



MILK Symposium review: Foodborne diseases from milk and milk products in developing countries—Review of causes and health and economic implications*

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ABSTRACT

Dairy production is rapidly increasing in developing countries and making significant contributions to health, nutrition, environments, and livelihoods, with the potential for still greater contributions. However, dairy products can also contribute to human disease in many ways, with dairyborne disease likely being the most important. Health risks may be from biological, chemical, physical, or allergenic hazards present in milk and other dairy products. Lacking rigorous evidence on the full burden of foodborne and dairyborne disease in developing countries, we compiled information from different sources to improve our estimates. The most credible evidence on dairyborne disease comes from the World Health Organization initiative on the Global Burden of Foodborne Disease. This suggests that dairy products may have been responsible for 20 disability-adjusted life years per 100,000 people in 2010. This corresponds to around 4% of the global foodborne disease burden and 12% of the animal source food disease burden. Most of this burden falls on low- and middle-income countries (LMIC). However, the estimate is conservative. Weaker evidence from historical burden in high-income countries, outbreak reports from LMIC and high-income countries, and quantitative microbial risk assessment suggest that the real burden may be higher. The economic burden in terms of lost human capital is at least US\$4 billion/yr in LMIC. Among the most important hazards are *Mycobacterium bovis*, *Campylobacter* spp., and non-typhoidal *Salmonella enterica*. The known burden of chemical hazards is lower

but also more uncertain. Important chemical hazards are mycotoxins, dioxins, and heavy metals. Some interventions have been shown to have unintended and unwanted consequences, so formative research and rigorous evaluation should accompany interventions. For example, there are many documented cases in which women's control over livestock is diminished with increasing commercialization. Dairy co-operatives have had mixed success, often incurring governance and institutional challenges. More recently, there has been interest in working with the informal sector. New technologies offer new opportunities for sustainable dairy development.

Key words: milkborne disease, developing country, pathogen

INTRODUCTION

Dairy production is rapidly increasing in developing countries, making significant contributions to health, nutrition, environment, and livelihoods, and it has the potential to make still greater contributions. At the same time, there are negative effects associated with dairy production, processing, and consumption. This paper focuses on one of the most important negative effects: human diseases that can be transmitted through milk and dairy product consumption. We focus on bovines which produce 96% of the world's milk (FAO, 2020). In this review, we describe the main health, nutrition, and other benefits of milk to place the health risks in a broader perspective. Next, we set out some important concepts that are needed to understand the health implications of dairyborne disease, including differentiating safety and quality, hazard and risk, and dairyborne diseases and diseases associated with dairy. Until the last century, milk was an important source of foodborne pathogens, which pasteurization and other hygienic technologies and practices helped to overcome. We describe evidence streams that can contribute to

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understanding milkborne disease, concluding that milkborne disease is likely to be an important public health issue in developing countries, but evidence on the burden is incomplete.

One of the most comprehensive and credible studies on foodborne contaminants is the Global Burden of Food-Borne Disease Initiative, under the aegis of the World Health Organization (WHO); we summarize its findings relevant to milkborne disease. The next section focuses on aflatoxin, a fungal toxin, of which a metabolite frequently appears in dairy products worldwide. We then review the scant literature on the economic implications of milkborne disease. The final section summarizes some of the approaches and options for reducing the burden of milkborne disease.

HEALTH, NUTRITION, AND LIVELIHOOD BENEFITS OF DAIRY PRODUCTION

Milk and dairy products are a source of essential nutrients, especially for children and pregnant woman. Milk contains protein and calcium and is a good source of vitamin B₁₂, thiamine, and riboflavin. Along with other animal-source foods, milk consumption has been found to improve anthropometric indices and cognitive function in children and to reduce nutritional deficiencies (Dror and Allen, 2011; Grace et al., 2017a).

Diets of young children in developing countries are often restricted to cereals and legumes; however, the inclusion of animal-source foods is necessary to optimize children's nutritional needs. There is convincing evidence that dairy protein improves linear growth even in well-nourished children; evidence is strongest for school-age children (Grenov and Michaelsen, 2018). A review on the importance of milk and dairy in children's diets concluded that its consumption is associated with improved bone development (Dror and Allen, 2011) in both wealthier and poorer populations.

Milk is widely consumed in low- and middle-income countries (LMIC), although this is strongly influenced by culture and geography. It is especially important in South Asia and North Africa as well as the East African highlands (Headey et al., 2017). Production of dairy may be easier to intensify and scale up than production of meat, and predictive models show how dairy products are among the leaders in the livestock revolution (Figure 1).

Dairy production as well as consumption contributes to livelihoods. In many LMIC, dairy value chains are a primary source of income for rural populations. Money earned from producing, processing, and selling milk can be used to improve quality of life. In many cultures, milk is one of the few resources that is under the control of women, both as food for the family and a source

of earnings from processing and sale. For example, a food safety project assessed gender roles in 20 animal-source food value chains (Grace et al., 2015). Overall, women were more involved in dairy and fish and less involved in meat and game value chains. In West Africa, men fed cattle and milked cows, but in Kenya this was women's responsibility. In all studies women were responsible for processing (e.g., fermentation). In 3 of the studies where traditional dairying predominated, women were in charge of marketing. In urban Cote d'Ivoire, where dairying was novel, men had taken over marketing. Entrepreneurship can also empower women, and several studies have shown positive links between women's empowerment and children's health. This fact is of great importance in the link between dairy production, consumption, and nutrition because women are generally in charge of household nutrition, are the main custodians of food cultures, and have been shown to prioritize food expenditures more than men do (Grace et al., 2015).

Moreover, whereas poultry, pig, and fish production have large economies of scale, making it hard for small-holders to compete with industrial production, dairying is much more land and labor intensive, so it is more likely to remain a viable option for smaller farmers for longer, thus supporting livelihoods in LMIC. Dairy production can also be environmentally sustainable, especially when cattle diets rely on crop by-products and non-commodity feeds such as pastures and forages (Britt et al., 2018). A comparative study found that dairy-based diets ranked more highly than vegan-, egg-, and omnivore-based diets in terms of feeding the greatest number of people while adhering to recommended agronomic practices for various classes of lands (Peters et al., 2016). Manure is also an important source of organic matter in soil.

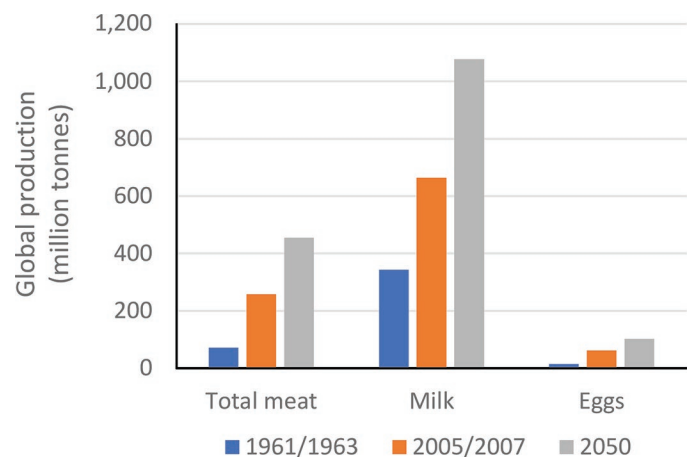


Figure 1. Global production of some livestock-derived foods (1961–2050). Data from Alexandratos and Bruinsma (2012).

Despite these benefits of dairy production and consumption, several important risks are associated with milkborne contaminants. These are discussed in the next sections.

HEALTH RISKS OF MILK

This section summarizes concepts that are important for understanding milk and health risks but that are often confused: (1) the difference between safety and quality, (2) hazards associated with consumption of milk, and (3) the difference between hazard and risk.

Food safety refers to the absence of substances, whether natural or artificial, that may make food injurious to the health of the consumer. Quality includes all other attributes that influence a product's value to the consumer. This includes negative attributes such as spoilage, adulteration, contamination with filth, discoloration, off-odors, and other nonhazardous substances as well as positive attributes such as the nutritional quality attributes (e.g., fat, protein), origin, color, flavor, texture, and processing method of the food. Adulteration always reduces the value of the product to the consumer (a measure of quality) and, depending on the type of adulteration, may introduce health hazards or reduce other aspects of quality, such as nutritional content (Spink et al., 2017).

In food safety terminology, a hazard is something that can harm human health. A wide range of hazards can be present in food.

- Biological hazards in the context of food are infectious organisms that can infect people or produce toxins that harm health. These include microorganisms (including viruses, bacteria, fungi, and protozoa) as well as larger organisms such as helminths. Studies estimate that biological hazards cause foodborne illness in between 10 and 30% of the population every year (Gkogka et al., 2011; Scallan et al., 2011; Havelaar et al., 2015).
- Chemical hazards include artificial industrial chemicals (e.g., pesticides or disinfectants) and natural chemicals (e.g., toxic metals such as lead) that are injurious to health. Most consider toxins produced by fungi (mycotoxins) to be chemical hazards. The health effects of foodborne chemicals and toxins can be serious and include illnesses ranging from mortality to cancer to immune system impairment (Wu et al., 2014; Havelaar et al., 2015; Gibb et al., 2019).
- Allergenic hazards are proteins that are naturally present in milk or other foodstuffs that can lead to an adverse immune response in some people.

Allergies usually start early in life and can cause gastrointestinal, skin, or respiratory symptoms. In countries with good data, milk allergies affect 0.25 to 5% of the population (Motala and Fiocchi, 2011). Milk allergies are believed to be less common, but increasing, in LMIC.

- Physical hazards include stones and fragments of metal or glass. They are not usually associated with sickness or death but may be reasons for recall and have considerable economic consequences.

Milk is an excellent substrate for bacterial growth and microbial survival at permissive temperatures (Hassan and Frank, 2011). Harmful bacteria may originate from the animal, the environment, milking equipment, or the milk handlers or be introduced with an adulterant such as contaminated water. Chemical contaminants may enter the milk through the feed or veterinary treatments of the animal or through later accidental or deliberate contamination.

Several chronic diseases have also been associated with milk consumption (especially at high levels), linking dairy consumption to cancer, cardiovascular disease, and obesity, which may be linked to milk fat or specific dairy proteins. Other studies show the opposite or no relation between dairy consumption and these diseases (Larsson et al., 2015; Mozaffarian, 2019).

A health problem unambiguously linked to milk consumption is lactose intolerance. (Food intolerances are nonimmunological adverse reactions to food as the result of pharmacological effects, non-celiac gluten sensitivity, or enzyme or transport defects.) Lactose is a sugar that is naturally present in milk that all infants can digest because they produce lactase. However, lactase production does not persist in many people. Undigested lactose is fermented by bacteria in the colon, resulting in mild to moderate gastrointestinal symptoms such as diarrhea and pain. About 70% of the world's population is lactose intolerant (Heine et al., 2017). The public health burden from deficiencies attributable to lactose intolerance has not been established, but the condition is mild and can be managed.

However, dairy production can affect health through other pathways (McDaniel et al., 2014). Cattle can be reservoirs for zoonotic diseases, which can be transmitted by direct contact or by environments contaminated with animal manure. For example, brucellosis is often acquired by handling aborted material (although it is also transmitted by milk), and campylobacteriosis may result from environment contamination in rural areas or contamination of the milk by bovine feces. Antimicrobial residues are chemical hazards commonly found in food, but their main health effects are through fostering pathogens resistant to antimicrobial treatment,

not through direct consumption of milk. Cattle may also cause acute injuries or be associated with chronic trauma (e.g., arthritis associated with repetitive joint stress from working in dairies).

Hazards, as discussed above, are important because they have the potential to cause sickness and, in some cases, even death. However, the mere presence of a hazard in milk does not mean that it is necessarily going to harm a person's health; "the dose makes the poison" (Grandjean, 2016). To understand the implication of hazards for human health, we need to assess risk. In food safety, risk is a combination of the severity of harm to human health and the probability of its occurrence. This has several important implications. First, just because a hazard is found in milk does not necessarily mean it will cause illness or death; this implies that regulation and control should be based on risks and not hazards. Second, substances may be harmless or even beneficial in small amounts but cause problems if they are consumed in large amounts. Third, for many chemical substances there may be a threshold below which a hazard is unlikely or unable to cause harm.

MILKBORNE DISEASE IN LMIC

Dairy products were an important cause of disease in the 19th century in now-developed countries. Milk became safer as the result of widespread pasteurization and improvements in hygiene and disease eradication schemes (especially addressing tuberculosis, brucellosis, typhoid, paratyphoid, and food poisoning) in combination with testing, regulation, and advances in hygiene. In developed countries, almost all milk is now pasteurized and standards for dairy products are effectively maintained. Consumption of unpasteurized milk continues to be associated with foodborne disease (FBD) outbreaks, even in developed nations where a small proportion of consumers choose to drink raw milk (Costard et al., 2017). A small number of studies from LMIC have also implicated dairy as a cause of FBD. For example, in India dairy products have been implicated as important in several studies (Abraham et al., 1997; Sudershan et al., 2014; Khare et al., 2018).

Until recently, there was very little solid evidence of the health and economic burden of FBD, let alone milkborne disease, in LMIC. However, we can triangulate different approaches to better understand the health burden. In the rest of this section, we summarize the methods and findings of 6 important approaches, including (1) global burden of disease studies, especially the World Health Organization study on the burden of FBD; (2) official records on FBD outbreaks; (3) historical evidence from high-income countries (HIC); (4) studies on hazard presence and

prevalence in milk; (5) assessments of the health risk posed by different hazards; and (6) studies on compliance with standards.

Global Burden Studies: WHO Foodborne Disease Burden Epidemiology Reference Group and Institute of Health Metrics and Evaluation

For many years, information on health effects of FBD was not available or was limited to selected HIC, such as the United States, Canada, and the Netherlands (Scallan et al., 2011; Thomas et al., 2013; Havelaar et al., 2015). To address this gap, an initiative was launched by the WHO Foodborne Disease Burden Epidemiology Reference Group (FERG) in 2006. Based on almost a decade of work by various experts and expert panel groups, the results were published in December 2015. The FERG used systematic reviews and meta-analysis to estimate the global incidence of disease, deaths, and disease burden (disability-adjusted life years, DALY; see, e.g., Devleeschauwer et al., 2014). They then used a structured elicitation of scientific judgment that consisted of expert panels combined with various mathematical models to estimate the proportion of FBD. They found that 31 FBD hazards (both biological and chemical hazards) globally accounted for around 600 million cases of FBD and 420,000 deaths, imposing a burden of around 33 million DALY each year (Havelaar et al., 2015). More recently, the FERG reported on the burden of disease due to 4 heavy metal chemical hazards; this was an additional 9 million DALY globally. The FERG estimates have been broken down by subregion based on the 6 WHO regions and further subdivided based on child and adult mortality. It was found that the largest share of FBD burden occurred in LMIC, where particularly children under 5 yr of age bear a large share of the burden (Havelaar et al., 2015).

A follow-up study by the FERG attempted to assess the contribution of animal-source foods. The study involved 13 out of 31 hazards that were included in the global burden of FBD estimates and can be associated with animal-source foods. These hazards accounted for just over 40% of the total foodborne DALY. The proportion of FBD attributable to 8 different animal-source food groups was estimated by structured expert elicitation (Hoffmann et al., 2017). By combining these attribution estimates with the burden estimates, dairy was estimated to be responsible for 20 DALY per 100,000 people in 2010 (Li et al., 2019). This corresponded to around 12% of the FBD burden associated with animal-source food and 4% of the overall FBD burden. The importance of dairy products and the pathogens causing the highest burden varied considerably by region, as shown in Figure 2. Globally, non-

typhoidal *Salmonella enterica*, *Campylobacter* spp., and *Mycobacterium bovis* are the most important hazards in dairy products, whereas *Brucella* spp. are of particular concern in the Eastern Mediterranean region. Shiga toxin-producing *Escherichia coli*, *Cryptosporidium* spp., and *Toxoplasma gondii* caused a relatively low burden through dairy.

The regional classification of the WHO does not completely correspond to World Bank income categories. For example, Cuba is an LMIC but along with Canada and the United States (both HIC) constitutes the region AMR A. However, the regions AMR A, EUR A, and WPR A comprise mainly HIC, and the other 11 regions comprise mainly LMIC. This allows us to make an approximate estimate of the health burden of milkborne disease in LMIC.

The FERG estimates may underestimate the true burden of FBD, including diseases related to dairy. Only a limited number of pathogens for which cattle can be reservoirs and that can be transmitted by dairy products were assessed due to a lack of reliable data (see Table 1). Furthermore, dairy products can be a vehicle for non-zoonotic pathogens. For example, ice cream from unreliable sources is frequently contaminated with hepatitis A virus, and dairy products can be a vehicle for listeriosis. Although the FBD burden

of these hazards has been quantified by FERG, it has not been attributed to dairy or other food products. Not all health outcomes from FBD could be included in the estimates, again because of a lack of data. For example, there is increasing evidence that asymptomatic infections with enteric pathogens, including those that can be transmitted by dairy, are associated with malnutrition, in particular stunting, which affects 155 million children globally (Rogawski et al., 2018). Also, FBD occurring in highly vulnerable populations, such as people with HIV or AIDS, were not included in the FERG estimates because they were already included in the burden of HIV infection. Nevertheless, these FBD would be prevented by improved food safety management.

Other sources of global disease burden estimates include the WHO Global Health Estimates, the WHO Childhood Epidemiology Reference Group, and the Institute of Health Metrics and Evaluation. A direct comparison of FERG results with those sources is difficult because of differences in methods and assumptions that may have an important effect on burden estimates, but the results are reasonably consistent. Table 2 shows estimates of the disease burden of milkborne hazards considered by different studies. Note that only the FERG study has estimated, for a limited number of

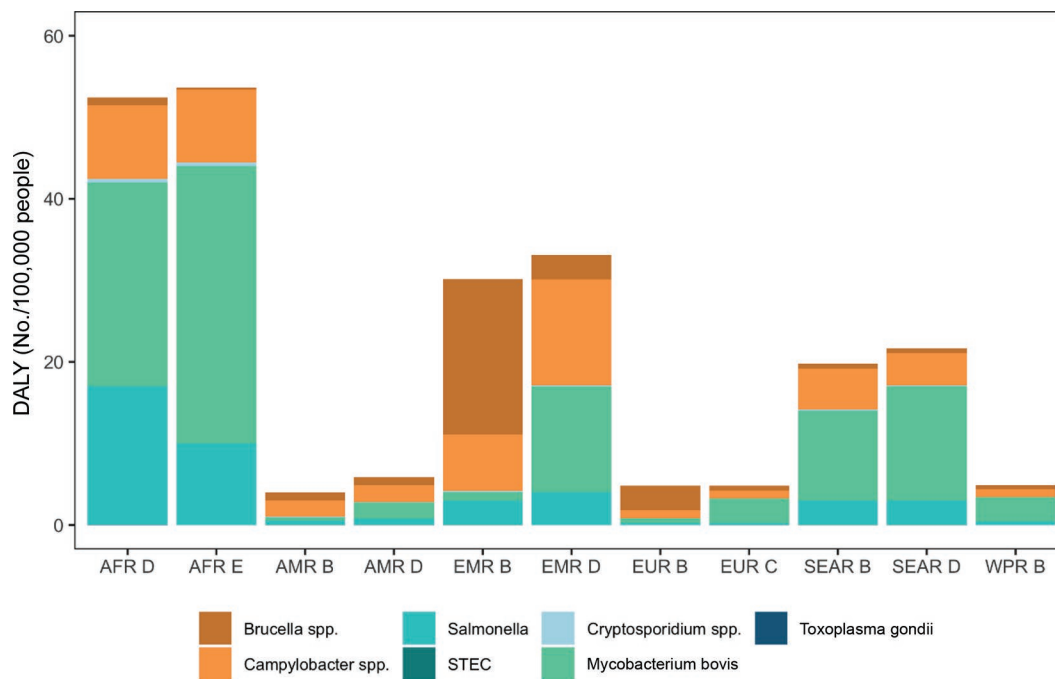


Figure 2. Global burden of disease from dairy products by region and some important hazards. DALY = disability-adjusted life years; STEC = Shiga toxin-producing *Escherichia coli*. The x-axis codes refer to WHO regions: AFR = Africa; AMR = the Americas; EMR = Eastern Mediterranean; EUR = Europe; SEAR = South-East Asia; and WPR = Western Pacific. Regions are further subdivided on the basis of mortality: B = low child mortality and very low adult mortality; C = low child mortality and high adult mortality; D = high child and adult mortality; E = high child and very high adult mortality. For more details, see Li et al., (2019).

Table 1. Comparing different burden of disease studies¹

Item	FERG	CHERG	WHO-GHE	IHME-GBD
Year of publication	2015	2013	2017	2012
Time period of data collection	1990–2012	1990–2011	1990–2013	1980–2010
Year represented in data	2010	2011	2010	2010
Geographical range of estimates	194 countries, grouped by 14 subregions	Global	183 countries	187 countries
Age groups	<5 yr, ≥5 yr	<5 yr	0–4, 5–14, 15–29, 30–49, 50–59, 60–69, ≥70 yr	0–6 d, 7–27 d, 28–364 d, 1–4 yr, 5–9 yr, . . . , 75–79 yr, ≥80 yr
Metrics ²	Incidence, deaths, YLD, YLL, DALY	Deaths	Deaths, YLD, YLL, DALY	Incidence, deaths, YLD, YLL, DALY
<i>Campylobacter</i> spp.	X	X		X
Shiga toxin-producing <i>Escherichia coli</i>	X			
Non-typhoidal <i>Salmonella enterica</i>	X	X		X
<i>Cryptosporidium</i> spp.	X	X		X
<i>Brucella</i> spp.	X			
<i>Mycobacterium bovis</i>	X			

¹FERG = World Health Organization Foodborne Disease Burden Epidemiology Reference Group (Havelaar et al., 2015); CHERG = World Health Organization Childhood Epidemiology Reference Group (Lanata et al., 2013); WHO-GHE = WHO Global Health Estimates (World Health Organization, 2017); IHME-GBD = Institute of Health Metrics and Evaluation, Global Burden of Disease (Lozano et al., 2012; Vos et al., 2012). Only FERG estimated foodborne disease hazards.

²YLD = years lived with disability; YLL = years of life lost; DALY = disability-adjusted life years.

hazards, how much of that burden is attributable to dairy products.

Official Records on Outbreaks

One must be cautious when extrapolating from outbreak data. Most cases of FBD do not occur as outbreaks but rather as sporadic cases. Moreover, in many countries there is no requirement to report FBD. Even if there is a requirement, the reporting system may not be adequate, resulting in massive underreporting. For example, in Gansu in China, there were an estimated 30 million cases of acute gastrointestinal disease, but only 400 cases were reported to the official system (Sang et al., 2014). Even when outbreaks are reported, the investigations may not be comprehensive. Nonetheless, data from outbreak investigations may be the most readily available and reliable source of information in some situations (Pires et al., 2014).

In HIC, dairy is responsible for around 1 to 6% of reported outbreaks (Claeys et al., 2013). However, these do not include dairy products incorporated into other foods (e.g., custards). When modeling is used to attribute the ingredients of complex foods, the burden of milkborne diseases is higher. Using data from outbreak-associated illnesses for 1998 to 2008, Painter et al. (2009) estimated annual US foodborne illnesses, hospitalizations, and deaths attributable to each of 17 food commodities. Dairy was responsible for 13.8% of all illnesses, 16.2% of hospitalizations, and 9.7% of deaths. Pires et al. (2012) analyzed official records of FBD outbreaks in the Caribbean and Latin America from 1993 to 2010 using a similar method. Overall, animal-source food was responsible for 85% of the food-associated outbreaks and dairy was responsible for 20% of the total outbreaks.

In HIC there is currently widespread pasteurization, animal disease control, hygienic milking, testing, and cold chains, which are lacking in many LMIC. This would imply that dairy is an important contributor to FBD LMIC. Interestingly, in the United States, drinking raw milk was associated with 840 times as many illnesses as drinking heat-treated milk (Costard et al., 2017). On the other hand, milk consumption is absolutely and relatively higher in HIC, which might imply that milk would contribute less to FBD in LMIC. Latin America and the Caribbean are more representative of LMIC. Here, the contribution of dairy to FBD declined 14-fold over the 2 decades (1990s and 2000s; Pires et al., 2012). This was associated with rapid growth and formalization of the dairy sector, which has not been seen in most LMIC, where smallholder and informal production continue to predominate.

Historical Importance of Dairy Products in FBD

Somewhat analogous to the situation in LMIC today, the 19th century saw many European and North American countries undergoing rapid urbanization, industrialization, and economic growth. This was associated with a decline in the wholesomeness of food as production shifted closer to cities, where conditions were often unhygienic and opportunities for food fraud increased (Grace et al., 2008a). Milk was a major cause of FBD, especially for infants. In the 19th century, typhoid was the major cause of FBD, followed by streptococcal disease and diphtheria, which were mainly attributed to milk (Currier and Widness, 2018), whereas in the mid 20th century, brucellosis and tuberculosis were important. In 1938, milkborne outbreaks accounted for 25% of all disease outbreaks from contaminated food and water in the United States (FDA, 2011). Introduction of widespread pasteurization of milk has dramatically reduced this disease burden. The pre-pasteurization era in developed countries can be considered analogous to the current situation in many LMIC, and major health benefits can be expected from more broadly adopting pasteurization or other effective processing methods.

Presence and Prevalence of Hazards in Milk

The isolation of disease-causing bacteria in raw milk is another indicator of potential risk to human health. As mentioned, the presence of a hazard in food is often a poor guide to the risk to human health. Storage, processing, amount consumed, diet, co-infection, and host factors may contribute to the amplification, reduction, or elimination of risk associated with hazards present in milk. Information on the presence and prevalence of hazards in milk is also useful as benchmarks and in prioritization for subsequent risk assessment. Systematic data from developing countries are largely lacking, but many individual studies have been conducted, and these often find hazards in milk.

Table 3 sets out hazards of concern, their potential health effects in LMIC, how they enter milk, and the limited evidence for their importance in LMIC (ordinal scale: major, moderate, minor, very low, possible). For milk contamination route, 4 pathways are considered: animal (direct passage from the blood into the milk), udder (udder infection), feces (contamination of milk with animal feces during milking or on-farm storage), and environment (e.g., air, dirty equipment, contami-

Table 2. Quantitative microbial risk assessments on dairy products in low- and middle-income countries

Location	Food	Hazard assessed	Risk	Reference
Debre Zeit, Ethiopia	Fermented milk	Staphylococcal enterotoxin	20 illnesses (90% CI: 14–27) per 1,000 people per year	Makita et al., 2012
Debre Zeit, Ethiopia	Raw milk	Staphylococcal enterotoxin	316 illnesses (90% CI: 224–423) per 1,000 people per year	Makita et al., 2012
Tigray, Ethiopia	Raw milk	<i>Salmonella</i> spp.	5.72% chance of illness per year for milk consumed on farm; 11.42% for milk collection	Weldeabezgi et al., 2020
Tigray, Ethiopia	Boiled milk	<i>Salmonella</i> spp.	1.8% chance of illness per year for milk consumed on farm; 4.02% for milk collection	Weldeabezgi et al., 2020
Tigray, Ethiopia	Fermented milk	Staphylococcal enterotoxin	2.54% chance of illness per year	Weldeabezgi et al., 2020
Tigray, Ethiopia	Raw milk	Staphylococcal enterotoxin	24% chance of illness per year for milk consumed on farm; 48% for milk collection	Weldeabezgi et al., 2020
Nairobi, Kenya	Formal-sector milk	Aflatoxin M ₁	0.003 cases of cancer per 100,000 (95% CI: 0.000012–0.011) per year	Ahlberg et al., 2018
Nairobi, Kenya	Informal-sector milk	Aflatoxin M ₁	0.006 cases of cancer per 100,000 people (95% CI: 0.000019–0.018)	Ahlberg et al., 2018
Rural Kenya	Milk	Aflatoxin M ₁	0.003 cancer cases per year per 100,000 adult females (95% CI: 0.003–0.0039)	Sirma et al., 2019
Rural Kenya	Milk	Aflatoxin M ₁	0.0014 cancer cases per year per 100,000 adult men (95% CI: 0.0012–0.0015)	Sirma et al., 2019
Dagoretti, Kenya	Informal milk	<i>Cryptosporidium</i> oocysts	1.02% of children ingesting oocysts per day (90% CI: 0.703–1.4157)	Grace et al., 2012
Dagoretti, Kenya	Informal milk	<i>Cryptosporidium</i> oocysts	0.88% of adults ingesting oocysts per day (90% CI: 0.614–1.218)	Grace et al., 2012
Urban East Africa	Raw milk	Shiga toxin	2–3 infections per 10,000 servings (CI: 0–22)	Grace et al., 2008a
South Africa	Raw milk	Shiga toxin	52 cases per 100,000 servings for children and 3.2 for adults	Ntuli et al., 2018
South Africa	Pasteurized milk	Shiga toxin	47 cases per 100,000 servings for children and 2.9 for adults	Ntuli et al., 2018
Egypt	Raw marketed milk	Organochlorine pesticides	Potential elevated cancer risk especially among children consuming goat milk	Raslan et al., 2018

nated water, milker, milk handler). The authors used largely subjective criteria to assess health importance based on their personal experience of working in LMIC. The category “possible” indicates that the role of milk consumption in disease transmission is still ambiguous.

Risk Assessments

Quantitative risk assessment is a predictive or inductive method that assesses risk by combining exposure, dose-response, and severity of health effects. It has been adopted by the Codex Alimentarius Commission and underpins trade in foods and livestock. By taking the core concepts of risk analysis and combining them with proven development analytic methods such as participatory rural appraisal and gender analysis, an approach emerged that could be successfully applied to the food safety challenges in developing countries (Grace et al., 2008b). The approach was subsequently used in Tanzania, Uganda, Vietnam, and elsewhere, and its strengths and weaknesses as well as the recommendations generated were captured in peer-reviewed publications (Häsler et al., 2018; Nguyen-Viet et al., 2019; Roesel et al., 2019).

This approach, involving rapid qualitative and quantitative studies on hazards and risk, has been applied to several dairyborne diseases; many of the studies were conducted by scientists at the International Livestock Research Institute in Kenya. Table 3 summarizes key findings.

These risk assessments confirm that aflatoxins in milk have lesser known health effects than biological hazards. The risk assessments also suggest that processing milk (boiling, fermentation, or pasteurizing) reduces but does not eliminate risk. Some assessments find relatively high risks for single pathogens, implying that milkborne disease may be more common than the estimates from the FERG. However, bottom-up quantitative risk assessments tend to produce higher estimates of risk than top-down epidemiologic methods.

Studies on Compliance

Public food safety standards are enacted to protect consumers' health by ensuring safe food and 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. More recently, standards often seek to incorporate a risk perspective but may also take a precautionary approach. Such standards

have been developed mainly in HIC. In the absence of resources and data to define standards that are appropriate for the local context, LMIC often copy standards from HIC. Compliance with standards is only a proxy for food safety, as food may not comply and yet pose little risk and vice versa. In LMIC, it is very common for a substantial proportion of food and feed to fail to comply with standards adopted from HIC, which may cause considerable concern among governments and consumers. Table 4 summarizes some studies on dairy products in Kenya that are not atypical for other LMIC.

It has been said that when 5% of milk fails to meet standards, there is a problem with milk, but when 90% fails, there may be a problem with standards. The high level of noncompliance, the many different regulations between and sometimes within countries, and the proliferation of regulations in advance of the ability to enforce them raise concerns, and there is an urgent need to develop approaches to develop standards for LMIC that are locally appropriate and focus on the most important health risks rather than hazards that are easily measured. There may also be severe tradeoffs between compliance with food safety regulations and other societal objectives such as food and nutrition security that raise difficult questions. For example, one study in Kenya found that if aflatoxin standards for maize and sorghum were strictly enforced, around 9,000,000 Kenyans would be deprived of the bulk of their diet and about 3,400,000 Kenyans would be deprived of milk (Sirma et al., 2018).

Appropriate Dairy Safety Regulation: Aflatoxin M_1 as an Example

Discovered in 1960, aflatoxins—toxins produced by certain *Aspergillus* fungi primarily in maize and nuts—have long been known to cause liver cancer in humans and diverse other adverse effects in humans and animals, including acute toxicity, growth impairment, and immune system dysfunction (Kensler et al., 2011; Khlanguiset et al., 2011; Wu, 2015). Lactating animals that consume aflatoxin B_1 (AFB_1 ; the most prevalent and toxic of the aflatoxins in maize and nuts) in their feed secrete a metabolite of that toxin in their milk, referred to as aflatoxin M_1 (AFM_1 ; Kensler et al., 2011). Although the human health risks of AFM_1 are far from well established, regulatory agencies have set standards for AFM_1 in milk and dairy products simply based on taking the existing AFB_1 or total aflatoxin standard (in a given nation) and dividing by a factor that roughly estimates how much AFM_1 is produced in milk when parent aflatoxin is present in dairy animals' diets (Wu and Saha Turna, 2019). Implicit in this calculation is

Table 3. Hazards found in milk and dairy products in low- and middle-income countries (LMIC)¹

Hazard	Potential health importance	Importance in LMIC
<i>Campylobacter coli</i> and <i>jejuni</i> ²	Major	High prevalence reported in West Africa and Kenya
Human pathogenic verocytotoxigenic <i>Escherichia coli</i> ^{2,3}	Major	Up to 2% of dairy products in Kampala and Nairobi, 10% in Nigeria and Tanzania, and 21% in Libya are positive (Garbaj et al., 2016)
<i>Listeria monocytogenes</i>	Major	Reported in milk in dairy products in India and Africa
<i>Mycobacterium bovis</i> ²	Major	Up to 10% of cases of tuberculosis in some areas. In Tanzania, 10% of the extrapulmonary and 4% of pulmonary cases. FERG has used an estimate of 1%.
Non-typhoidal <i>Salmonella enterica</i> ²	Major	High; among the most common causes of bacteremia in under-fives and a common cause of meningitis and septicemia
<i>Staphylococcus aureus</i>	Major	May be important; present in 6% of raw milk samples in Tanzania
<i>Brucella abortus</i> ²	Moderate	High; 40% cows in Africa serologically positive. 35% of raw milk samples produced and sold in peri-urban Bamako in Mali contained antibodies from <i>Brucella abortus</i> .
<i>Brucella melitensis</i>	Moderate	Typically a disease of small ruminants; in some countries has also been found in cattle at high levels (Kolo et al., 2018)
<i>Cryptosporidium parvum</i> ²	Moderate	Recent studies have shown a high prevalence in Kenya milk
Dioxins	Moderate	People eating a North American diet ingest 23% of dioxins through dairy products (Grace et al., 2017a)
Heavy metals	Moderate	In developed countries, dairy products contribute to about 10% of dietary lead, less than 10% of dietary cadmium, and are major contributors of arsenic for children and minor for adults (Grace et al., 2017a)
Hepatitis A and E virus ⁴	Moderate	Hepatitis E is highly prevalent in milk in China (Huang et al., 2016). Hepatitis A is associated with ice cream and milk, among other foods.
<i>Streptococcus</i> spp.	Moderate	In rare cases group A can be spread by milk and milk products; group B is a potential zoonosis; group C are zoonotic and the main origin is animals and dairy products
<i>Shigella</i> spp.	Moderate	Milk and dairy have been associated with a few outbreaks, including in India
<i>Salmonella enterica</i> serovar Typhi and serovar Paratyphi	Moderate	In HIC, ⁵ dairy products are associated with 25% of typhoid outbreaks of known origin (Glynn and Bradley, 1992). Reports from LMIC of milk and dairy contamination.
<i>Vibrio cholera</i>	Moderate	In Morocco, 7% of dairy products were contaminated; in India, 12% of milk sampled (Sharma and Malik, 2012)
<i>Bacillus cereus</i> (enterotoxigenic)	Minor	High presence in dairy products in Abidjan, India, China, and Thailand (Kumari and Sarkar, 2016)
<i>Corynebacterium ulcerans</i>	Minor	Very low, reported mainly in HIC, which may be due to reporting bias
<i>Cronobacter sakazakii</i>	Minor	Emerging pathogen associated with rehydrated milk; it has been reported in Asia and Africa (Parra-Flores et al., 2018)
Pesticides	Minor	Pesticide residues are often detected in milk in LMIC, including residues from banned pesticides
Mycotoxins	Minor	High prevalence in tropical feeds; has been detected in milk in East Africa; one study found positive association with stunting
Rift Valley fever virus	Minor	Drinking raw milk has been identified as a risk factor, but most risk through slaughter
<i>Toxoplasma gondii</i> ²	Minor	Raw goat milk has been identified as a source of infection in Ethiopia and Uganda
<i>Trueperella pyogenes</i>	Minor	Common in HIC but not well documented in LMIC. Zoonotic potential unclear.
<i>Yersinia enterocolitica</i>	Minor	In Morocco, 7% of dairy products were contaminated
Viruses of the tick-borne encephalitis complex	Minor	A problem in Europe and Asia. Raw goat milk responsible for several cases.
<i>Citrobacter freundii</i>	Very low	Has been isolated from milk in Kampala (Kateete et al., 2013), Cameroon (Moh et al., 2017), and Ethiopia (Worku et al., 2012); considered emerging but few studies in LMIC
<i>Clostridium botulinum</i>	Very low	Spores often detected in feces of cattle and occasionally in milk and dairy products in HIC. Milkborne outbreaks reported in HIC, Kenya, Latin America (Lindström et al., 2010).
<i>Clostridium perfringens</i>	Very low	Few studies conducted in LMIC but reported in milk from Egypt
<i>Corynebacterium diphtheriae</i>	Very low	Often detected in milk but mainly a problem in India, Haiti, and parts of central Africa. Current role of dairy unknown, but historically milk an important vehicle
Histamine	Very low	Microorganisms in cheese can produce histamine, which can have life-threatening symptoms. Aged cheese is second to fish as a source of disease (Stratton et al., 1991). Importance in LMIC not known.
<i>Leptospira</i> spp.	Very low	Common in cattle in HIC and LMIC; most infections are transmitted by cattle urine but can be present in milk (Fratini et al., 2016).
<i>Streptobacillus moniliformis</i>	Very low	Reported in Kenya, Nigeria, and China (Zhang et al., 2019). Milk-associated disease only reported from United States.
Antibiotic residues	Possible	High; prevalence of 6% (Mali), 50% (Niger), 36% (Tanzania), 33% (Uganda), and 6–15% (Kenya)
<i>Coxiella burnetii</i>	Possible	Urban outbreaks are increasingly reported and may be associated with milk
<i>Mycobacterium paratuberculosis</i>	Possible	Infections common in cattle; implicated in the pathogenesis of Crohn's disease (Bharathy et al., 2017)

¹Table adapted and updated from Grace et al. (2007); references given in that paper are not repeated here.²Considered by the World Health Organization Foodborne Disease Burden Epidemiology Reference Group (FERG) in attributing foodborne disease to milk and other animal-source foods.³Only certain strains of *E. coli* that are transferred by cattle, which contain a combination of virulence factors and that are pathogenic to humans. Strains of the serotype O157:H7 are the most frequently reported, but strains of other serotypes can result in human cases as well (e.g., O26, O91, O103, O111, O121 and O145).⁴Only genotype 4 of hepatitis E has been found in cattle; genotypes 3 and 4 are zoonotic, but the main host is pigs.⁵HIC = high-income countries.

that AFM₁ is as toxic as AFB₁, which no evidence has shown. Indeed, existing studies suggest that AFM₁ toxicity and carcinogenicity are far less than that of AFB₁ (EFSA, 2020). Unfortunately, many policymakers worldwide have assumed that AFM₁ is just as toxic as AFB₁. Consequently, newspaper headlines have warned people to avoid drinking locally produced milk; this has set back early childhood milk-based nutrition interventions and paralyzed the dairy industry in Ethiopia, for example. Similar headlines have been published in other countries such as Kenya. As ever more nations suffer market losses due to AFM₁ in dairy products exceeding regulated levels, especially the stringent EU limit of 0.05 µg/kg, there is a need to better characterize the true human health risk of this chemical in our daily diets in order to inform policy decision making and public health officials on the true nature of the risk.

For the purposes of sensible policymaking on food safety that does not cause excessive economic loss (Wu, 2004), there is a critical need to compare both the toxicity of and the exposure to AFM₁ with AFB₁ to be able to judge relative risks. It is also important to understand whether AFM₁, like AFB₁, has a synergistic interaction with hepatitis B virus infection to increase liver cancer risk and to compare exposure patterns of these 2 chemicals. In multiple LMIC, high AFM₁ contamination levels have been detected in milk (as reviewed in Wu and Saha Turna, 2019). This is likely be-

cause maize grain and oil seed cakes are used in animal feed, and these can have extremely high aflatoxin levels (Liu and Wu, 2010; Liverpool-Tasie et al., 2019). For instance, studies in Ethiopia and Rwanda have identified oil seed cakes as the main source of AFB₁ in feed (Gizachew et al., 2016; Nishimwe et al., 2019). There is a need to continue to identify which feed components contribute most to AFB₁ exposure of cattle and how to control this contamination.

ECONOMIC BURDEN OF DAIRYBORNE DISEASE

Foodborne diseases are associated with a wide range of economic costs. These can be divided into (1) the harm caused by the disease (e.g., lost productivity from illness), (2) the cost of response (e.g., treatment, food recalls), and (3) cost of prevention (e.g., food safety governance, risk-reducing practices). Alternatively, costs may be allocated to different actors (consumer, health care, 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. Costs associated with market access and trade are not further discussed in this paper.

Valuation of health benefits is now an established tool for identifying the highest priorities for public health investments. Although valuation methods have recognized limitations, they can provide insights into

Table 4. Dairy products failing to comply with standards in Kenya¹

Site	Sample	Failure to comply with standards ²	Reference
Lamu County	Milk vendor (informal)	25% unacceptable composition 18% were outside limit for AM residues 29% failed composition or AM residue	Ondieki et al., 2017
Nakuru	Peri-urban milk	43% were outside limit for sulphonimides	Orwa et al., 2017
Nanyukii and Isiolo	Camel milk	75% were outside microbiological limits	Kaindi et al., 2011
Not reported	Camel milk	92% exceeded TVC 100% exceeded coliform	Matofari et al., 2013
Kisumu and Eldoret	Informal and pasteurized	43% of informal milk and 71% of formal milk did not meet total bacterial count standards	Alonso et al., 2018
Nandi	Raw and boiled vended	60% of raw and boiled milk were outside coliform	Ogot et al., 2015
Nairobi	Raw and pasteurized	53% exceeded acidity standards 96% of raw and 21% of pasteurized exceeded TVC 78% of raw and 5% of pasteurized exceeded coliform	Wanjala, 2017
Kiambu	Shop milk	64% of milk exceeded coliform 54% exceeded total plate count 27% exceeded adulteration (compositional) 0% exceeded AM residue 0% with hydrogen peroxide	Orregård, 2013
Nairobi	Informal	66% of samples above aflatoxin limits	Kuboka et al., 2019
5 Urban centers	Formal	31% exceeded the WHO/FAO levels for aflatoxin	Kang'ethe and Lang'a, 2009
Nairobi	Informal	55% were over EU maximum for aflatoxin	Kirino et al., 2016
Bomet County	Formal	No aflatoxin in processed milk or UHT	Langat et al., 2016

¹Adapted from Harcourt-Brown et al. (2018).

²AM = antimicrobial residues; TVC = total viable count; WHO/FAO = World Health Organization and Food and Agriculture Organization of the United Nations.

the economic cost of illness and the potential value of reducing the burden of illness. It is important to understand the basis for such estimates, as they can be misinterpreted. For example, estimates of the economic burden of FBD in the United States vary from \$14 billion to \$77 billion due to differences in methodology and pathogen coverage (Hoffmann and Anekwe, 2013).

Gross national income per capita can be used as a measure of lost productivity. Intuitively, for each year lost to illness, disability, or premature death, the economy loses the economic output associated with that year. Using this approach, a recent paper by the World Bank estimated the cost of FBD at US\$95.2 billion for LMIC in 2016 (Figure 3; Jaffee et al., 2019). Using the FERG estimates that 4% of the FBD burden in term of DALY is due to milk and combining it with the approach used in the aforementioned World Bank paper, this would imply that the economic cost is around US\$4 billion, which likely is an underestimate.

REDUCING THE HEALTH AND ECONOMIC BURDEN OF DAIRYBORNE DISEASE

There have been many approaches to improving milk safety and quality in LMIC. Some of the most important, summarized in Grace (2017), are as follows:

- Training farmers in hygienic milk production
- Organizing farmers into dairy co-operatives that can better control quality
- Linking farmers to a variety of services through dairy hubs to improve milk production
- Supporting the formal sector processing and retail
- Training and legitimization of the informal sector
- Improving consumer awareness on milk handling and safety
- Technologies that improve health of cattle, such as mastitis detection and treatment
- Technologies that help preserve milk, such as lactoperoxidase, heating, and chilling
- Technologies that improve handling of milk, such as wide-necked milk cans
- Technologies that improve access to information and services, such as obtaining information or making payments using mobile phones
- Enforcing food safety legislation

Milk safety can also be improved as a by-product of more general development interventions such as improving road, water, and electricity infrastructure and better primary and secondary education. In most countries these broad-based interventions have been associated with improvement in a wide range of health outcomes.

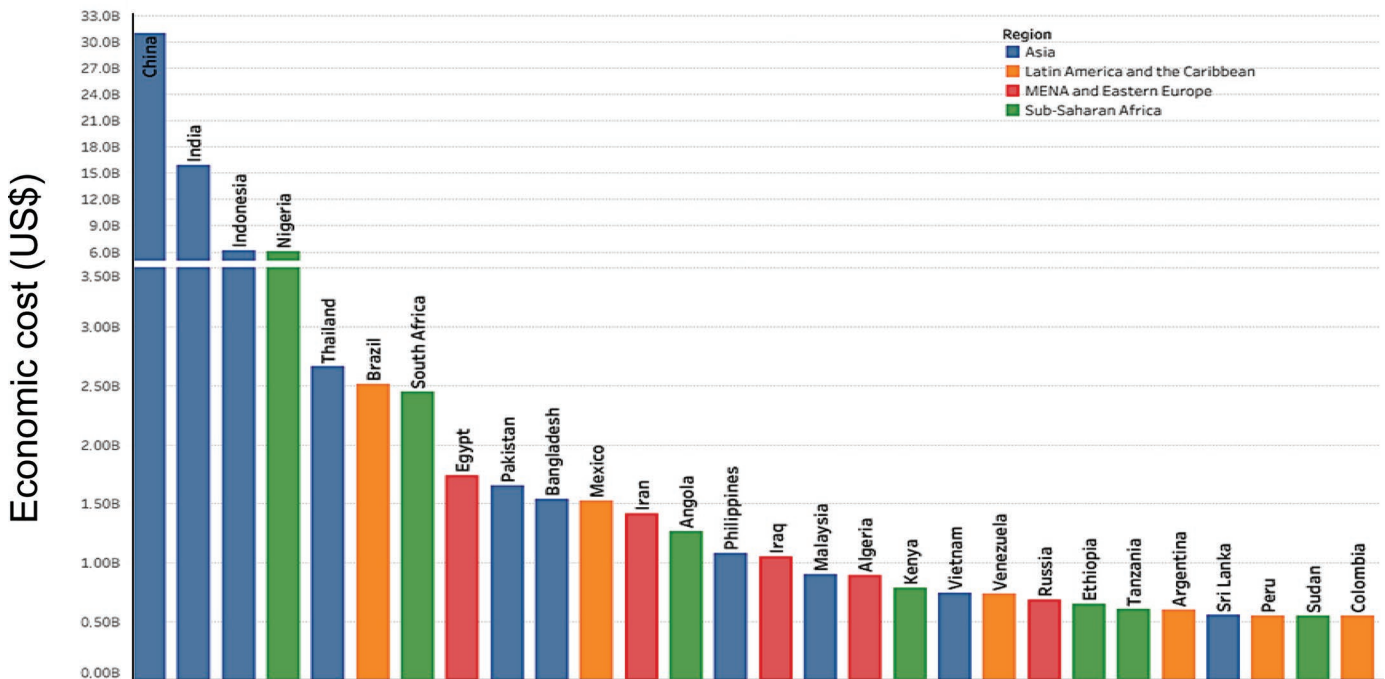


Figure 3. Economic cost per year of foodborne disease in low- and middle-income countries (Jaffee et al., 2019). MENA = Middle East and North Africa.

Although many of the more specific approaches have had some success, major problems with milk safety persist in many countries (Grace et al., 2007). One key aspect is that most milk is still obtained from informal markets. For example, in Tanzania more than 90% of marketed milk goes through the informal sector (Kilelu et al., 2017), and in more urbanized Kenya 86% of milk is informal (Kaitibie et al., 2010). Even in India, the world's top milk producer and which has heavily invested in co-operatives, 83% of the milk is consumed in the unorganized sector (DAHD, 2020). These markets are favored by consumers because, for example, milk is cheaper than that sold in the formal sector, there is more flexibility in the quantity sold, outlets are closer to the consumer's house and some hawkers even deliver to the doorstep, and consumers prefer the taste of unprocessed milk. The lower price of informal-sector milk is especially important to poor consumers. A recent study in Nairobi found that poor households spend 38% of their total food expenditure on livestock products and fish, and of that, 37% was spent on milk and dairy product. In this context, increasing the price of milk could have adverse effects on nutrition (Cornelsen et al., 2016).

Working with the informal sector is likely to be necessary if widespread and rapid improvements in food safety and quality are desired. In Kenya in the early 2000s, a training and certification scheme was designed and launched to improve quality and safety in informal dairy markets by improving the practices of traders and at the same time supporting the livelihoods of dairy value chain actors. The scheme was taken up by a large proportion of eligible traders (with project support). They received capacity-building training in hygienic milk handling and business practices and at the end of training could apply for a certificate from the Kenya Dairy Board that entitled them to legally sell milk. Participant tests before and after training showed that trader knowledge and practices improved, and microbiological tests showed that there was a substantial and significant decrease in unsafe milk. A later economic evaluation found an important reduction in transaction costs attributable to less harassment by authorities, less confiscated equipment, and fewer bribes paid but also fewer losses of milk due to spoilage (Kaitibie et al., 2010).

There is also much scope to improve milk safety in high-risk communities. Especially relevant are pastoralists who often have high dietary dependence on milk yet risky practices such as drinking raw milk. In these communities, women often play a key role and must be engaged (FAO and CARE, 2019).

CONCLUSIONS

This paper draws on the literature in order to assess the health and economic burden of milk and dairy products in LMIC and to identify the priority hazards. Much is unknown about the disease burden of milk-borne disease. The best estimates come from the FERG study, which suggests that milk and dairy are responsible for 4% of the overall global FBD burden, corresponding to 20 DALY per 100,000 people in 2010. In Africa, the burden is considerably higher at 50 DALY per 100,000 people. This study covers a small number of known pathogens and is likely to underestimate burden. Historical studies and outbreak investigations suggest that between 14 and 25% of all cases of identified FBD are related to dairy. Depending on the hazard and method, quantitative microbial risk assessment gives even higher estimates, but these may be inflated. This high disease burden corresponds to a high economic burden. Taking a conservative estimate of 4% of the FBD, it would correspond to around US\$4 billion/yr in poor countries and warrants greater investment in assessing, communicating, and managing dairyborne disease. There are many successful and promising approaches for reducing the burden of dairyborne disease, but caution should be used in their application to avoid unintended consequences such as disempowerment of women or reducing access to dairy. For example, there are many documented cases in which women's control over livestock is diminished with increasing commercialization (Kristjanson et al., 2010).

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