FOODBORNE DISEASE & FOOD SAFETY

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Preface

The issue of a safe food supply, particularly concerning direct food additives and pesticides, has received considerable publicity and engendered a great deal of emotion among the informed and uninformed. The aim of this book is to put the subject of foodborne disease and food safety in perspective by providing concise information on foodborne illness and the measures taken to assure a safe food supply.

The book is organized in two sections: (1) Foodborne Disease and (2) Food Safety. The first section deals with the surveillance, epidemiology, and diagnosis of foodborne diseases of contemporary public health importance in the United States. The second section focuses primarily on food additives, including pesticides, animal drugs, substances used in food packaging, and substances added directly to food. Subjects include: the role of food additives in food production, storage, processing, packaging, and distribution; food safety laws, regulations, surveillance programs, and procedures used by food manufacturers to assure microbiological quality and food safety; how the safety of food additives is evaluated scientifically; incidence of human illness resulting from approved usage of food additives; and national and international organizations concerned with food safety.

The book is intended primarily for medical students and practicing physicians, but should also be a useful reference for students and professionals in other biological sciences, and in food science and technology.

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Angela Gilchrist

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FOODBORNE DISEASE

This section of the handbook is concerned with illness that results from ingestion of contaminated food or naturally toxic plants or animals. Determination of the diseases to be included was based primarily on annual summaries of foodborne disease outbreaks published by the Center for Disease Control (CDC), Public Health Service, U.S. Department of Health, Education, and Welfare (now Health and Human Services).[1] Only those diseases of primary and contemporary public health importance in the United States are included.

Certain diseases transmitted by food are traditionally referred to as "food poisoning." This is a generic term that is applied rather loosely and its definition is arbitrary. In common usage the term includes both infections and intoxications. It frequently implies illness of abrupt onset, enteric in nature, but including acute disturbances of the central nervous system. Some diseases transmitted by foods usually are not classified as "food poisoning," e.g., trichinosis, shigellosis, hepatitis A, and streptococcal pharyngitis. Consequently "foodborne disease" seems to be a more appropriate term to describe diseases transmitted by food.

Foodborne Disease may be defined as disease due to ingestion of (1) food contaminated with infectious microorganisms or toxic substances; or (2) inherently poisonous animals, plants or parts of plants mistaken for food. Illness may be of an infectious or toxic nature, acute or, rarely, chronic. Infectious diseases or intoxication of bacterial origin, manifested by acute gastroenteritis are, by far, the most common type of foodborne disease in the United States.

Infections are caused by pathogenic microorganisms and the reaction of body tissues to their presence or to the "toxins" they generate within the body. Two types of foodborne infections are known[2]: (1) The infecting organism penetrates the intestinal mucosa and multiplies within (salmonella, shigella, and some strains of enteropathogenic *Escherichia coli*) or passes to other tissues where it multiplies or lodges (virus of hepatitis A, brucella, *Trichinella spiralis*). (2) The infecting organism multiplies, sporulates, or lyses in the intestinal tract and releases enterotoxins (*Clostridium perfringens* and some strains of enterotoxigenic *E. coli*).

Intoxication may be produced by (1) chemical contaminants (e.g., heavy metals); (2) pathogenic bacterial contaminants that elaborate toxins during growth and multiplication in food (e.g., staphylococcal and botulinal toxins); (3) a variety of organic substances present naturally in "food" as a result of normal physiologic or metabolic processes (e.g., toxins present sporadically in shellfish as a result of animals feeding on toxic marine organisms, amanita toxins present in certain species of wild mushrooms); or (4) a toxic substance thought to be formed by the action of marine bacteria on fish flesh ("scombrotoxin" in scombroid fish poisoning).

The principal causes of foodborne illness reported in the United States may be classified according to etiologic agents into four broad categories:

MICROBIOLOGICAL AGENTS

Bacterial
- *Clostridium botulinum*
- *Clostridium perfringens*
- Salmonella
- Shigella
- *Staphylococcus aureus*
- *Vibrio parahaemolyticus*

Parasitic
- *Trichinella spiralis*

Viral
- Hepatitis A virus

TOXIC PLANTS: chiefly toxins in wild mushrooms

TOXIC ANIMALS: fish and shellfish toxins

CHEMICAL AGENTS: heavy metals, miscellaneous chemicals

Strictly speaking, intoxication due to ingestion of inherently toxic plants should not be classified as foodborne illness since they are not food. However, in a broad sense they are associated with eating and food.

The CDC uses a somewhat different classification of etiologic agents for reporting foodborne disease: Toxic plants and animals are listed under chemical etiologic agents. Also, monosodium glutamate (MSG) is included as a chemical cause of food poisoning. Illness caused by MSG ("Chinese restaurant syndrome") is not a true intoxication since only sensitive persons are affected.

Surveillance

Foodborne disease surveillance consists of seeking notification of illness, identifying outbreaks, investigating outbreaks, interpreting investigative data, and disseminating findings.[3]

Reporting. Reporting of foodborne illness in the United States began about 60 years ago when state and territorial health officers recommended that cases of gastroenteritis be investigated and reported to develop information concerning the association of contaminated milk, food, and water with these outbreaks.[4] In 1923, the Public Health Service began preparing annual summaries of milkborne disease outbreaks reported by the states and, in 1938, added reports of water and foodborne outbreaks.[4] These actions resulted from earlier observations made on the spread of such diseases as infant diarrhea and typhoid fever through milk and water. From the beginning, the reports indicated that water and milk were implicated in outbreaks less often than other foods.[4] These early surveillance efforts led to the enactment of public health measures (e.g., pas-

teurization of milk and chlorination of water supplies), which have had an important influence in decreasing the incidence of enteric and other diseases, particularly those transmitted by milk and water.

From 1951 through 1960, reported outbreaks of foodborne illness were reviewed and published annually in Public Health Reports by the National Office of Vital Statistics. In 1961, responsibility for reporting was transferred to the Communicable Disease Center.[5] From 1961 to 1966 the publishing of annual reviews was discontinued, but statistics and detailed individual investigations were reported in the Morbidity and Mortality Weekly Reports.[5]

The present national system for collecting and disseminating data on foodborne and waterborne disease began in 1966 with the incorporation of all reports of outbreaks attributed to the microbiological or chemical contamination of food or water into an annual summary.[5] At that time, the National Communicable Disease Center, now the Centers for Disease Control (CDC) instituted a national, voluntary program for intensive surveillance of outbreaks of foodborne illness. In 1968, a standard form for reporting outbreaks to the CDC was made available to all state health departments.

The CDC's annual summaries of foodborne and waterborne disease outbreaks contain statistical information, data on etiologic agents, food vehicles, food-handling errors that contributed to outbreaks, locations where such errors occurred, and guidelines for confirmation of foodborne outbreaks.

Source of Data. Information on foodborne outbreaks reported by CDC in its annual summaries is derived from a number of sources.[5] The general public, and local, state, and federal agencies that are responsible for public health and food protection participate in foodborne disease surveillance. The public, physicians, hospital personnel, and persons involved with food service or processing report complaints of illness to health departments or regulatory agencies. Local health deparment personnel (epidemiologists, sanitarians, public health nurses, etc.) carry out epidemiological investigations of these reports and report their findings to state health departments. State agencies concerned with food safety sometimes participate in the initial investigation of an outbreak and provide laboratory support. Occasionally, on request, Epidemic Intelligence Officers, Epidemiology Program, CDC participate in an investigation, particularly if the outbreak is large or involves products that move in interstate commerce. On completion of an investigation, state or other officials summarize the findings on the standard CDC reporting form.

Two federal agencies that have major responsibility for food protection, the Food and Drug Administration (FDA) and the Department of Agriculture (USDA), report episodes of foodborne disease to CDC and to state and local health authorities. CDC, state, and local authorities, in turn, report to the FDA or USDA any foodborne disease outbreaks that might involve commercial products. The U.S. Armed Forces also report outbreaks directly to CDC.

By special arrangement, Connaught Laboratories of Canada, the only producer of botulinal antitoxin in the Western Hemisphere, immediately reports all requests for antitoxin to the CDC. This is sometimes the first communication of a botulism outbreak to public health authorities, although physicians are urged to promptly report all suspect botulism cases.

Extent of Reporting. Foodborne disease is grossly underreported. For example, in the state of Washington where foodborne surveillance has been well developed, 68 outbreaks were reported to the CDC in 1970. The estimated number of episodes for the entire country, proportionate to the population of Washington was 3,600; however, only 366 outbreaks were reported to the CDC in 1970.[6] The fact that only 10% of the "expected" number of outbreaks were reported suggests the probable extent of foodborne outbreaks in this country and the discrepancy between the expected incidence and the reported incidence. Moreover, these estimates must be multiplied by a factor of unknown magnitude — the number of outbreaks not reported to the local or state Health Department in Washington.

During the years 1970 through 1977,[1] the number of states that reported no outbreaks for each of the years ranged from 4 in 1971 to 11 in 1972, and the number of states reporting one or two outbreaks each year ranged from 6 in 1974 to 24 in 1970. Three state health departments Pennsylvania, Washington, and California, and, in most recent years, New York City consistently contributed the most reports. The inconsistencies among states in reporting foodborne illness are probably a reflection of the relative emphasis given by health departments to the detection and investigation of outbreaks rather than any regional differences in actual incidence. Furthermore, some of the larger cities do not regularly notify their state health departments when outbreaks occur or by periodic summaries.

The likelihood of an outbreak coming to the attention of health authorities varies considerably from one locale to another depending largely upon public awareness and interest of physicians.

According to the CDC,[5] interstate outbreaks, large intrastate outbreaks, and outbreaks of a serious nature such as botulism are more likely to come to the attention of health authorities, including the CDC. The quality of investigations conducted by state or local health departments varies considerably according to the department's interest in foodborne disease outbreaks and its investigative and laboratory capabilities. The likelihood that the finding of an investigation will be reported depends upon a state's commitment to foodborne disease surveillance.

Physicians' Role. A problem must be defined before it can be brought under control. Defining the problem of foodborne illness depends on notification of all cases. The Food Protection Committee of the Food and Nutrition Board, National Research Council-National Academy of Sciences has long urged physicians to improve their reporting to health agencies, and the latter to give more emphasis to the detection and investigation of outbreaks:[4]

> The practicing physician is the key to locating cases of foodborne diseases . . . Coordinated efforts among medical societies and health agencies at the national, state, and local levels could do much to encourage individual physicians to take a more active role in detection, investigation, and reporting. Among the possible results of such efforts are:
>
> (a) greater awareness of the prevalence of foodborne disease through reports of outbreaks,
> (b) better understanding of the importance of finding cases of foodborne illness,

(c) willingness to question all patients with possible food poisoning to elicit information regarding a common source,
(d) more consistent reporting of positive or suggestive information to appropriate public health authorities,
(e) greater efforts to establish etiological diagnosis by use of laboratory tests, and
(f) improved understanding of foods as vehicles for the transmission of diseases.

Purpose of Surveillance. Surveillance of foodborne disease is the continuing scrutiny of all aspects of the occurrence and distribution of an illness that are pertinent to effective control. Surveillance has three main objectives: (1) control and prevention of disease, (2) knowledge of disease causation, and (3) administrative guidance. Investigation of outbreaks may also provide information useful in the diagnosis and treatment of foodborne illness.

Disease Control and Prevention. Early identification and removal of contaminated food from the commercial market prevents additional cases and further spread of an epidemic. The discovery of improper food handling practices in food service or catering establishments or in the home, or in commercial food processing operations can lead to correction of such procedures, training programs for personnel, and development of material to educate the general public in proper practices. The identification and appropriate treatment of human carriers of foodborne pathogens is also a fundamental control measure resulting from surveillance of foodborne disease.

Examples:
One investigation of an outbreak of botulism[7] illustrates (1) the interaction between patients, physicians, health agencies, the news media and private industry involved in the investigation and control of a foodborne outbreak; (2) The value of early identification and removal of contaminated food; and (3) the valuable clinical and laboratory information that can be gained.

• On May 6, 1973, twenty-eight members of five families gathered at the home of one of the families in Pittsburgh. They ate two meals, which included a variety of commercial products but no home-canned foods. Within three days, several members of the group experienced gastrointestinal symptoms, one was hospitalized in West Virginia with a tentative diagnosis of bowel obstruction, and another member was hospitalized in Pennsylvania with possible poisoning. On May 9th and 10th, five more members of the group went to the physician caring for the first patient, and were hospitalized with presumptive diagnosis of botulism; the physician notified CDC, which in turn, notified the FDA and state health departments, and sent a team of investigators to Pennsylvania.

On May 10, all seven patients received botulinal antitoxin, serum and stool specimens were examined for botulinal toxin and *Clostridium botulinum*. An epidemiological investigation was initiated, commercially canned hot peppers in oil were implicated, samples of leftover food were taken to FDA laboratories, and the plant producing the peppers investigated. Public health authorities issued an alert through new media in the tristate area where most of the peppers

had been distributed. Persons who had eaten the peppers in the previous week were advised to see a physician. Several such individuals who had experienced gastrointestinal symptoms were reported by physicians and given botulinal antitoxin; none developed neurologic symptoms. Persons who had the incriminated pepper product in their homes were advised to return it to the store where it had been purchased.

On May 11, type B botulinal toxin was detected in the peppers. A plant investigation disclosed that the product was not acidified and the company did not use a pH meter to monitor its products. On May 12, at the request of the FDA, the canning company issued a voluntary recall of all pepper products. The company's production was discontinued until safe practices could be established under supervision of state health authorities.

This investigation also afforded an opportunity to carefully document the presenting symptom profile and the results of serial electromyographic (EMG) studies and studies to detect toxin in stools in simultaneously acquired cases.[7] At the time of this outbreak, both EMG and stool toxin detection had only recently been applied diagnostically in botulism investigations, and most previous data had been obtained on single cases. The usefulness of EMG studies in diagnosing botulism was reaffirmed. This was the first outbreak in the United States in which botulinal toxin was detected in patients' stools. Today this is considered an important diagnostic tool in botulism, particularly in suspect cases with mild motor neurological signs and symptoms.

- Information collected during an investigation can be used to prevent subsequent outbreaks from occurring in a food service establishment where the incriminated food was prepared and throughout the entire or appropriate segment of the industry. An outbreak of *Clostridium perfringens* that resulted from contaminated turkey prepared and served in a school illustrates this point.[8] After the turkeys were cooked, the ovens were turned off and the turkeys remained in the ovens overnight. During this period, spores that survived cooking germinated and the resultant vegetative cells multiplied. Reheating practices used the next day were inadequate to kill the vegetative cells. During surveys and discussions with school lunch supervisors, it was learned that this practice of preparing turkeys was not uncommon. Practical methods of rapidily cooling turkey and stock were developed, and a training program was instituted for school lunch supervisors. The program emphasized the hazardous practices and outlined practical methods of preventing growth of pathogens during chilling operations and methods of destruction during reheating. The control measures developed could also be used to educate restaurant operators and the general public.
- Investigation of cases of "food" poisoning can also lead to a public alert and programs in public education directed toward avoiding potentially hazardous practices in the home. Two cases (one fatal) of poisoning associated with consumption of "herbal teas" mistakenly made with a poisonous substance were reported in 1977.[9]

The cases involved infants who had been fed large quantities of a tea prepared from a locally marketed product, gordolobo yerba, which is usually made from leaves of plants of the *Gnaphalium* species. This tea is widely used as a gargle

and cough medicine by Hispanic populations to which the children belonged. Analysis of the tea fed to the infants revealed that it had inadvertently been made from *Senecio longilobus*, a hepatotoxic herb containing pyrrolizidine alkaloids.

As a result of these cases, the Arizona State Department of Health Services began working with local health departments to disseminate information about this problem, particularly in Hispanic communities.

Knowledge of Disease Causation. Foodborne disease of microbiological origin is the principal hazard to health associated with the food supply (see p. 159). Providing safe food requires intimate knowledge of the agents of foodborne infections and intoxications.

Investigation of foodborne disease outbreaks of microbiological origin provide information about the nature of the agent, its source, reservoirs, vehicles and modes of transmission, and the factors that contribute to outbreaks. Once the factors that contribute to outbreaks have been established, control measures can be developed.

During the last fifty years the number of bacterial agents found to be implicated in foodborne disease has increased.[10] In addition to salmonella and shigella species, *Staphylococcus aureus, Clostridium perfringens, Vibrio parahaemolyticus, Bacillus cereus, Escherichia coli* and certain streptococci have been responsible for outbreaks of foodborne illness.

As a result of investigations of epidemics and bacteriological surveys the patterns of disease and their changing cycles become clear. For example, at the beginning of the century many people thought that rodents were the most important reservoir for Salmonella; then emphasis shifted to the human carriers; now domestic food-producing animals are thought to be the most important reservoirs and foods of animal origin the most important mode and vehicles of transmission.[11]

Agents now unknown may be important causes of disease. *Clostridium perfringens* first appears in surveillance reports in 1959 but not until recently was it recognized as an important agent of foodborne disease in the United States. From 1972 through 1977, *C. perfringens* was responsible for 61 outbreaks and 3,956 cases and accounted for 6.5% of all outbreaks and 11.2% of all cases confirmed by the CDC.[1] *Vibro parahaemolyticus* has been a well-documented cause of disease since the early 1960's, but not until the 1970's was it recognized as a significant cause of gastroenteritis in the United States. It was first suspected when investigation of an outbreak in 1969 revealed large numbers of vibrios in oysters that had been implicated in the outbreak.[11] The first full laboratory documentation of foodborne disease caused by this organism was reported in Maryland in 1971 when the organism was isolated from patients and food in several outbreaks.[12] By the end of 1977, 20 outbreaks had been reported in the United States.[12,1]

From 1970 through 1977, the responsible pathogen was not identified in 30% to 60% of foodborne outbreaks reported each year to the CDC.[1] According to the CDC,[4] in many of these outbreaks, pathogens known to cause foodborne illness may not have been identified because of late or incomplete laboratory investigation. In others, the responsible pathogen may have escaped detection even when

a thorough laboratory investigation was carried out because the pathogen is not yet appreciated as a cause of foodborne disease or because it cannot yet be identified by available laboratory techniques.[5] These pathogens might be identified and suitable measures to control diseases caused by them might be instituted as a result of thorough clinical, epidemiologic, and laboratory investigations. Pathogens suspected of being, but not yet determined to be etiologic agents in foodborne disease include Group D streptococcus, *Citrobacter*, *Enterobacter*, *Klebsiella*, *Pseudomonas aeruginosa*, and the presumably viral agents of acute infectious nonbacterial gastroenteritis (e.g., coxsackie, parvo). Although pathogens such as *E. coli* and *B. cereus* are known causes of foodborne illness, the extent and importance of their role have not yet been fully determined.

Administrative Guidance. Rational planning, setting priorities, and allocation of budgets for long-range prevention of foodborne disease should largely depend upon the collection of sufficient data from outbreak investigations that permit assessment of current trends in causative agents, food vehicles, and common practices of mishandling and mistreating foods. The data once compiled and published serve as a guide for such preventive efforts as education of the public, training managers and workers in food service establishments, inspection of food service and processing plants, and food production and processing regulations. The following examples illustrate the use of such data in developing food safety regulations, training programs, ordinances, and public education programs.

- Following outbreaks of salmonellosis caused by cake mixes, cream pies, and other products containing dried or frozen eggs, regulations were passed to require the pasteurization of all liquid eggs that are dried or frozen and shipped interstate.[13]
- Investigations of foodborne disease outbreaks have shown that the proximate cause of the great majority of cases is the direct result of food handling practices at the food service level. For over 40 years, the U.S. Public Health Service has been concerned with protection of food prepared for service to the public.[14] Throuh its technical assistance to states and municipalities, it has encouraged the development and maintenance of food protection programs and the adoption of uniform ordinances and codes regulating the food service operations. It has also cooperated with the food service industry in developing training programs and materials for industry personnel. Examples include the Food Service Sanitation Manual 1976;[14] and a plan for training food service managers[15] — Final Report-Development of a Uniform National Plan for Sanitation Training of Food-service Managers prepared by the National Institute for the Food Services Industry on contract from the Food and Drug Administration.
- The Manual[14] also contains a model restaurant inspection ordinance, Food and Drug Administration Food Service Sanitation Ordinance (1976 Recommendations), recommended for adoption by state and local jurisdictions. The ordinance defines and places emphasis on "potentially hazardous foods" and on food protection measures designed to prevent contamination with filth, pathogenic microorganisms, and toxic chemicals, and the rapid and progressive growth of pathogenic microorganisms.

• Because epidemiologic data showed barracuda were frequently associated with ciguatera poisoning in Miami and the Caribbean, the Miami City Code now prohibits the sale of barracuda.[16] However, ciguatoxic fish are a continuing foodborne disease problem in Miami. Modifications of the usual foodborne disease surveillance and control efforts of the Dade County (Miami) Department of Public Health during 1974 through 1976 enabled collection of detailed information on ciguatera illnesses in that area.[16]
• In response to an increase in outbreaks of botulism reported to the CDC in 1974, most of which were caused by home-canned foods, the U.S. Department of Argiculture increased its efforts to educate the estimated 25 million home canners in the United States in proper canning techniques.[17]

Epidemiology

Although it is impossible to establish the true incidence of foodborne disease in the United States, as noted in the section on reporting, data from the Center for Disease Control (CDC) do show the predominance of certain etiologies; geographic distribution; vehicles of transmission; places where food is mishandled; and the factors that contribute to foodborne disease.

Etiology, Incidence, and Mortality. In 1972, the CDC began distinguishing between confirmed and unconfirmed outbreaks and cases of foodborne illness in its annual summaries of foodborne disease. The CDC defines a foodborne disease outbreak as an incident in which two or more persons experience similar illness after ingesting a common food that epidemiological analysis implicates as the source of the illness. There are two major exceptions: one case of botulism or chemical poisoning constitutes an outbreak.

The etiology of an outbreak is classified as confirmed if specific clinical, epidemiological, and laboratory criteria are satisfied; if these criteria are not met, the etiology is classified as unknown.

During the most recent six years for which annual foodborne disease summaries are available (1972-1977),[1] the etiology was confirmed in 30% to 45% of the total outbreaks reported each year. During this period, a total of 940 confirmed outbreaks and 35,227 confirmed cases were reported to the CDC (Table 1).

Of the 940 confirmed outbreaks, the etiology was bacterial in 66%, "chemical" in 23%, parasitic in 8%, and viral in 3%. As in previous years pathogenic bacteria accounted for the great majority (91%) of the total confirmed cases from 1972 through 1977. Of these confirmed cases, salmonellae, *Staphylococcus aureus*, and *Clostridium perfringens* were the most frequent etiologic agents. Outbreaks of shigellosis, and *Vibrio parahaemolyticus* gastroenteritis involving large numbers of people put these diseases among the leading causes of foodborne illness during certain years in this six-year period.

According to the CDC's classification of "chemical" foodborne disease (Table 1), toxic fish (scombrotoxin and ciguatoxin) were responsible for the largest number of confirmed cases of chemical etiology, followed by heavy metals,