public health methods. The FERG study estimates that 46% of the overall burden was related to manifestations other than gastrointestinal disease, which is compatible with other estimates that around half the total burden of FBD is due to non-gastrointestinal illness (Gkogka et al. 2011). However, the FERG study did not include some known and potential burdens (e.g. the effect of FBD on stunting or the mental illness associated with toxoplasmosis infection).

How research can contribute to better public health measures and metrics

Methods and approaches: There are different methods that can help identify the source of infection, the most useful being sequencing of pathogen genomes and linking these with transmission, but these techniques are not routinely used in LMICs. Drawing from development, rather than public health, may help fill this gap (Box 3). Moreover, because HICs have been very successful in tackling most infectious diseases, FBD are relatively more important and of concern because they are not trending downwards, while in LMICs, FBD are just one of many infectious disease problems, some of which get considerably more attention. Although information infrastructure is limited in LMICs, there is much interest in using information and communication technology in health. In the 2010 cholera outbreak in Haiti, HealthMap and Twitter estimates correlated well with official case data and were available up to two weeks earlier (Chunara et al. 2012). Another retrospective study in Haiti found the risk of epidemic onset of cholera in a given area and the initial intensity of local outbreaks could have been anticipated during the early days of the Haitian epidemic using case reports and the mobility patterns of mobile phones (Bengtsson et al. 2015).

Metrics: The DALY is likely to remain a key metric in understanding the health impacts of FBD in LMICs. However,

research can help in building capacity in its use and acceptability and in addressing ethical questions around its use. The FERG report was a major breakthrough in understanding FBD in LMICs but the methods used will require continued development and refinement.

Information: Country-level studies on the health burden of FBD would generate buy-in and improve national prioritization. Experience from the Global Burden of Disease studies suggests that estimates of FBD are most useful if repeated on a regular basis, allowing monitoring of trends and stimulating continued interest by food safety investors. More information is needed on hazards of known high importance, which were not included (such as Staphylococcus aureus), as well as hazards of high concern but where evidence on impacts is scarce and difficult to obtain (such as pesticides in food).

Economic outcomes

These can be divided into (a) the harm caused by the disease (e.g. lost productivity from illness), (b) the cost of response (e.g. treatment; food recalls) and (c) the cost of prevention (e.g. food safety governance; risk-reducing practices) (Shaw et al. 2014). Alternatively, costs may be allocated to different actors (consumer, healthcare, agro-food industry, government) (McLinden et al. 2014). Zoonotic diseases often exert additional burdens on the livestock sector and it is important that estimates of costs cover multiple sectors. Two frameworks for categorizing costs of FBD are given in Annex 4.

Economic measures in the context of LMICs
Economic information on FBD from LMICs is even more lacking than health information. Most work has been conducted on trade issues and costs of compliance, and a relatively substantial literature exists (Unnevehr and Ronchi 2014; Humphrey 2017); however, this covers only a small proportion of food produced and has little relevance to FBD in LMICs. Some studies assess economic burden of specific FBD hazards, either nationally or for a region. Fewer studies address the costs of FBD as a category. Almost no literature exists on the cost-effectiveness or cost–benefit analysis of different interventions to improve food safety in domestic markets of LMICs. Lack of information on economic costs is often cited as a major reason for lack of prioritization by decision-makers.

How research can contribute to better economic measures and metrics
Even in HICs, the different methods chosen and costs considered as well as gaps in data result in estimates that differ by billions of dollars for some countries. Simplified and comparable methods for assessing economic costs of FBD in developing countries would be helpful. There is little information on the costs and cost-effectiveness of different options for reducing FBD. This information, which has been developed for other diseases such as malaria, would be a useful guide for policymakers and investors.

2.2.3. Food safety performance metrics

Food laws can be traced back to the earliest civilizations and can be found in most legal codes. During the late 19th and early 20th centuries, a general consolidation of food control took place, as well as the creation of a separate branch of law relating to foods (Lásztity et al. 2004). In European colonies and formal colonies, early legislation was often drafted on the basis of the law and the administrative system operating in the colonial power (WHO 2005). In southeast Asia, both concerns over food safety and modern food control were introduced relatively late (1940s to 1960s) (Jussaume et al. 2000; Rimpeekool et al. 2015), but food safety is now an important societal issue (Grace and McDermott 2015).

Performance metrics measure how well the food safety system delivers safe food. Performance indicators can help show progress against plans in the results chain, i.e. input, process, output, outcome and impact. Metrics for impact indicators (e.g. longevity or age at death) are closest to measuring the performance of the system but may be more difficult to collect and as they are usually the result of many factors, they may be difficult to interpret. Metrics for indicators at other levels (output, outcome) are easier to collect and interpret; they are more actionable but may be easier to manipulate (Smith et al. 2008).

Performance can be measured in different dimensions or aspects. Health systems have often been measured in terms of effectiveness, efficiency and equity (Reinke 1994), and even more complex conceptual frameworks often subsume these pillars (e.g. the OECD framework). The 3E framework asks whether the health system is effective (Does it produce desired outputs, outcomes or impact?), efficient (Are inputs wisely used to secure goals? Is there avoidable waste?) and equitable (Is it fair? Is it reaching certain beneficiaries or addressing specific health needs?). Other performance domains such as continuity, environmental sustainability or responsiveness are used in some health systems. Our review found only three approaches to assessing food safety system performance at a multi-national level.

1. The most systematic and transparent was that developed by Safe Food Canada (Box 4) and applied to a number of OECD countries. Based on the 10 food safety performance metric benchmarks assessed in this study, Canada, Ireland and France earned top overall grades in food safety performance. The UK, Norway and the USA made up the remaining top-tier countries. A4NH is currently adapting this tool for use in LMICs.

Box 3: Novel approaches to assessing foodborne disease applicable to low and middle income countries

Participatory epidemiology (PE) is the application of participatory methods to epidemiological assessments. Participatory disease surveillance (PDS) is a form of active clinical surveillance. It involves the use of participatory approaches and is aimed at detecting clinical cases, which can then be confirmed by specific biological tests. ILRI has been involved in researching and supporting PE and PDS for over a decade. A recent review (Allepuz et al. 2017) inventoried PE/PDS and found PE activities were being conducted in 52 different countries in LMICs.

HealthMap is an automated surveillance platform that continually identifies, characterizes and maps events of public health and medical importance, including outbreaks and epidemics. Information sources include news media sources and discussion groups as well as data from the community through the 'Outbreaks Near Me' mobile phone application, wherein any user may contribute reports via their phone, and online contributions on its website.

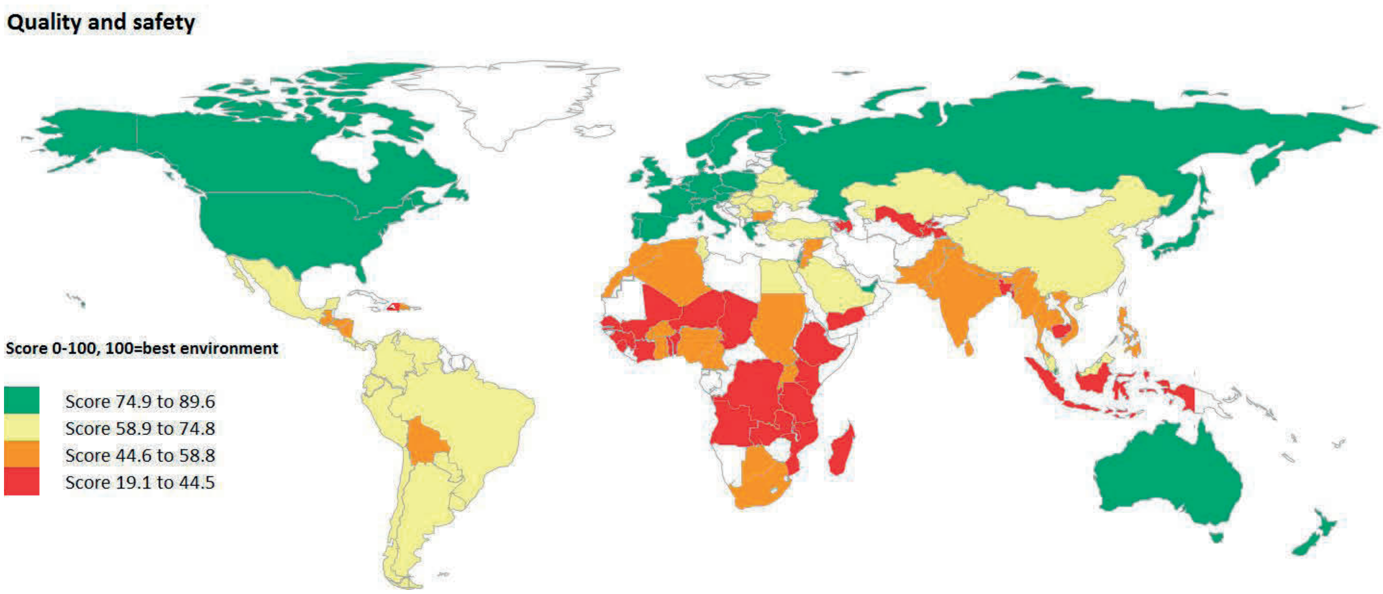
2 The Economist Intelligence Unit includes a food safety indicator in its annual Global Food Security Index but it is limited to three indicators that are only weakly associated with food safety outcomes (existence of an agency to ensure the safety of foods, access to potable water and presence of a formal grocery sector) (EIU 2016). Nonetheless, it provides a qualitative assessment of food safety. Safety is combined with four food quality measures—diet diversification, nutritional standards, protein quality and micronutrient availability—into a 'Quality and Safety Index'. In 2016, the best 27 performers were all HICs (led by Portugal, France, USA, Australia and Greece) (Figure 1).

3 The global food source monitoring company Food Sentry created a ranking on the number of food safety violations exporting countries had in 2013. The incident data were gathered from multiple sources, including the USA, the European Union and Japanese regulatory entities, and covered most countries with substantial exports. At the top of the list was India, with about 380 of the incidents identified worldwide. China followed with about 340, Mexico with 260, France with 190 and the USA with 180. Vietnam, Brazil, the Dominican Republic, Turkey and Spain rounded out the top 10. More than one-third of them were due to 'excessive or illegal pesticide contamination'. The next main causes of food safety problems were pathogen contamination and excessive filth or insanitary conditions. These figures are strongly influenced by the quantities and types of food exported from each country; taking this into account, India and China remain relatively over-represented.

Food safety system performance in LMICs

Various evaluations have found consistent and systemic problems with food safety systems in LMICs: inadequate policy and legislation; multiple organizations with overlapping mandates; outdated, fragmented or missing legislation; inappropriate standards; lack of harmonization and alignment of standards; failure to cover the informal sector; limited civil society involvement and limited enforcement (Grace 2015a; Grace 2015b).

Figure 1: Qualitative assessment of food safety of 109/193 countries in 2015.[1]



[1] Generated using the 2015 Global Food Security Index model, Economist Intelligence Unit: http://foodsecurityindex.eiu.com/Resources (Accessed on 25 April 2018)

How research can contribute to better food safety system performance

Measures, metrics, tools and indices to assess food safety performance could contribute to better understanding. Many attempts to improve food safety system performance have involved restructuring (with a single agency model often recommended) and research is needed into the optimal architecture in LMICs. The much-discussed gap between legislation and implementation requires multi-disciplinary research which brings insights from institutional and behavioural economics, political economy and sociology.

Box 4: Benchmarking of food safety performance by Safe Food Canada

The 2014 World Ranking – Food Safety Performance report took common elements of global food safety systems and compared them objectively. During a food safety metrics workshop held in Helsinki in 2011, the working group examined benchmarking metrics and debated the collection of data. This session was a first international meeting of its kind. Together, as a group of experts from 17 different countries, they were able to come up with 10 indicators to update a previous set of indicators that was more subjective in scope. Consensus and appreciation of multiple perspectives from around the world were vital for identifying these 10 indicators, categorized within three risk governance factors:

Risk assessment

1. Pesticide use (chemical risk in agricultural production)
2. Total diet studies (reporting of chemical food hazards)
3. Foodborne illness rates (microbial risk)
4. National food/dietary consumption studies

Risk management

5. National food safety response capacity
6. Food recalls
7. Food traceability
8. Radionuclides standards

Risk communication

9. Food allergies (allergenic risk)
10. Public trust

Source: Le Vallée and Charlebois (2014)

3 Measures and metrics: caveats and best principles

3.1 Metric manipulation

It is a truism that '*what cannot be measured cannot be managed*' but it is also commonly noted that '*you get what you measure*' and that '*meeting the target can lead to missing the point*'. Health measures, based on appropriate metrics, can support rational resource allocation, enhance accountability, facilitate comparison, help in monitoring progress and exert pressure to improve performance. At the same time, they can be prone to manipulation and their implementation may entail more costs than benefits. While metrics are considered key to monitoring and improving performance, they can also have unintended consequences, including focusing efforts on the thing to be measured rather than the ultimate goal of improving the thing being measured; stifling innovation through standardization; costs that increase in disproportion to benefits attained; incentivizing perverse behaviour to game metrics and decreased attention to things that are not measured (Bardach and Cabana 2009). In LMICs, metrics or our ability to measure things cheaply and accurately can introduce new incentives that have unintended consequences (Box 5).

Box 5: Unintended consequences of measures intended to improve public health

The 2008 Chinese melamine milk scandal was one of the largest of recent decades. Milk and infant formula were adulterated with melamine, a toxic industrial chemical. At least 300,000 Chinese children were affected and at least six died. Melamine was added to milk to increase the protein content and comply with standard tests. These tests estimated protein levels by measuring the nitrogen content so could be misled by adding nitrogen-rich compounds such as melamine. The incentive to comply with these tests followed directly from a renewed emphasis on minimum protein standards for infant formula after at least 13 babies died and over 200 were made ill from malnutrition after consuming diluted milk products in 2003.

Source: Ross (2012)

3.2 Best principles for developing measures and metrics

Bearing in mind the challenges of measures and associated metrics, and drawing from the broader literature on research metrics (Butler 2010; Hicks et al. 2015; Wilsdon et al. 2015), some principles relevant to appropriate design of food safety measures and metrics might include:

- A strategic plan must precede the development of measures with clear and realizable goals and practical steps for implementation including metrics (method of measurements). It is important to align the measure with the desired goal and communicate the goal not just the measure (e.g. tests are in place to ensure that milk is nutritious, not just that it complies with protein standards).
- When a measure becomes a target, it ceases to be a good measure. While effort is needed in ensuring data are accurate, targets should be designed with the possibility of gaming in mind and avoid using metrics as performance targets. For example, if restaurants are given scores by inspectors for certain hygiene practices (e.g. clean floors; metal surfaces) these may be more emphasized than aspects which inspectors do not directly measure (e.g. length of time food is outside the fridge) but which are actually more important to food safety.
- Food safety is complex and single measures can be misleading, which means that multiple measures are needed to obtain a comprehensive measure that describes food safety. For example, it is not uncommon to find that total bacteria counts are high but specific hazard concentrations (e.g. toxigenic *E. coli*) are low and vice versa.
- Measures should assess outcomes and impact as well as processes. For example, one study found that formal sector outlets had better hygienic practices (e.g. clean hands, protective clothing) but bacteriological counts were worse when compared with informal sector outlets (Fahrion et al. 2014).
- A good measure should be designed in a way that it encourages actions to improve outcomes, such as improved hygiene practices, safe and appropriate use of chemicals in food production and enhanced traceability. A poor measure encourages actions to achieve high scores.
- Consider the context of measures; if large changes outside the control of the agency are occurring (e.g. migration, climate change) then metrics should be interpreted in light of this.
- Measures should be easily understood and accepted by a range of stakeholders and the underlying data should be widely available.
- Measurements have costs and the benefits should be demonstrated to outweigh the costs.

Surveillance is a case in point. Having the surveillance information without a clear idea of what to do with it (which still happens far too often), e.g. which decisions to take or which interventions to inform, is not particularly useful and the surveillance value is limited.

3.3 Metrics and measures: what matters for food safety in LMICs

The approaches and metrics for understanding food safety described previously have mostly been developed in HIC to meet their evolving food safety needs. Based on a series of food safety stakeholder workshops and situational analyses conducted in a number of African and Asian countries, we suggest three aspects of food safety which should be of most interest to developing-country food safety decision-makers, especially government policymakers, development planners, researchers and donors.

- **Impact:** Is this a problem? If so, how big a problem and what are its impacts? What are the trends? Where is this a problem? Who is affected by it? What foods are responsible for the problem?
- **Concern:** Who is concerned about this problem? How will their concerns affect their behaviour? How can their concerns be managed? How can their concerns lead to behaviour or system change? Do concerns align with evidence and risk? How can concerns be better aligned to reality?
- **Management:** How does current food safety management work? What can best be done to improve food safety management? What specific processes/stakeholders are involved? Which aspects need to be managed first? What are the options for management? How effective are they? What are their costs and benefits? Where do these costs and benefits fall? What behaviour change is needed for better management and what are the incentives for this?

Having identified key areas, measures and associated metrics should provide information on:

- Importance of FBD as a health problem in frequency and severity
- High-risk foods, stakeholders, processes, industries or geographies
- Trends in FBD and changes under different scenarios (e.g. urbanization, climate change)
- Relevance of FBD to other areas e.g. trade, nutrition, economic performance
- Differential impacts of FBD e.g. impacts on the poor, children, elderly or HIV-positive patients
- Public attitude towards FBD and how public sentiment affects decision-makers
- Prioritization of FBD
- Options for management of FBD with cost, efficacy and practicability
- Unintended consequences of interventions to improve FBD management
- Incentives for changing behaviour around FBD management
- Enabling environment for FBD assessment and management
- Performance of food safety management systems
- Effectiveness of risk communication

4 Conclusions

Historically, FBD has not been considered a development priority in many LMICs. Assessing FBD in developing countries is not easy for reasons discussed earlier and there is often a perception that FBD is a minor inconvenience and that it is largely unavoidable. This situation has changed in some middle income countries and this trend is likely to continue and extend, in the short term as the result of the publication of the first global assessment of FBD which suggested the burden was comparable to HIV/AIDS, malaria or tuberculosis, and in the long term as consumers become more urbanized and food quality conscious.

As concern over food safety in LMICs ratchets upwards, there is a tendency to promote the measures and metrics that have proven useful in HIC. However, this paper argues that focusing on too narrow a set of measures and indicators can have unintended consequences, and that understanding unintentional consequences as well as the multiple burdens of FBD is key to better managing FBD in LMICs.

Currently, food safety research does not have a consensus toolkit of metrics. Different aspects have well-developed metrics but, in many cases, these are not widely applied or suited to widespread application in the mass markets of LMICs which are responsible for the great majority of cases of FBD. Indeed, it may be argued that the constraint in LMICs is largely a lack of management options, rather than a lack of metrics.

Nonetheless, interest in FBD is increasing and there are likely to be more research and development initiatives in the coming years. Given the context of agri-food systems in LMICs, some of the more promising approaches are those that 'skip a generation of technology'. These include infodemiology, participatory risk analysis, rapid diagnostics and molecular techniques for understanding prevalence and incidence transmission. These in turn will benefit from rigorous evaluation, standardizing of protocols and methods and development of libraries of metrics to be flexibly used in different contexts.

FBD occurs at the intersection of health and agriculture and it is likely that the current fragmented framework of health governance and disconnections between agriculture, health and ecosystems results in systematic under-estimation of the problem of FBD and undermines its management. Greater collaboration among food, water, health and nutrition sectors is needed in the design and use of measures and metrics.

One Health, a broad movement that recognizes that human, animal and ecosystem health are interdependent and that multidisciplinary collaborations are often necessary in order to attain optimum health solutions, offers an appropriate framework for better assessing, communicating and managing food safety in developing countries.

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Annex 1
Information sources for foodborne disease

While there are relatively few initiatives focusing on measuring FBD health outcomes, some more general initiatives to standardize and harmonize health measures and metrics globally or regionally collect measures are potentially relevant to FBD. These include:

- WHO International Health Regulations
- United Nations Inter-Agency Group on Indicators to track progress on SDGs (https://unstats.un.org/sdgs). (Interestingly, the proposed SDG targets do not specifically include FBD).
- World Bank Health Systems Analysis (Bitrán et al. 2010)
- OECD Health Care Quality and Outcomes data (http://www.oecd.org/els/health-systems/health-care-quality-indicators.htm)

Other initiatives, not related to human health, that provide indirect information on FBD include:

- World Organisation for Animal Health (OIE) tool for the evaluation of the performance of veterinary services (http://www.oie.int/support-to-oie-members/pvs-evaluations/oie-pvs-tool)
- OIE's World Animal Health Information System (http://www.oie.int/wahis_2/public/wahid.php/Wahidhome/Home) which reports on animal diseases including those that may be classified as foodborne hazards (e.g. trichinellosis, brucellosis)
- ProMED-Mail (https://www.promedmail.org)
- World Bank 'Enabling the Business of Agriculture' tool (http://eba.worldbank.org)
- FAO information on use of agricultural chemicals (http://www.fao.org/faostat/en/#data/RP)

Annex 2
Risk-based measures and metrics

Risk-based measures, indicators, targets and metrics include:

- Safe level of intake of hazards: an acceptable daily intake, or tolerable daily intake for contaminants (FAO/WHO 2006).
- Appropriate level of protection (ALOP): An ALOP is defined in the Sanitary and Phytosanitary (SPS) agreement[2] as: "The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory". An ALOP is derived from a risk assessment and can be expressed as probability of infection, or maximum incidence of FBD in a population or other public health measure.
- Food safety objective (FSO): The FSO translates public health risk into a definable goal. It is defined as the maximum frequency and/or concentration of the hazard in a food at the time of consumption that provides or contributes to the ALOP. FSOs are met by the application of Good Hygienic Practice (GHP), HACCP systems, performance criteria, process/product criteria and/or acceptance criteria.
- Performance objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides, or contributes to, an FSO or ALOP as appropriate.
- Performance criterion (PC): The effect of one or more control measures that contribute to meeting a PO. While ALOP and FSO are uniquely decided on and established by national competent authorities, PO and PC can be established by industry as part of organizing their food safety management systems along the farm-to-fork chain in such a way as to meet FSO levels when set by government.
- Microbiological criteria define the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites per unit(s) of mass, volume, area or lot.
- Process criteria are parameters of processing that must be controlled/achieved to meet the PO/PC (e.g. time, temperature and pH).

[2] SPS measures are measures to protect humans, animals and plants from diseases, pests or contaminants.

Annex 3
Public health or epidemiology measures

Incidence refers to the occurrence of new cases of disease in a population over a specified period of time.

Prevalence is the proportion of persons in a population who have a particular disease or attribute at a specified point in time or over a specified period of time. Prevalence differs from incidence in that prevalence includes all cases, both new and pre-existing, in the population at the specified time, whereas incidence is limited to new cases only.

Food-specific attack rate is the number of persons who ate a specified food and became ill divided by the total number of persons who ate that food.

Outbreak carries the same definition of epidemic but is often used for a more limited geographic area.

Cluster refers to an aggregation of cases grouped in place and time that are suspected to be greater than the number expected, even though the expected number may not be known.

Epidemic refers to an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area.

Pandemic refers to an epidemic that has spread over several countries or continents, usually affecting a large number of people.

Disability adjusted life year: DALYs for a disease or health condition are calculated as the sum of the Years of Life Lost due to premature mortality in the population and the Years Lost due to Disability for people living with the health condition or its consequences. Source: CDC (2006)

Various study designs can be used to determine the extent of under-reporting. These are summarized from Gibbons et al. (2014).

- **Community-based studies** generally involve active searching within the community for disease episodes, pathogen carriage or infection, with questionnaire-based data acquisition often accompanied by biological sampling.
- **Serological surveys** are a specific type of community-based study that measure sero-incidence (the rate of new infections) or sero-prevalence (the total number of infections in the community or cohort) as quantified by antigen or antibody positivity.
- **Returning traveller studies** are further examples of community-based studies where individuals returning from abroad represent sentinel populations for the reported national incidence of infection in a traveller's destination of travel.
- **Capture-recapture studies** are based on studying populations of wildlife by marking subjects on first encounter and recovering information from them on subsequent encounters. Two or more data sources are compared to identify the cases that would have been missed if using only a single data source and this is used to calculate a new estimate of incidence.

Annex 4
Economic measures and metrics for food safety

(a) Individual-level component costs and data sources from 84 cost of foodborne illness studies published between 1972 and 2012 identified from a scoping review by McLinden et al. (2014).

COMPONENT COSTS	No.	DATA SOURCES											
Direct costs		H	D	L	OC	S	O	C	P	E	M	N/P	N/A
Medical costs	16	1	3	2	-	-	3	-	-	-	-	2	5
Treatment costs	14	4	2	3	-	1	-	-	-	-	3	-	1
Drug costs	29	3	3	6	1	3	2	1	-	-	4	3	3
Prescription	18	3	3	1	-	6	-	1	-	-	1	1	2
Over-the-counter	6	-	1	1	-	4	-	-	-	-	-	-	-
Non-personal transportation (ambulance)	12	1	1	3	1	-	-	-	1	2	1	-	2
Rehabilitation	10	-	1	3	1	-	1	1	-	-	2	-	1
Materials	7	1	2	-	-	1	1	1	-	-	-	1	-
Home visits	5	-	-	-	-	-	-	-	-	-	1	3	1
Rehydration treatment	2	1	-	-	-	1	-	-	-	-	-	-	-
Palliative care	1	-	1	-	-	-	-	-	-	-	-	-	-
Laboratory costs	20	5	3	2	1	2	1	-	-	1	2	1	2
Pathogen diagnosis analysis	15	3	2	1	-	2	3	-	-	-	3	-	1
Ancillary diagnostics	10	3	2	1	1	-	2	-	-	-	-	-	1
Laboratory sampling	7	1	1	2	-	3	-	-	-	-	-	-	-
Personnel costs	7	2	3	-	-	2	-	-	-	-	-	-	-
Physician	31	1	6	5	1	3	3	1	-	1	6	2	2
GP physician	17	2	5	4	-	3	-	-	-	-	3	-	-
Non-physician	2	-	-	-	-	1	-	-	-	-	1	-	-
Nurses	4	1	-	1	-	-	1	-	-	-	1	-	-
Laboratory technician	3	1	-	-	-	-	2	-	-	-	-	-	-
Consultants	7	-	1	2	-	1	2	-	-	-	1	-	-
Specialists	5	1	1	-	-	-	-	-	-	-	1	1	1
Hospital services costs	46	5	6	11	1	2	5	1	-	1	7	3	4
Emergency room	14	4	3	1	-	1	-	-	-	-	3	-	2
Intensive care unit	5	1	1	-	-	-	-	1	-	-	2	-	-
Surgical services	3	-	1	-	-	-	-	-	-	-	1	-	1
Dialysis	2	1	1	-	-	-	-	-	-	-	-	-	-
Community services (out-patient) costs	11	-	3	1	-	-	-	-	-	-	3	1	3
Long-term care services	4	-	2	-	-	-	-	-	-	-	-	1	1

Indirect costs													
Productivity losses	30	-	2	6	1	4	2	-	-	-	3	4	8
Sick leave from work	42	1	6	7	1	10	3	1	1	-	4	1	6
Caring for others (caregiver)	19	-	5	3	-	6	2	-	-	-	3	-	-
Care of sick children	11	-	2	1	1	1	1	-	-	-	1	2	2
Lost leisure time	14	-	3	6	1	-	1	-	-	-	1	-	2
Due to long-term or permanent disability	8	-	1	2	-	-	2	-	-	-	2	-	1
Patient transportation (non-ambulance) costs	20	-	2	6	-	5	1	-	1	-	1	2	2
For visitors and relatives	6	-	-	1	-	1	1	-	-	-	1	-	2
Parking fees	1	-	-	-	-	1	-	-	-	-	-	-	-
Additional costs	-	-	-	-	-	-	-	-	-	-	-	-	-
Value-of-life lost	29	-	1	15	1	1	1	-	-	-	3	2	5
Pain and suffering	21	-	-	8	2	2	1	-	-	-	2	2	4
Risk aversion behaviours	9	2	2	-	1	2	-	-	-	-	-	-	2
Facility (operational) costs	9	1	2	2	1	-	-	-	-	-	2	1	-
Non-medical materials	7	-	-	1	1	3	-	-	-	-	-	1	1
Totals		**49**	**84**	**108**	**17**	**72**	**41**	**8**	**3**	**5**	**69**	**34**	**68**

(b) A framework for assessing multiple burdens of diseases with an agriculture interface adapted from Shaw et al. (2014).

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