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FOODBORNE ILLNESS: A REVIEW FROM NATIONAL, STATE AND LOCAL PERSPECTIVES WITH AN OUTBREAK INVESTIGATIONAL REPORT

By

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ABSTRACT

FOODBORNE ILLNESS: A REVIEW FROM NATIONAL, STATE AND LOCAL PERSPECTIVES WITH AN OUTBREAK INVESTIGATIONAL REPORT

By

Susan Elaine McIntosh

Foodborne illness has become a major public health concern in recent years. Surveillance of foodborne illness at the national, state and local levels has been instrumental in obtaining information necessary to track patterns and determine causes of illness. Regulatory agencies use this information to form public health policy. The new public health interventions included in the FDA 1999 Food Code are a result of knowledge gained through surveillance of foodborne illness. Local health departments must continue to improve their investigational skills in order to effectively contribute to this knowledge base. In 1998 the Ingham County Health Department developed a written protocol to investigate foodborne illness outbreaks. The collaborative writing of this protocol is discussed, and an example of an outbreak investigation is described.

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INTRODUCTION

Public health surveillance can be defined as the routine collection, analysis and dissemination of all data that may be relevant for the prevention and control of a public health problem.[18] Epidemiology is defined as the study of the distribution and determinants of health-related states or events in specified populations and the application of this study to control of health problems.[31] The control of communicable disease requires a clear understanding of the epidemiology of the disease in addition to a reliable surveillance system. Reporting of communicable disease is an essential part of any public health surveillance program.

Foodborne illness continues to be a serious public health problem. It is estimated that foodborne diseases cause 76 million illnesses, 325,000 hospitalizations and 5,000 deaths in the United States each year. The epidemiology of foodborne illness is constantly changing, which makes it necessary to learn from and adapt to those changes in order to effectively institute prevention measures. A typical learning model can be used to illustrate how this is accomplished (Figure 1).

Surveillance systems are necessary to track patterns of foodborne illness in the U.S. The epidemiological investigations of foodborne outbreaks are a necessary part of the process. Surveillance at the local or state level will indicate if a foodborne illness outbreak is occurring. Results from these outbreak investigations are compiled at a national level of surveillance. At this level much can be learned about causes of foodborne illness. Along with scientific research stimulated by these results, prevention measures can be put into place.

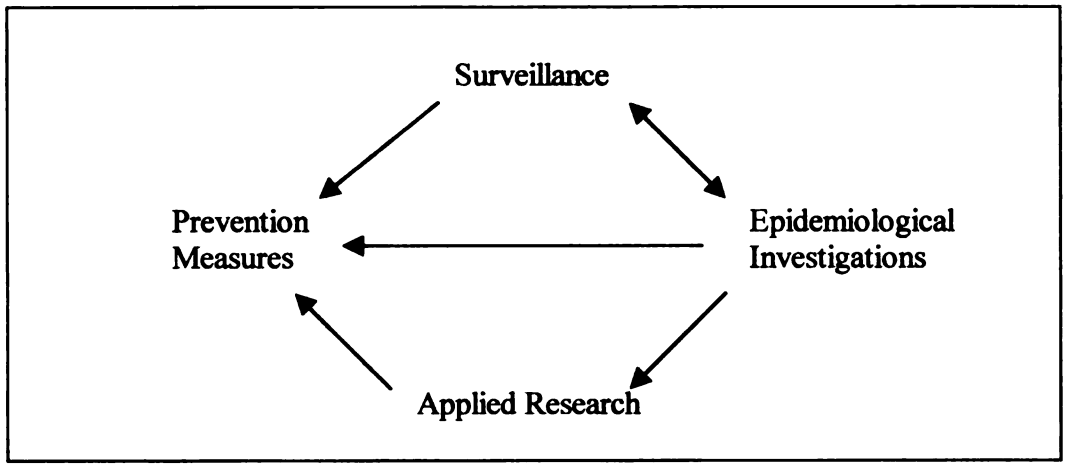

Figure 1. Learning Model for Public Health Issues

This paper will discuss the current state of surveillance in the United States, the State of Michigan and Ingham County. The FDA 1999 Food Code has recently been adopted into the Michigan Food Law 2000. The major changes in the code are a result of knowledge gained from the analysis of data collected by various surveillance methods at the national level. These changes will be critiqued with regard to how effectively they will address current problems in food service sanitation.

Finally, the development of a local health department protocol for investigating foodborne illness outbreaks will be described, and an example of a local outbreak investigation using the protocol will be outlined.

CHAPTER 1

SURVEILLANCE AND INVESTIGATION OF FOODBORNE ILLNESS OUTBREAKS IN THE UNITED STATES

History of Surveillance of Foodborne Illness

Early in the 20th century, state and territorial health offices in the United States became concerned about the high levels of morbidity and mortality caused by infantile diarrhea and typhoid fever. Investigation and reporting of "enteric fever" was recommended in order to better understand the role of milk, food and water in outbreaks of intestinal illness. This knowledge would become the basis for public health action. The Public Health Service began publishing summaries of outbreaks of gastrointestinal illness attributed to milk in 1925. By 1938 all foods were included in the summaries.[8] The surveillance system in the U.S. continued to develop into the multi-faceted program it is today. National surveillance systems for foodborne diseases now in place in the U.S. include outbreak surveillance, laboratory based passive surveillance of individual cases, physician-based surveillance and active surveillance. The Centers for Disease Control (CDC) now assumes the responsibility for publishing reports of foodborne illness on a national level.

Purpose of Foodborne Illness Surveillance

Foodborne disease outbreak surveillance has served three main purposes: [8,48]

1. Disease prevention and control: Local and state public health officials are responsible for correction of faulty food preparation practices in food service

establishments and prompt identification and removal of contaminated products from the commercial market.

2. Knowledge of disease causation: Outbreak investigations have provided invaluable information regarding new and emerging pathogens as well as the long-standing pathogens. Prompt and thorough investigations of foodborne outbreaks aid in the timely identification of etiologic agents of the disease.
3. Administrative guidance: Trends in the prevalence of outbreaks caused by specific organisms, food vehicles and food handling can be analyzed. Changes can then be made in the regulatory and educational areas in order to more effectively implement preventive actions.

Reporting of Outbreaks

The reporting of outbreaks to CDC Foodborne Disease Outbreak Surveillance System is considered passive surveillance. A foodborne Disease Outbreak is defined by CDC as "the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food. Only a small percentage of foodborne illness is identified through this passive system. In order for a foodborne illness to be reported all the way to the CDC it must first be reported to the local health department, recognized as an "outbreak", investigated, reported to the state health department and then passed on to the CDC. Alternatively, a case of foodborne illness is reported when a person becomes ill, seeks medical care, is culture-confirmed with a particular pathogen and this case is reported to the state health department and then to the CDC. It is estimated that only 5% of bacterial foodborne illness is reported to the CDC by this system.[3]

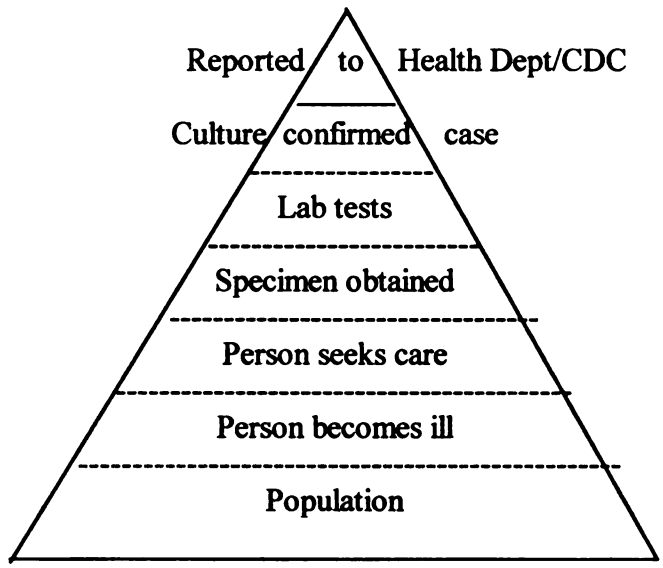

Figure 2. Passive Surveillance Pyramid [53]

There are several reasons why foodborne disease is underreported. Often the ill person does not seek medical care. In many cases the illness is not severe and is of short duration or is mistaken for the "stomach flu" and not recognized as being transmitted by food. Often the health care provider fails to obtain a specimen for diagnosis. The laboratory may not have performed the necessary diagnostic test or the test results may not be reported to the local health department. Michigan's communicable disease rules (section 5111 of Act No. 368 of the Public Acts of 1978, as amended, being 333.5111 of the Michigan Compiled Laws)[45] require certain human pathogens to be reported to the local health department. The foodborne pathogens that are required to be reported by laboratories include: *Campylobacter jejuni, Clostridium botulinum, Cryptosporidium* species, *Cyclospora* species, *Giardia lamblia*, Hepatitis A, *Listeria monocytogenes*, *Salmonella* species, Shiga toxin producing *E. coli, Shigella* species, *Trichinella spiralis*

and *Yersinia enterocolitica*.[18] The illnesses associated with these organisms are required to be reported by physicians to the local health department. Sporadic illness caused by some pathogens such as *Clostridium perfringens* or *Bacillus cereus* is not reportable. Therefore the only cases reported for these two organisms and others that are not reportable are those associated with outbreaks. In addition, local health departments may not be equipped with the resources necessary to thoroughly investigate an outbreak.

FoodNet

In 1995 the Foodborne Diseases Active Surveillance Network (FoodNet) was established as the foodborne disease component of the Emerging Infections Program (EIP) of the CDC. FoodNet is a population-based active surveillance program that provides a network for responding to emerging foodborne disease and for determining more accurately the frequency and severity of foodborne illnesses that occur in the United States. By 1998 there were seven CDC EIP sites (Minnesota, Oregon and selected counties in California, Connecticut, Georgia, Maryland and New York) collaborating with the U.S. Department of Agriculture (USDA) and the U.S. Food and Drug Administration (FDA). The total population of these sites was 20.5 million people or 7.7% of the U.S. population.[13] In 1999 the remaining counties in Georgia and eight counties in the metropolitan Albany, New York, area were added. In 2000, 11 counties in Tennessee and Contra Costa County in California were added, bringing the FoodNet surveillance population to 29.5 million persons (10.8% of the 1999 U.S. population). In 2001 selected counties in Colorado and Maryland will be added to the FoodNet area,

bringing the FoodNet population to approximately 33.1 million persons (12% of the 1999 population).

Data on nine foodborne pathogens (*Campylobacter, Cryptosporidium, Cyclospora, Escherichia coli* O157, *Listeria, Salmonella, Vibrio and Yersinia*) is collected. More than 300 clinical microbiology laboratories in the catchment areas are contacted regularly to obtain information on all laboratory-confirmed cases of diarrheal illness. Physician stool-culturing practices vary greatly. FoodNet surveyed more than 5000 physicians to determine how often and under what conditions they order these tests. A population survey was conducted (approximately 9000 randomly selected people per year) in order to estimate the percentage of the population that seeks medical care when afflicted with diarrheal illness. Case control studies of *E.coli* O157, *Salmonella* serogroups and *Campylobacter* have also been conducted to provide information on food items and other risk factors associated with diarrheal illness. Information from all of these investigations has been combined and analyzed each year in order to more precisely monitor the burden of foodborne illness and to compare these findings with time.

Surveillance for Foodborne Disease Outbreaks from 1993-1997 in the U.S.

During the years 1993-1997 2,751 outbreaks of foodborne illness were reported to the CDC (489 in 1993, 653 in 1994, 628 in 1995, 477 in 1996 and 504 in 1997).[8] This study was based on the Foodborne Disease Outbreak Surveillance System. These reported outbreaks caused 86,058 persons to become ill over the five year period.

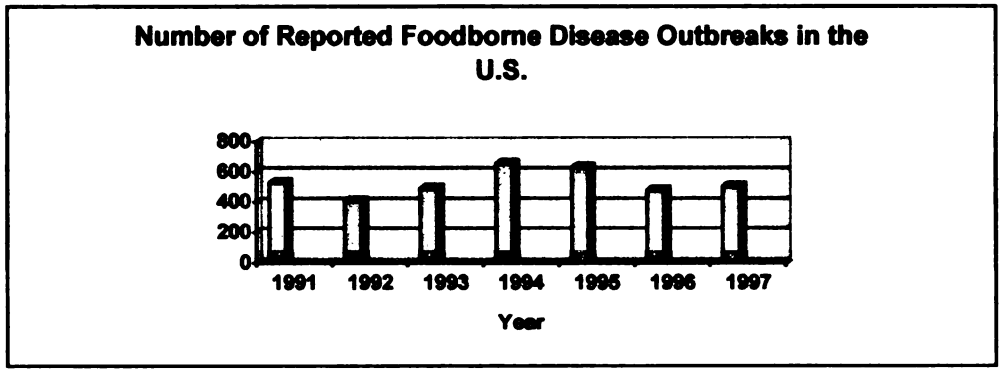

Figure 3. Reported Foodborne Disease Outbreaks in the U.S. 1991-1997 [8,16]

In 1999 the CDC published results of a comprehensive study designed to more accurately estimate the burden of foodborne illness in the United States. Sources of data for this project include the Foodborne Diseases Active Surveillance Network (FoodNet), the National Notifiable Disease Surveillance System, the Public Health Laboratory Information System, the Foodborne Disease Outbreak Surveillance System, the National Ambulatory Medical Care Survey, the National Hospital Ambulatory Medical Care Survey, the National Hospital Discharge Survey, and the National Vital Statistics System as well as selected published studies.[46] Selected results of this study are shown in Table 1. Known pathogens cause approximately 38.6 million illnesses per year, which include 5.2 million (13%) due to bacteria, 30.9 million (80%) due to viruses and 2.5 million (7%) due to parasites. Of these 38.6 million, 13.8 million are believed to be of foodborne transmission. For known foodborne transmitted illnesses, approximately 30% are caused by bacteria, 67% by viruses and 3% by parasites (see Table 1).

Table 1. Reported and estimated illnesses, frequency of foodborne transmission and estimated foodborne illness in the U.S[33]

Disease or Organism Bacterial	Estimated Total Cases	Reported Cases	% Foodborne	Estimated Foodborne
Bacillus cereus	27,360	792	100	27,360
Botulism, f.b.	58	29	100	58
Brucella spp.	1554	111	50	777
Campylobacter	2,453,926	102,219	80	1,963,141
C.perfringens	248,520	7,194	10	248,520
E.coli 0157:H7	73,80	6,899	85	62,458
E.coli, other	158,840	4,389	30-70	79,420
L.monocytogenes	2,518	1,632	99	2,493
Salmonella typhi	824	412	80	659
Salmonella, other	1,412,498	78,653	95	1,341,873
Shigella	448,240	41,212	20	89,648
Staph., f.b.	185,060	5,357	100	185,060
Strep, f.b.	50,920	1,474	100	50,920
V. cholerae, (toxigenic)	54	27	90	49
V.vulnificus	94	47	50	47
Vibrio,other	7,880	505	65	5,122
Y.enterocolitica	96,368	2,536	90	86,731
Subtotal	**5,204,934**			**4,175,565**
Parasitic				
C.parvum	300,000	9,418	10	30,000
C.cayetanensis	16,264	526	90	14,638
Giardia lamblia	2,000,000	129,907	10	200,000
Toxoplasma gondii	225,000	15,000	50	112,500
Trichinella spiralis	52	26	100	52
Subtotal	**2,541,316**			**357,190**
Viral				
Norwalk-like virus	23,000,000		40	9,200,000
Rotavirus	3,900,000		1	39,000
Astovirus	3,900,000		1	39,000
Hepatitis A	83,391	27,797	5	4,170
Subtotal	**30,883,391**			**9,282,170**
Grand Total	**38,629,641**			**13,814,924**

Symptom-based data was used to estimate the total number of acute gastrointestinal illnesses. Known cases were subtracted from this total to estimate illness due to acute gastroenteritis of unknown agents. In Figure 4 the estimates for both the known and unknown pathogens are added together to give a grand total of 76 million foodborne illnesses per year in the United States.

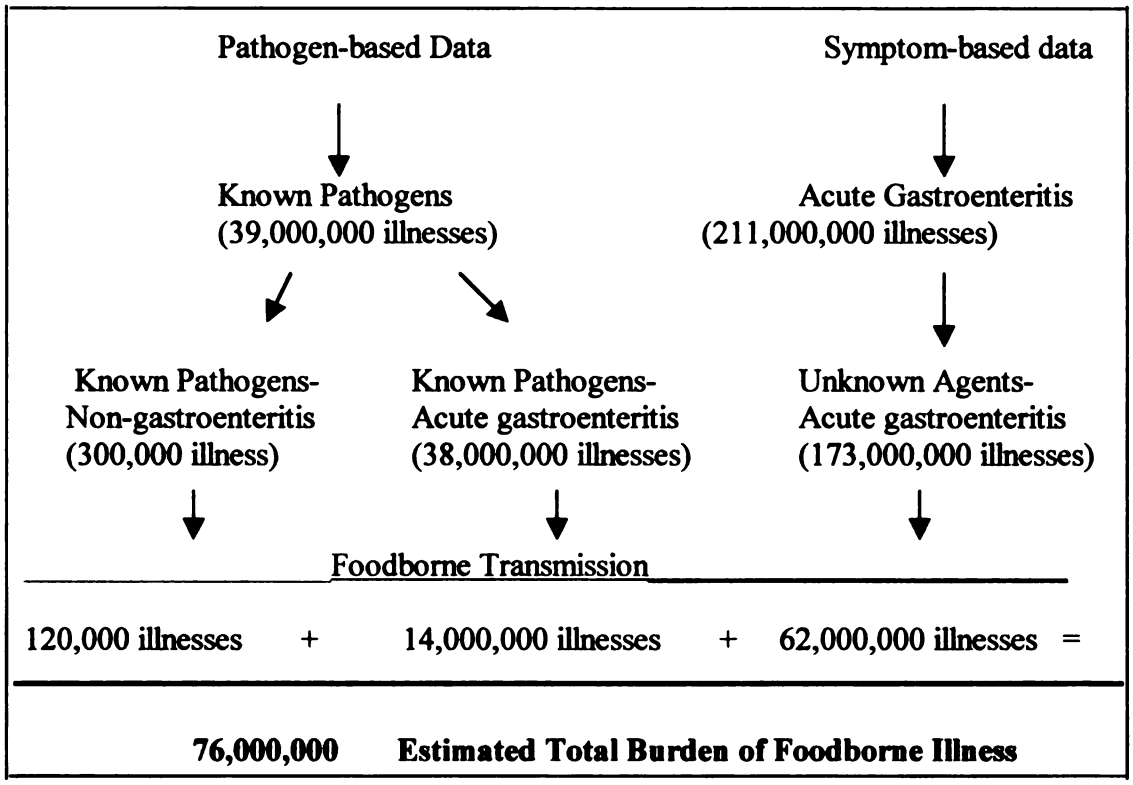

Figure 4. Estimated frequency of foodborne illness in the U.S.[33]

Preliminary results from FoodNet data on the incidence of foodborne illnesses in 2000 have recently been published. [15] The number of sites and the population under surveillance has nearly doubled since 1996. Therefore, to be consistent, temporal trends in rates of foodborne illness were compared using data from only the original five sites (Table 2). Included in the table is the incidence rate for all sites for 2000.

Table 2. Incidence rate (per 100,000 population) of diagnosed infections for pathogens at the five original FoodNet sites, 1996-2000, for all eight sites for 2000*, by year and pathogen and the Healthy People 2010 goal# (when applicable)(2000 rates are preliminary) [8,12]

Pathogen	1996	1997	1998	1999	2000	2000*	HP2010#
Campylobacter	23.5	25.2	21.4	17.5	20.1	15.7	12.3
Cryptosporidium	NR	3.7	2.9	1.8	2.4	1.5	
Cyclospora	NR	0.4	0.1	0.1	0.1	0.1	
E. coli O157:H7	2.7	2.3	2.8	2.1	2.9	2.1	1.0
Listeria	0.5	0.5	0.6	0.5	0.4	0.3	0.25
Salmonella	14.5	13.6	12.3	13.6	12.0	14.4	6.8
Shigella	8.9	7.5	8.5	5.0	11.6	7.9	
Vibrio	0.2	0.3	0.3	0.2	0.3	0.2	
Yersinia	1.0	0.9	1.0	0.8	0.5	0.4	

For all five years *Campylobacter* was the most frequently diagnosed pathogen, followed by *Salmonella, Shigella* and *E.coli* O157:H7. Although the relative order of incidence rates are the same between the 2000 five-site and 2000 eight-site statistics, the differences show regional differences in pathogen isolation rates. The preliminary 2000 rates were based on the 1999 census population. Once the final 2000 census is determined the adjusted rates will be lower. These FoodNet foodborne disease rates will continue to be a more accurate measure of the progress toward the Healthy People 2010 national health objectives as the percentage of total U.S. population encompassed by FoodNet increases.

Purpose of Outbreak Investigation

Although the number of outbreaks investigated by local health departments reported to the CDC represent only the tip of the iceberg, there are several specific reasons why these investigations must be done: [27]

1. To identify illnesses associated with an incident or outbreak and to verify that the causative agent is foodborne
2. To detect all of the cases, the causative agent, the implicated food and the location where the food was mishandled
3. To determine the source and the mode of contamination or practices by which the proliferation and/or survival of the etiologic agent occurred
4. To stop the outbreak or prevent further exposures
5. To gather information for the surveillance purposes on the epidemiology of foodborne diseases and the etiology of the causative agents that can be used for education, training and program planning which can make an impact on preventing foodborne illness.

Michigan Law

By law, local health departments in Michigan are required to investigate foodborne illness outbreaks. Michigan's Public Health Code Sec. 2433 (2) (c) states that "A local health department shall make investigations and inquiries to (i) the causes of disease and especially of epidemics (ii) the causes of morbidity and mortality (iii) the causes, prevention, and control of environmental health hazards, nuisances and sources of illness." [45] Under the authority of Michigan's Public Health Code, Section 12909, Food

Service Sanitation Administrative Rule 5402 (2) states "Procedures for investigating suspected foodborne illness outbreaks shall be implemented in accordance with the publication entitled "Procedures to Investigate Foodborne Illness" prepared and published by the International Association of Milk, Food and Environmental Sanitarians, Incorporated, or an alternative local plan submitted to and approved by the department...A complete summary report shall be prepared and submitted to the department." Section 12912 of the Michigan Public Health Code states that "(1) A local health department shall investigate foodborne diseases and poisonings or suspected foodborne diseases and poisoning connected with a food service establishment, temporary food service establishment, or vending machine located within its jurisdiction and shall promptly make a report of its findings to the department." [45]

Until 1996, local health departments were conducting food service inspections under the direction of the Michigan Department of Public Health. Retail grocery operations were inspected by the Michigan Department of Agriculture using a different food safety standard. Grocery stores have ventured into more food service activities over the past decade. The result was that many grocery stores were being regulated by both agencies with two different standards. The need for a "unified code" became clear. In 1996 the food service program was moved to the MDA and the development of a uniform code was initiated. Michigan Department of Agriculture convened a group of industry, regulatory and academic experts to evaluate the current FDA Model Food Code for possible adoption in Michigan. Michigan adopted the Michigan Food Law 2000 in November of 2000, House Bill 5196.[44] In this Law the FDA 1999 Food Code was adopted by reference.

Section 3129 of the Food Law 2000 states "(1) A local health department shall investigate an allegation of foodborne diseases and poisonings or suspected foodborne diseases and poisonings connected with food service establishments within its jurisdiction and delegated authority and shall promptly make a report of its findings to the department. (2) If an investigation indicates that a source of a foodborne disease or poisoning was from a food processing, food storage, or similar type of food establishment over which the department has legal jurisdiction or responsibility, the local health department shall immediately notify the director while the local health department is completing the investigation." Section 3131 states that " (1) A local health department shall develop and implement a communications system with other applicable governmental agencies, individuals, and organizations including, but not limited to, hospital emergency rooms and state employees and basic information necessary to initiate a foodborne illness outbreak investigation. The information provided in the communications system shall be updated annually. (2) Procedures for investigating suspected foodborne illness outbreaks shall be implemented, consistent with procedures contained in the publication entitled "Procedures to Investigate Foodborne Illness, 5th Ed.," prepared and published by the International Association of Food Protection and incorporated by reference or an equivalent plan submitted to and approved by the department. (3) All information gathered during the investigation which is not exempted from disclosure under section 13 of the Freedom of Information Act, 1976 PA 442, MCL 15.243, and shall be made available to the owner, operator, or his or her employees to minimize the possibility of reoccurrence of the foodborne illness and to assure compliance with the code and this act." [44]

Generally, foodborne disease outbreaks investigated by the local health department such as Ingham County are then reported to the state health department who then report to the CDC through the Foodborne Outbreak Surveillance system. In Michigan, the local health departments report directly to the Michigan Department of Agriculture (MDA) Food and Dairy Division. This division provides support to local health departments in the areas of consultation and training. The Science and Technology Section of this division also maintains a Foodborne Illness Surveillance Database. The information for this database is taken directly from complaints and reports filed by local health departments and MDA food inspectors. MDA then forwards this information to the MDCH and the CDC.

Complaints received by the MDA are classified as follows: [35]

Family: Two or more related cases with symptoms compatible with foodborne illness etiology, i.e., gastroenteritis.

Alert: Generally, a single reported case of foodborne illness

FBI/FBIO: (foodborne illness/foodborne outbreak): an incident involving two or more unrelated cases having similar clinical features or having the same pathogen. There is also a time, place or person association among the cases. Single cases of botulism, mushroom poisoning, ciguatera or paralytic shellfish poisoning or other rare illness, or a case that can be definitely related to food also are classified as FBIs.

ICC: (Isolated Consumer complaint): Incidents of adulterations of food or complaint of food quality (ex: hair found in potato salad)

The Michigan local health departments rely on a cost-sharing system with the State of Michigan to operate its mandated programs. Therefore they must conform with

certain requirements, "minimum program requirements" (MPRs) in each of their mandated programs in order to continue the cost-sharing relationship. The MPRs became effective October 1,2000 and contain detailed requirements for fulfilling the Michigan Public Health Code (now Michigan Food Law 2000). The local health department is reviewed yearly for compliance with these MPRs. Ingham County continues to improve their system for reporting and surveillance of foodborne illness and the investigation of foodborne disease outbreaks.

Surveillance for Foodborne Outbreaks in Michigan from 1990-1999

Although the MDA has been collecting local health department data on suspected foodborne illness and outbreaks for several years, the department began summarizing their yearly surveillance of foodborne illness beginning with the year 1998 in order to provide oversight for the MPRs.

Figure 5 shows the number of foodborne illness complaints received by the MDA from 1990-1999. In 1997 MDA began using the IAMFES subcategories described earlier. In 1998 alerts and family related illnesses have been separated.
The number of people reportedly ill due to foodborne illnesses increased in 1997 but leveled off in 1998 and 1999. In 1998 only 102 incidents of the total 1250 events met the legal definition of foodborne illness outbreak. These 102 incidents included 986 ill people. In 1999, 141 of the 1143 reported incidents met the legal definition, including 1236 ill people.[36] In 1998 final investigative reports were not received from local health

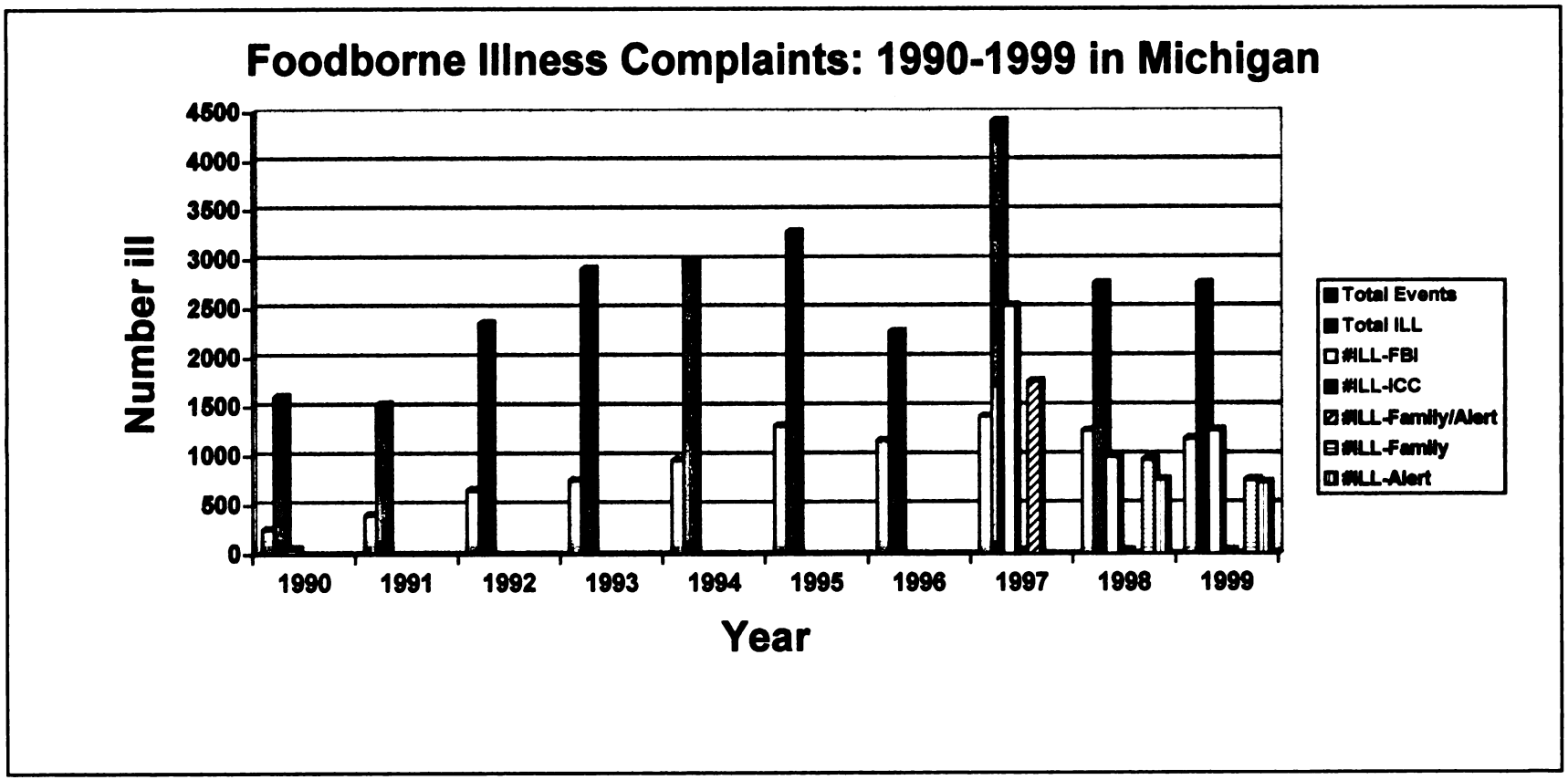

Figure 5. Foodborne illness complaints reported to MDA, 1990-1999 [35,36]

departments for 57 (56%) of the total 104 outbreaks. The MDA yearly report for 1999 pointed out that final investigative reports were not received from local health departments for 28 (19%) of the 141 outbreaks. Table 3 shows that the etiology of foodborne outbreaks was identified in only 4 (9%) of the 45 outbreak reports in 1998 and in 45 (40%) of the 113 reports received in 1999.

Table 3. State of Michigan Reported Outbreaks and Final Reports with Confirmed Etiology, 1998 and 1999 [35,36]

	1998		1999	
Agent	**# events**	**#ill**	**#events**	**#ill**
B. cereus	2	44	1	2
C. perfringens			2	23
Campylobacter			5	5
E. coli O157:H7			5	5
E.coli, other			1	2
Salmonella			11	25
Shigella			1	1
S. aureus			2	4
Calcivirus			1	62
Hepatitis A	1	3	11	51
Norwalk virus	1	34	3	75
Total (etiology confirmed)	4	81	45	255
Total reports	45		113	
Total outbreaks	102	986	141	1236

Improvement is shown between 1998 and 1999. The percentage of final investigative reports submitted to MDA increased from 44% to 72% of total outbreaks. With the enforcement of MPRs at the local level, this percentage will continue to

increase. The percentage of outbreaks where the etiology was confirmed in the reports also increased, from 9% to 40%. This may be due to several factors:

1. More testing of stool and food specimens is being requested as the local health departments improve their investigative epidemiological skills and apply the required guidelines according to MPR's.
2. More testing requests are being accepted by the MDCH laboratories.
3. Testing for Norwalk-like viruses is becoming more available and local health department personnel are becoming more educated on when to request testing for these viruses.

The publication of the Year-End Summaries for Foodbore Illness Surveillance by the MDA as well as increased opportunities for consultation with MDA staff and laboratory support services will continue to improve participation by local health departments and improve the surveillance system for foodborne illness in Michigan.

Surveillance for Foodborne Outbreaks in Ingham County, 1996-2001

Ingham County keeps a complete log of foodborne illness complaints received. Figure 6 indicates a slight increase in the number of complaints received yearly. There has also been a slight increase in the number of illnesses determined to be outbreak related. The preliminary data for 2001 indicate a sharper increase for the year 2001. This increase may be attributed to improved reporting by the public as well as improved response by the ICHD in investigating possible outbreaks.

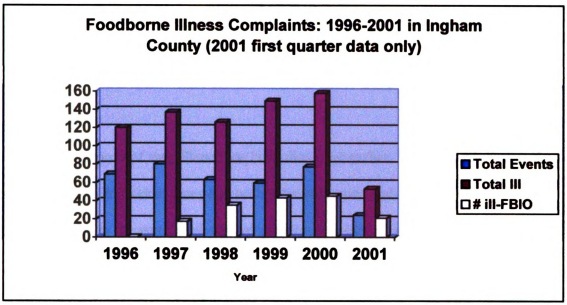

Figure 6. Foodborne illness complaints received by ICHD, 1996-2001.

CHAPTER 2

MICHIGAN FOOD LAW 2000

The purpose of surveillance has been discussed earlier. When the etiology and epidemiology of individual cases and outbreaks is documented and reported by the local health agencies to the state level, this information is compiled at a national level. The CDC, part of the U.S. Public Health Service, is not a regulatory agency. Its mission is to monitor, investigate, control and prevent public health problems. The CDC works closely with the state health departments to monitor the frequency of specific diseases and conducts national surveillance for them as well as providing expert epidemiologic and microbiologic consultation to health departments. Trends in the occurrence of outbreaks caused by specific organisms, food vehicles and food handling practices can be analyzed. This information is then used by regulatory agencies to direct public health policy.

The CDC has published summaries of the surveillance of foodborne disease outbreaks. There have been three comprehensive studies summarizing data compiled from the years 1983-1997 (1983-1987, 1988-1992 and 1993-1997) [11,16,17] Individual epidemiological studies performed by local or state health departments that were reported to the CDC are included in these nationally comprehensive studies. Vehicles of transmission and contributing factors were tabulated for these outbreaks. From this data the CDC has concluded that there are five leading causes of foodborne illness outbreaks:

Five Leading Causes of Foodborne Illness Outbreaks:[11,17]

1. Improper holding temperatures
2. Poor personal hygiene of food workers
3. Inadequate cooking of foods
4. Contaminated equipment
5. Obtaining food from unsafe sources (example: oysters harvested from contaminated oyster beds)

The FDA publishes the Food Code,[51] a reference that guides retail food outlets such as restaurants and grocery stores on how to prevent foodborne illness. It is neither federal law nor federal regulation and is not preemptive. It is commonly adopted and used by agencies at all levels of government that have regulatory responsibilities for food safety. The food code is updated every two years. This process is a collaborative effort by FDA, CDC, Food Safety and Inspection Service (FSIS) and the Conference for Food Protection. The conference is comprised of representatives from regulatory agencies at all levels of government, the food industry, academia and consumer organizations that work to improve food safety at the retail level. . The most recent edition is the 1999 Food Code. In November 2000 The Michigan Food Law, Public Act 92 was enacted which adopts the most recent edition of the Food Code. Prior to that the 1976 Edition was used in Michigan.

The provisions of the Food Code establish a system of prevention and safeguards designed to minimize foodborne illness, ensure employee health, industry manager knowledge, safe food, nontoxic and cleanable equipment and acceptable levels of

sanitation of food establishment premises. The Food Code has addressed controls for risk factors identified by the CDC as contributors to foodborne outbreaks (those listed above). Five important public health interventions are established in this edition of the Food Code designed to address these contributing factors:

1. Time and temperature parameters for controlling pathogens
2. Demonstration of knowledge by the foodservice manager
3. Employee health controls
4. Controlling hands as a vehicle of contamination
5. Consumer advisories of risks of eating raw or undercooked foods of animal origin.

These additions and changes have been made based on the scientific evidence gained through surveillance and supportive research, that foodborne illness is caused primarily when these controls are not in place. Each of these new code items will be discussed with regard to how successful they should be in limiting foodborne illness.

Time and Temperature Parameters for Controlling Foodborne Pathogens

The most frequently cited food handling practice associated with foodborne illness outbreaks is improper food holding temperatures, both hot-holding and cold-holding. New scientific research has resulted in the following changes.

One of the changes in the code is the lowering of the maximum cold-holding temperature of potentially hazardous food from 45° F. to 41° F. In conjunction with this requirement is the time limit for refrigerated storage of ready-to-eat potentially hazardous foods. Until recently it was believed that pathogens would not grow at temperatures of

45° F. or below. However, in the last several years two emerging foodborne pathogens, *Listeria monocytogenes* and *Yersinia enterocolitica*, have been found to grow in refrigeration temperatures.

L. monocytogenes, recently found to be predominantly foodborne, is found in a variety of ready-to-eat foods such as soft cheeses and meats. It causes an estimated 2500 illnesses and 500 deaths in the United States each year.[28,33] Although Listeriosis is rare, septicemia and meningitis may result from infection and the case fatality rate is estimated at 20 percent.[12] Listeriosis in pregnant women may lead to miscarriage, stillbirth, or meningitis in newborns. The disease is more severe in individuals with weakened immune systems.

Y.enterocolitica has been recently found to be associated with undercooked pork.[47] It causes an estimated 96,000 illnesses per year with a very low case fatality rate.[33] As a result of increased surveillance for these organisms and the discovery that they grow at higher refrigeration temperatures, the FDA revised the code to 41° F. as a maximum for refrigeration.[21]

The Michigan Food Law 2000 has given industry ample time to comply with this change. Commercial refrigeration units built in the last few years have already been designed to be capable of holding temperatures at 41° F. or below. Food service establishments will have until May of 2006 to comply with this rule. All of their refrigeration units must be capable of holding at 41° F. or below by that date. Local health department sanitarians have begun to document and track the temperatures of every refrigeration unit in every food service facility. Until May of 2006, ready-to-eat potentially hazardous food must be consumed or disposed of within 7 days if held at 41°

F. or below. If the refrigeration units are holding temperatures between 41° F. and 45° F., the time limit is 4 days storage. These foods must be labeled with the date by which the foods must be discarded if not sold or served. Since food service operators have been given over five years to comply with the new temperature requirement and they will be reminded of this at each inspection until then, it seems very reasonable that they will comply. The practice of date marking is new to most food service facilities except some national chains. New to almost all of them is the requirement for marking the end date. It will take some time for management to train staff to date mark the appropriate food items with the correct dates. Although these regulations will help prevent the growth of these psyphrophilic pathogens, perhaps the greater responsibility for control rests on the food processor where the foods are initially contaminated. The issue of control of *L. monocytogenes* is currently being addressed by a multi-faceted action plan designed collaboratively by the Health and Human Services (HHS) and the USDA to specifically reduce the risk of illness and death caused *by L .monocytogenes* in ready-to-eat foods. Lowering refrigeration temperatures is only a small part of the plan. The incidence of illness caused by *L. monocytogenes* has decreased 29% from 1990 to 1997.[43] This reduction may also be a reflection of an intensive public education campaign directed at those people most at risk, such as pregnant women.

Another change in the code allows for more time allowed in the cooling of potentially hazardous foods to refrigeration temperatures. The former code allowed only four hours to move the food item through the "danger zone" of 140° F. to 45° F. The new code, based on scientific research requires that the food item cool from 140° F. to 70° F. within 2 hours and then from 70° F. to 41°F. or below within an additional 4 hours. This

allows a total of 6 hours of cooling. The important feature, however, is that potentially hazardous food must move more quickly through the higher end of the "danger zone" than the lower end. Many outbreaks have been caused by inadequate cooling of foods. The outbreak (to be described in Chapter 4) that occurred in 1998 in Ingham County was most likely caused by inadequate cooling of a sauce for a chicken entrée (too slowly cooled). An earlier outbreak of C. perfringens in Ingham County in 1990 was caused by improper cooling (too slowly cooled) of minestrone soup.[41]

This new regulation must be put into practice immediately. Proper cooling practices have been required in former codes. The emphasis on the new code is quick chilling. The most efficient way to cool bulk foods such as soups and casseroles is in a blast chiller. These are very expensive and therefore only available to a small number of food service facilities. Ice baths, ice filled stirring paddles and cooling in shallow containers in walk-in coolers are all affordable. These methods of cooling will be expected and monitoring of temperatures will also be expected. The person in charge will need to know correct cooling procedures and implement them. During the plan review process for new food service operations the need for cooling will be examined and the necessary equipment and policies will be required to comply with the code. Training of the person in charge and food handlers is necessary in order to convey the importance of this rule.

Time alone is now an approved method of public health control (as opposed to time in conjunction with temperature) when the process is done according to code. Four hours is allowed from the point in time when food is removed from temperature control, provided a written procedure is available describing how the food is marked and that the

food is discarded after 4 hours. For example, cooked rice may be kept at room temperature for 4 hours if documented. Oriental restaurants will often prefer to keep cooked rice at room temperature for stir-frying or for sushi. This has been considered a critical violation in the past. Rice has been implicated in foodborne illness outbreaks caused by *Bacillus cereus* due to this common practice.[2,9] It may appear that this new code allowance is a step backward in food sanitation. However, it also appears that this food handling practice has continued even after citation of code violation, due to language barrier and other cultural differences. If the regulator can educate the operator in the correct way to use time as a control and insist on the required documentation, it may result in a compromise that is safe and acceptable to both the operator and the regulatory agency. This has been done recently in Ingham County with oriental and middle eastern restaurants. Falafel is kept at room temperature for a two hour period at lunch time at a local middle eastern restaurant and is discarded at the end of that period. These arrangements were documented very recently. It will take time, 6-12 months, to determine if the practice is actually followed, by return visits and inspections of these establishments.

Required cooking temperatures of some animal foods has changed. Raw shell eggs that are broken and prepared to a customer's order must be cooked to 145° F. for 15 seconds. Other eggs such as batched scrambled eggs must be cooked to 155° F. for 15 seconds. During 1993-1997 *Salmonella* caused 357 (55%) of the 655 reported bacterial foodborne disease outbreaks with a known etiology (32,000 cases). Approximately half of those were caused by *S. enteritidis*, associated with shell eggs. *S.enteritidis* was the most frequently reported cause of outbreaks and resulted in more deaths than any other

pathogen. Of the 10 persons who died as a result of *S.enteritidis*, four were residents of nursing homes.[17] An outbreak caused by *S. enteritidis* in Ingham County in 1997 associated with undercooked eggs resulted in 21 people becoming ill after eating at a popular family restaurant.[26] Illness with *S. enteriditis* is considered highly underreported, and is estimated to cause over 1.4 million cases of foodborne illness annually during this time period (1993-1997). Once these new requirements are in place, the number of illnesses due to *Salmonella* should be greatly reduced. In fact, a "progress report" from the CDC on the Healthy People 2000 states that the number of outbreaks of *Salmonella enteritidis* has decreased 22 percent from 77 outbreaks in 1989 to 45 outbreaks in 1998.[43] The HP2000 goal was 25 outbreaks. At that time 16 states had adopted the new 1999 Food Code and 23 were in the review process prior to adoption. It appears that the number of outbreaks due to *Salmonella* will continue to decline as more states adopt the new code.

Comminuted meats such as ground beef must now be cooked to 155°F. for 15 seconds. *E.coli* O157:H7 was first identified as a pathogen in1982 in an outbreak of bloody diarrhea traced to hamburgers for a fast-food chain. It was subsequently shown to have a reservoir in healthy cattle. During the years 1993-1997 *E.coli* spp. caused a reported 84 outbreaks including 3,260 ill people.[17] The estimated number of total cases of *E.coli* O157:H7 alone for this time period was 73,480 cases per year. [33] Some of the *E.coli* O157:H7 cases reported from 1993-1997 were caused by unusual foods such as apple cider in 1993, apple juice in 1996, leaf lettuce in 1995 and 1996, alfalfa sprouts in 1997. [46] Most illness, however, has been associated with eating undercooked, contaminated ground beef. The CDC Progress Report for Healthy People 2000 found

foodborne infections by *E.coli* O157:H7 are down 75 percent from 1987 to 1997.[43] This exceeds the HP 2000 goal of a 50% reduction. This reduction can be attributed to the massive public health education campaign resulting from the earlier outbreaks causing death in young children. Consumer vigilance and food service retailers conforming to the advisories recommended by the FDA to thoroughly cook burgers has continued to lower the incidence. Solidifying this requirement in the code will provide a legal basis to require food service establishments to recognize this hazard.

Demonstration of Knowledge

The code now requires a "person in charge" to be present in a food service at all times during operation. This person must be able to demonstrate knowledge of foodborne disease prevention, application of the Hazard Analysis Critical Control Point (HACCP) principles and the requirements of the Code.

Consumers may be surprised to know that prior to the adoption of this code a food service operator was legally allowed to open a business without any knowledge of food safety. A plan review was conducted in accordance with the current food code, including physical and structural aspects of the facility such as plumbing, mechanical, finishes of floors, walls and ceilings and equipment. The proposed menu was reviewed to determine suitability of equipment and storage space requirements for dry goods and refrigerated foods. Once these plans were approved and the construction was approved at the final inspection, the facility was approved to operate. The burden of educating the food service operator in food safety issues rested on the sanitarian at the time of the final pre-opening inspection and subsequent inspections when violations were cited.

Under the new code the person in charge is required to demonstrate knowledge in any one of three different ways:

1. Compliance with the 1999 Food Code;
2. By responding correctly to the inspector's questions as they relate to the specific food operation;
3. Becoming certified as a food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program.

The implied goal for this requirement is, of course, that this knowledge will be passed down to the food handling employees in order to ensure safe food handling practices. None of the above measures will guarantee the level of knowledge necessary to prevent foodborne illness.

Compliance with the code simply means that during a routine unannounced inspection at some time after the food service has been open and operating, no "critical" violations are cited. These are the most serious violations most commonly associated with causing illness. Most routine inspections are conducted during regular hours, but in between busy meal times, out of courtesy to the food service manager. However, critical violations are more likely to be seen during lunch or dinner "rushes" when there are greater opportunities for failure in practicing safe food handling techniques. An example is the grill cook who is responsible for placing a raw burger on the grill, cooking it and then assembling the burger on a bun with condiments. The opportunities for cross-contamination of raw burger juices onto ready-to-eat food items, undercooking, as well as poor employee hygiene are greatest when the cook is solely responsible for this process during busy periods. In addition, if the employees are not adequately trained or

supervised, critical violations will continue to occur even if the manager or "person in charge" is determined to be fully knowledgeable of the food code. Therefore, the reliance on an inspection without critical violations is not a good measure of the level of manager food safety knowledge. Further, having a well-trained manager does not fulfill the intent of this code requirement if the employees are not well trained or motivated to follow code requirements. If the inspections were more comprehensive, including evaluation of entire food preparation processes before and during meal times, then the lack of critical violations would be a good indicator that the food safety knowledge of the manager is being passed on to the employees and incorporated into practice

Similarly, answering questions pertaining to food safety relevant to the operation may not cover all aspects of the particular food service. There is no standard set of questions to use when interviewing the person in charge. This process will be largely subjective, non-uniform and incomplete. The procedures for inspection of food service establishments are evolving. Sanitarians are encouraged to take a more HACCP type of approach in their evaluation of food preparation from the time it is delivered to the facility until it is served. HACCP plans are not required for menu items of restaurants, so this will be a difficult task. Most local health departments lack the resources to accomplish this task in every food service establishment to the level that will truly ascertain the knowledge level of the person in charge.

Certification of food service managers through an accredited program is the most reliable measure of the level of knowledge of the code. The typical accredited program includes 12-16 hours of training on all aspects of food safety and a standardized test to pass. Public expectation will be that there is a "certified manager" on site at all times of

operation. Many of the national restaurant chains require certification of their managers. Currently 21 states have laws requiring manager certification of some sort, and more are pending. Although certification of managers is a more reliable measure of manager knowledge, it still does not guarantee that safe food handling practices will be passed along to employees.

The FDA, USDA and FSIS, co-lead agencies responsible for the Healthy People 2010 goals, recognize the need for thorough training of retail employees in order to reduce the number of foodborne illness outbreaks.[12] The food service industry has a large employee population with high rates of turnover. Language and literacy barriers as well as a general lack of training pose additional challenges. It may be more of a hardship on the smaller businesses that find it difficult to afford the cost of the program and the time away from the business. It is becoming increasingly important for local health departments to offer training programs that are affordable to food service operators that cannot afford training from an independent consultant. In addition to manager certification training, it is also important for local health departments to offer shorter, simpler courses for food handlers. In some cases interpreters are used as well as written materials in different languages. These classes can be used as a tool by the food service managers to incorporate as part of their general training, especially if there is no corporate training program already in place.

It is unreasonable to expect compliance with the food code or to expect correct answers to questions about proper food safety procedures if there has not been adequate training of food service managers or employees. Michigan law still allows for the requirement of food service sanitation certification to be used as an enforcement tool in

cases of repeated non-compliance with the code. This is not common and many months of non-compliance with critical code requirements occur before this intervention is put into place. A combination of all three methods of ascertaining manager knowledge would adequately measure the level of knowledge required. By using all three methods the intent of the code would more likely be fulfilled. Manager knowledge will be tested in a tangible way through manager certification. The other two methods, actual code compliance and interviewing the manager on specific practices, will determine if that knowledge is passed on in practice. Many states have required certification and the general public will expect it as awareness of food safety increases through the public education efforts catalyzed by the Food Safety Initiative.

Michigan could have required manager certification, but fell short of that in the adoption of Michigan Food Law 2000. The Presidents Food Safety Initiative of 1997 should have provided enough political backing for this requirement. Funds could have been appropriated to the state and local health departments to provide for this service over a reasonable period of time. Until required at the state or federal level, this requirement could be picked up by local governmental bodies. In fact, three counties in Michigan now require manager certification. Hopefully, the remaining counties will follow suit.

Employee Health controls

The 1999 Food Code requires the person in charge of a food service facility to require employees to report illness. Specifically, the employee must report to the employer any past or present diagnosis of illness with one of the "Big Four" foodborne

pathogens: *Salmonella Typhi, Shigella* spp., *Escherichia coli* O157:H7 or Hepatitis A virus. The person in charge must, in turn, report these to the local health department. These illnesses are separated out because they are especially virulent and infectious. The "big four" illnesses have historically been linked to transmission by an ill employee contaminating food. "Typhoid Mary" was a well known example. In the late 1800's she worked as a domestic cook for eight families in New York state. Mary became an asymptomatic carrier of *Salmonella typhi*. Twenty-two people in seven of those families became ill with typhoid fever and one died. Later, she changed her name and became employed as a cook at a maternity hospital where twenty-five people became ill and two died. If she had worked in a modern day fast-food restaurant the results would have been even more disastrous.

There are close to 300 organisms associated with foodborne illness. Some of the more common symptoms of illnesses that can be easily spread by food include: diarrhea, vomiting, fever, jaundice, sore throat with fever, discharges from the eyes, nose, and mouth or infected wounds or boils. The symptoms listed are common to foodborne illnesses transmitted by the hands or respiratory tract of an infected food handler. The food service manager must recognize these symptoms and must exclude the ill employee from working or restrict the employee to non-hazardous duties, depending on the type of illness and type of population served (high-risk or general).

The "big four" are already reportable diseases. There is a system already in place in the more well-equipped and well-staffed local health departments to help exclude employees with these diseases from work in a food service. In the Ingham County Health Department, when a positive laboratory result is received by the Communicable Disease

Division for pathogens such as *Shigella* spp., *Salmonella, E.coli* 0157:H7 or Hepatitis A virus, the patient is interviewed by a public health nurse. If it is found that the patient works in a food service establishment, the nurse works with a sanitarian in Environmental Health to inform the patient and the food service manager that the employee must be excluded from work until reinstatement is approved by the health department and physician documentation. Although this approach is effective in some health departments, there is a possibility of delay that may result in the ill employee exposing the general public to disease. Some health departments lack the infrastructure necessary for this cooperative effort. In any case, it makes good sense to educate food service managers and employees of the importance of reporting these illnesses and the reasons for excluding the ill employees so the food service manager can more quickly and effectively prevent exposure of the food service environment to the ill employee. The manager is the front line of protection and it is their responsibility to know and understand the causes and prevention of foodborne illness.

This new code requirement will help to decrease the number of outbreaks caused by the "big four" by catching them earlier than they have been in the past. *Shigella* is estimated to be the most common of the four, followed by *E.coli* 0157:H7, Hepatitis A and *S. typhi* which is very rare. We should see a decline in foodborne illness outbreaks caused by this pathogen after this code is in full effect. In addition, we should see a decline in other types of outbreaks primarily caused by contamination of food by ill employees such as those caused by Norwalk-like viruses, *Salmonella,* other *E.coli* species and *Staphylococcus aureus* from infected wounds.

Controlling Hands as a Vehicle of Contamination

The requirement for hand washing by food handlers is not new. However, there are more stringent guidelines on the proper procedure in the new code, including a minimum of 20 seconds of lathered scrubbing prior to rinsing.

One of the most important and controversial additions to the food code is the prohibition of bare-hand contact with ready-to-eat foods except when washing fruits and vegetables. Poor personal hygiene is the second most frequently cited food handling practice resulting in foodborne illness outbreaks.[11,16,17] Pathogens on food handlers' hands are passed on to the foods they are working with. If this food is ready-to-eat, such as a sandwich or salad, the food will not be undergoing a subsequent cooking process that would kill organisms left on the food. Therefore, preventing contact with ready-to-eat foods should reduce greatly the number of illnesses caused by direct contamination of food. This will be accomplished by providing a barrier between the food and the bare hands. Examples include the use of utensils, plastic single-use gloves or deli paper. These are not substitutes to proper hand washing. To be effective, these barriers must be used correctly. Employees must be trained to wash hands before and after using gloves. Care must be taken not to contaminate the gloves while in use and they must never be re-used.

It is clear that consumers have expected this standard of "no bare-hand contact" for quite some time considering the number of complaints received by local health departments. Until now, bare-hand contact was allowed in Michigan. This has been the most controversial of changes to the code in Michigan. Some of the food service industry has had (and is having) a difficult time conforming to this requirement. Use of utensils

and gloves is more awkward than bare-hand use and it will take some time to become comfortable with these practices. The Michigan Law spells out guidelines that may be used to develop a written alternative practice and procedure that allows bare-hand under controlled circumstances. This is a very rigorous set of guidelines requiring the food service establishment to be in consistent compliance with the critical requirements of the food code and to conform with approved written HACCP-based operating procedures. These guidelines were designed to ensure that consumer safety will not be compromised when bare-hand contact with ready-to-eat foods occurs. Bare-hand contact with ready-to-eat foods should be the rare exception to the rule.

Shigella spp., Norwalk-like viruses, hepatitis A and *Staphylococcus aureus* are some of the organisms that are more commonly transferred to foods by direct handling of foods. Poor food handler hygiene is the second most common documented cause of outbreaks. The added protection of gloves or utensils (when used correctly) as barriers between the contaminated hands of food service employees (with less than perfect hygienic practices) and foods should result in a decrease in incidence of foodborne illness.

Consumer Advisories

The third most frequently reported cause of foodborne illness is inadequate cooking of foods. The fifth most frequent cause is obtaining food from unsafe sources. The general public has only recently been informed of some of the risks involved in eating these foods. In 1995 the CDC, the FDA and several state health departments collaboratively developed a multi-state surveillance study of food-handling, preparation

and consumption behaviors associated with foodborne diseases. Data were collected from questionnaires administered with the 1995 and 1996 Behavioral Risk Factor Surveillance Systems (BRFSS) in these states. The report indicates that behaviors associated with foodborne diseases were common. Fifty percent of respondents reported consumption of undercooked eggs. Twenty percent of respondents reported eating pink hamburgers and eight percent reported eating raw oysters. [54]

Another interesting result of this study was the observation that there was a direct positive relationship between the education level and the frequency of eating pink hamburgers or raw oysters. The prevalence of consumption of pink hamburgers increased with education (less than grade 12: 12.0%, high school graduate: 16.5% and any college education: 24%) and also increased with yearly salary (less than $15,000: 11.8%, $15,000-$34,999: 17.6%, $35,000-$49,999: 22% and greater than or equal to $50,000: 28.6%). This contrasts with other findings that persons with higher education levels are more likely to pursue other health-promoting behaviors such as seat belt use and abstinence from smoking that persons with lower education levels. This difference suggests that highly educated persons are still not being educated on the associated risks or they are choosing to ignore the hazards associated with these behaviors. In any case, it is important that public education regarding these hazards continue to be emphasized.

The new food code now requires food service establishments to include a "consumer advisory" in the menu (or other easily visible place) for ready-to-eat animal foods that they choose to serve raw, undercooked or not otherwise processed to eliminate disease causing organisms and poses a significant risk. It is a customer's right to know if foods served at a restaurant may not be safe to eat. A food-safety survey of 2,197

homemakers found a high reliance on government inspection for the prevention of bacterial contamination of raw meat and poultry, underrating their responsibility for safe food-handling and preparation practices.[1] Similarly, restaurant patrons believe that since restaurants are inspected, the food served may be considered safe to eat. The food code stops short of prohibiting raw or undercooked animal foods from being served, except for those establishments serving high-risk populations. The general population is not ready to give up some of these undercooked food items. Therefore, in order to leave the choice up to the consumer and at the same time provide them with accurate information, the requirement for an advisory makes sense.

An example of an advisory is the placement of an asterisk (*) next to the menu item "hamburger" with a footnote reading "Can be cooked rare or to order. Consuming raw or undercooked beef may increase your risk of foodborne illness, especially if you have certain medical conditions." The more the public sees this reminder in the menus of their favorite restaurants, the more educated they will become. The result will be a continued decrease in the incidence of foodborne illness caused by undercooked animal foods.

Conclusion

The science-based knowledge gained by the interpretation of data from years worth of surveillance for foodborne illness outbreaks is already proving to affect a decline in certain types of foodborne illnesses. This cycle of surveillance, epidemiologic investigation and the institution of prevention measures must continue. The continually improving surveillance systems described earlier will more accurately measure the

burden of foodborne illness in the United States. In addition, the epidemiology of foodborne illness outbreaks is changing. New pathogens are emerging along with new vehicles of transmission. Surveillance has never been more important in determining how to control foodborne illness. The evolution of the FDA Food Code is the result of diligent analysis made possible by the cooperation and collaboration of local health departments' investigations and reporting of outbreaks.

The adoption of this code is an outstanding improvement from the former code used by the State of Michigan. The five public health interventions introduced in the new food code clearly address the most reported causes of foodborne illness outbreaks. Excluding ill employees from food service operations and limiting bare-hand contact with foods will prevent spread of foodborne illness organisms to foods eaten by the public. Applying the new temperature requirements will kill pathogenic organisms in raw animal foods and will prevent the growth of incidental contaminants that would result in illness. Consumer advisories will educate the general public to make better choices when considering eating raw or undercooked animal foods.

None of the above objectives will be realized without adequate training of food service managers. The requirement in the new food code for demonstration of knowledge is an important addition to the code. However, the code does not go far enough to meet this objective. As discussed earlier, the method for assessing knowledge of a "person in charge" is too subjective, non-uniform and incomplete. The first step in ensuring food service sanitation practices is to be sure the manager is well educated on these matters. If the manager is not knowledgeable of the code requirements, then there cannot be an expectation that the employees will follow through with the practices

required. In order to protect the public health we should not be relying on voluntary enrollment in an accredited program run by private industry. The number of food safety manager certification training programs is rapidly growing. Many food service chains and individual restaurants are acquiring training from these resources. More and more local health departments are offering the same training at a lower cost. In order to offer this service, local health departments must have adequate funding to provide and train staff to fulfill this service. The food service support industries are also responding to the need. Food service equipment and food suppliers are now offering certified training programs to their clients. Some of the larger restaurant corporations hire their own food service safety specialists to train their own managers. The National Restaurant Association and affiliated state chapters support and publish the "Serv Safe" Training Program which has been used by all the above industries.

The Michigan Food Law has fallen short of requiring mandatory food safety training. However, several states are in similar situations. They have adopted the new FDA code but do not require above that, mandatory training. Instead, localities, either cities or counties have adopted ordinances requiring manager certification. This is still a possibility in Michigan. If it appears that food service establishments are not voluntarily becoming "certified" and there is still a lack of conformity with the code, Ingham County may attempt to pass an ordinance requiring certification of managers.

CHAPTER 3

DEVELOPMENT OF THE ICHD FOODBORNE ILLNESS INVESTIGATION PROTOCOL

The Role of ICHD in FoodBorne Illness Investigation

Foodborne illness outbreaks have been investigated by Ingham County Health Department (ICHD) for many years in the compliance of the Michigan Public Health Code, Act 368, P.A. of 1978. Two divisions have been involved in these investigations. The Communicable Disease Division (CD) of Ingham County Health Department is responsible for the surveillance of Infectious Disease within Ingham County. Whenever a food service establishment is implicated in any of their cases interviewed, the Environmental Health Division (EH) is consulted. The food service establishment may be either a place of employment for the case or may be a suspected source of the infection. In addition, if an illness or outbreak is suspected to be caused from food and no food service establishment is implicated, the Environmental Health Division will also be consulted.

For many years these two divisions of Ingham County Health Department have worked together to investigate foodborne illness outbreaks. The expertise possessed by each division has been invaluable in the professional teamwork approach used to investigate outbreaks. In recent years the knowledge base in these two divisions has overlapped somewhat due to the cooperative cross-training between the two divisions. This has provided a greater assurance that foodborne outbreaks are investigated as thoroughly and professionally as possible.

The Public Health Nurses in CD routinely monitor infectious disease. They have a working knowledge of common communicable disease, including diseases spread by foods, the clinical presentation and the incubation periods involved. They are very knowledgeable and experienced in the task of interviewing clients. Training is necessary in order to interview clients with or without a questionnaire to provide uniform and standard results. Requisition forms for laboratory testing of patient specimens and foods are completed by CD prior to collection of specimens and subsequent delivery to the Michigan Department of Community Health Laboratory.

The Registered Sanitarians in EH have received specialized training in the area of food service sanitation. Knowledge of the microbiology of foodborne pathogens is necessary in educating food service managers in area of food safety. There are nearly 300 known foodborne pathogens and new pathogens are emerging constantly. The science involved in the control of these pathogens is also changing. The Sanitarian must be educated constantly to keep up. The Sanitarians spend many hours each week inspecting food services. They are very knowledgeable of situations and conditions that would cause foodborne illness, such as poor employee hygiene, improper cooling and heating of potentially hazardous foods, cold and hot-holding practices of potentially hazardous foods, cross-contamination, etc. This knowledge is necessary in the investigation of outbreaks in order to determine the vehicle and improper food handling techniques responsible for the outbreak. The rapport developed between the Sanitarian and the foodservice manager is also important in order to effectively educate the manager in future prevention of foodborne illness. Follow-up by the Sanitarian is necessary in order to help ensure that changes are made in faulty food handling.

Collaboration on the Writing of a Protocol

Early in 1998 the Divisions of Communicable Disease and Environmental Health were charged by the Health Officer to develop a written protocol for investigation of foodborne outbreaks. Prior to that date the association of the two divisions was more informal causing some confusion at times over which division would do certain tasks. In an effort to solve this problem and to work more efficiently during the flurry of an outbreak investigation, several members of each division met on 1-28-1998 including the supervisors of each division to discuss the development of a protocol for foodborne illness investigation. Two Public Health Nurses and two Registered Sanitarians (including the author of this paper) were chosen to work on the committee that would write the protocol. The two Sanitarians were (not coincidentally) working on their Masters Degrees in Epidemiology at Michigan State University at the time. Their experience and knowledge gained in the area of epidemiological analysis were very helpful in developing a protocol.

Over the next several months this committee met to discuss all aspects of the protocol after dividing up the responsibilities for each section. Periodically, the document was circulated among the two staffs for comments. Although this committee's final draft was completed late in 1998, the protocol remains a "living" document that has already been modified since that date.[25] Revised MPRs (State of Michigan minimum program requirements)[37] will require some modification and it will continue to be updated as the science involved is also changing.

The format used for the document was the standard format used for many of the protocols within the ICHD consisting of the "Purpose", "Policy Statement" and

"Standard" written prior to the body of the document. The body of the document is an outline of the investigation guidelines. An appendix includes a telephone list, forms used, supporting documents and a glossary.

Purpose

In this section background is provided on the legal basis for intervention by the ICHD as well as the objectives in the investigation of foodborne illness outbreaks. The current Public Health Code at that time was the Michigan Public Health Code, Act 368, P.A. of 1978, as amended, Sections 12912 and 2422 which states that the local health department is responsible for investigating all suspected and confirmed foodborne related outbreaks involving Ingham County residents or facilities. The "Purpose" also stresses the importance of initiating the investigation as soon as possible in order to identify the source of a potentially life-threatening situation. Prompt action will allow appropriate interventions to be put into place in order to protect the public health.

Policy Statement

This section is standard in all ICHD protocol documents. It simply states that all Ingham County Health Department employees will follow the guidelines for suspected and confirmed foodborne outbreaks.

Standard

This statement is also standard in all ICHD protocol documents. It is a commitment to "achieve and maintain a performance level of employees at ICHD through a systematic process which protects the health and well being of the residents of

Ingham County". This document will provide a means to investigate outbreaks in a consistent and professional manner.

Guidelines for Outbreak Investigation

Section I

Section I covers the initial surveillance stage of foodborne illness or outbreak situations. This is a very important stage. In the past, some outbreaks may have been undiscovered due to a lack of attention at this point. When a call is received from the public reporting an illness suspected of being a foodborne illness it could be directed to either the office of Environmental Health or the office of Communicable Disease. There must be a system in place that assures that EH is notified immediately if a commercial food service is implicated. The clerical staff of both divisions must have clear guidelines on referring these calls to the appropriate staff members in order for to effectively determine if there is an outbreak. It is also important that the pertinent information be recorded on the correct form. Section I is divided into two parts, clearly defining the responsibilities of each division when a report is called in.

In Environmental Health , these calls are usually from a member of the public who is reporting their own illness suspected to have been caused by eating food at a particular food service establishment. When such a call is received by a clerk, it is directed to the Sanitarian who is responsible for the geographic area the food service is in. If the Sanitarian is unavailable and the call is forwarded to an answering machine, it may not be handled in a timely fashion. Initially it was written that the area Sanitarian would be paged, but after input from the Supervisor it was decided that the clerk would

collect essential information on a short form, "Clerical Illness Reporting Form" and give this form to the Sanitarian as well as a copy to the Supervisor. The Supervisor would then be able to re-delegate or take other appropriate action if necessary in the absence of the area Sanitarian.

The next step is collecting the information necessary from the complainant in order to determine if an outbreak is occurring. On the day the complaint is received, the "Foodborne Illness Form" is completed by the Sanitarian. In addition to demographic information the complaint is summarized. The complainant is asked several questions pertaining to the illness, such as: how many were ill, if they were seen by a physician, who the physician was, other group meals eaten within 72 hours, onset date and time, date and time the meal was eaten, duration of illness, symptoms, other people who ate with them and then a complete three day food history from two days before onset through the day of onset of illness.

The Sanitarian would then call the food service establishment implicated to discuss the complaint and ask if they had received any other complaints. The manager would be asked to contact us immediately if they received any similar complaints.

The Sanitarian would then enter information about the complaint into an "Alert Log" posted outside the Supervisor's office. This is the master compilation of all suspected foodborne illness complaints received in Ingham County and serves as the primary record of foodborne illness surveillance at ICHD. It is a line listing of abbreviated information including Sanitarian's initials, complaint number, date received, onset date, number ill, predominant symptoms, alleged suspect food and eating places other than home in the three days prior to illness. When a complaint is recorded,

previous entries are reviewed for relevance to the current case. In addition, a short summary is written on a bulletin board seen daily by all Sanitarians that will alert all area Sanitarians of the report.

The file for the establishment implicated may be reviewed for more information on compliance, past complaints, manager's name and phone number, etc.
The original Foodborne Illness Form is placed in the food service establishment file and a copy is sent to the Food Sanitation Section of Michigan Department of Agriculture.

Occasionally a complaint about a possible foodborne illness from a commercial food service will be received by the CD office. The clerk will transfer the call to EH Division. Occasionally a possible foodborne illness will be reported directly to a CD nurse. The nurse will fill out the Foodborne Illness Form and provide a copy to the area Sanitarian in EH. The nurse will then enter the appropriate information into the "Alert Log". Sometimes foodborne illness is recognized through the passive surveillance system. During the course of a routine enteric illness case investigation by a CD nurse, the patronage of a commercial food service is mentioned during the typical incubation period for that disease. In this case also, the nurse will fill out a Foodborne Illness Form and provide a copy to the area Sanitarian and enter information into the "Alert Log".

If all the above steps are followed, it would be highly unusual for a foodborne illness to be missed or for an outbreak to be unrecognized due to lack of proper notification of the Sanitarian. Proper recording and notification of these calls will result in timely decisions on whether an outbreak is occurring or has occurred.

Section II

Section II covers the definition of an outbreak. Further investigation is not initiated unless the illness reported is determined to be an outbreak. An outbreak is officially determined when two or more unrelated persons have the same condition, or similar symptoms with a time, place and person association between them. The definition of the term "unrelated" was debated. After consultation with MDA it was concluded that persons were considered related if they lived in the same household. For example, if two co-workers both became ill after eating at the same restaurant together, they would be considered unrelated. Likewise, if two fraternity brothers living in the same fraternity house both become ill after sharing a meal at a restaurant, they would be considered related. Along with the definition given in IAMFES Procedures to Investigate Foodborne Illness exceptions include single cases of suspected botulism, mushroom poisoning, ciguatera, paralytic shellfish poisoning, typhoid fever, other rare diseases, or a case of a disease that can be definitely related to ingestion of a food. These exceptions are considered incidents of foodborne illness that warrant immediate further investigation.[27] Once it is determined that a foodborne outbreak has occurred (or an incident of one of the exceptions listed), outbreak investigation activities are initiated.

Section III

Section III delineates the steps involved in initiating investigations. First, the supervisors in EH and CD must be informed that an outbreak has been identified. If one of them are not available, the next in charge should be notified. These supervisors and Medical Director (if available) will confer about the advisability of initiating a full

investigation. Once this is approved the two divisions will work together to conduct the investigation.

If there is a suspected food item it should be set aside for collection as a specimen at a later time. The manager of the food service establishment will be directed to mark the food item and keep it refrigerated until it is picked up for delivery to the laboratory. If there are any other control measures that could be taken to halt an ongoing outbreak they should also be done. For instance, if complaints are continuing to be reported of illness after eating at a particular food service, the food service may need to be closed until the cause has been identified.

Other agencies must be notified at this time. Michigan Department of Community Health and Michigan Department of Agriculture Food Sanitation Division work together in state-wide surveillance of foodborne illness and may be able to track clusters of outbreaks not seen on a local level. If outbreak related specimens, either stool samples or food samples are available, MDCH Division of Laboratory Services must be contacted for approval prior to testing. A phone list was compiled and has been attached as an appendix for easy reference.

Section IV

Section IV outlines the investigation process. Once an outbreak has been identified, a meeting is held including administrative staff, EH and CD personnel. It is at this meeting that the following assignments are made:

Staff members from each division will be designated to work on the investigation to work as a team. Lead investigators will be assigned from each division. These lead

persons will be responsible for assigning tasks to other team members throughout the investigation as they become necessary in consultation with the supervisors. They will also jointly complete the summary report at the end of the investigation.

A preliminary case definition will be determined at the initial meeting. The most pronounced symptom (usually diarrhea or vomiting) should be included along with a reasonable incubation period from the time of common exposure.[27] For example, a case of gastroenteritis may be defined as a person who was at risk or exposed to the implicated food or meal and developed diarrhea within a specified period of time. The case definition will become more well-defined as the investigation proceeds.

An initial hypothesis is formed based on preliminary information. Referring to a manual such as IAMFES or Benenson's Control of Communicable Diseases, onset times of the predominant symptoms as well as the symptoms themselves will provide clues to narrow down the possibilities of organisms responsible for the outbreak. As much as possible the hypothesis should explain the most likely type of illness, the most likely food involved, where and by what manner the food may have become contaminated. The hypothesis will become more well-defined as the investigation continues. Before the initial meeting is over, assignments must be made for both EH and CD personnel. The clerical staff must be informed of the outbreak and directed to forward all calls that come in regarding the outbreak to a designated staff member. These calls may be additional cases reporting illness or persons concerned about potential exposure or they may be calls from the media. Plans must be made to handle the different type of calls that may come in.

The CD office will be responsible for the preparation of stool specimen containers so staff from CD must be assigned to this task. Procedures for assembling these client mailable specimen kits can be found in the appendix. Included in this kit will be instructions for the client on how to collect the specimen and mail it in. Staff members (usually including clerical staff) will be assigned to assemble these kits and various other staff members (from either division) will be assigned to deliver them to clients. In ICHD the EH division employs more field staff than CD so EH usually delivers specimen containers. MDCH laboratory must approve testing of the specimens prior to delivery to the lab. The EH office will be responsible for obtaining and submitting food specimens so this task must be delegated. Directions for these procedures are also included in the appendix. The MDCH laboratory will not accept food samples unless prior arrangements have been made.

A menu or list of all food and beverage items served at the event must be obtained. This list must be as complete as possible. It is very difficult to add items to a questionnaire at a later time. This task could be done during a site visit. However, it is often more efficient to get a list started by phone or fax by staff members working on the questionnaire. The field Sanitarian or Nurse could then confirm the menu when they are on site at the food service establishment.

A staff member must be assigned to obtain a list of all persons exposed to the suspect meal must be obtained. Attendance lists, reservation lists, credit card receipts or a roster of usual clientele may be used to help make the list as complete as possible.

Staff members must be assigned to develop a questionnaire, conduct interviews and enter data onto Epi-Info statistical program for analysis.[10] A sample of the

questionnaire is in the appendix of the protocol. It should include demographic information, the health of the individual, foods eaten, date and time of meal and their willingness to submit a stool specimen if asked. The questionnaire may need to be changed and updated as new information is obtained or if additional analysis is necessary. Both ill and well clients will be interviewed using this questionnaire. Interviewers will be directed by a lead person on how to conduct the interview in a consistent and non-biased manner. Clients may be re-interviewed as warranted by progress and resolution of the outbreak.

As information on individual incubation periods become available, an epidemic curve must be plotted. One of the team members working with this information should be assigned the "epi curve". This graph will have as its X-axis the time of onset in hours or days and will have the number of ill people as its Y-axis.

Follow-up meetings will be scheduled for team members in order to update the whole team on the progress made on the investigation. The preliminary case definition may be revised to more accurately reflect the situation. The study design will be determined based on the information available and the results of case-finding activities. Control measures may be re-evaluated and changed if necessary. The team will review the information received from the environmental inspection (outlined below) and results from the Epi-Info analysis and make any changes necessary to the hypothesis.

Section V

Section V describes the environmental inspection or "site visit". This was included as a separate section because it is usually done at the same time section IV is

taking place at the office. It is considered an important part of the overall investigation because this physical investigation will usually provide clues to the mystery of how the foodborne outbreak began. It is preferable that the area Sanitarian perform this inspection along with a nurse from CD. The Sanitarian has a pre-established rapport with the manager which is helpful in this stressful situation. At Ingham County our policy has always been to have more of an educational relationship with food service managers than a strictly regulatory one. In addition to having a second set of "eyes", the nurse's presence is helpful in obtaining information on sick employees and answering questions they are more experienced with answering.

Guidelines for the Environmental Investigation can be found in the appendix of the protocol. The manager should already have been called to alert him or her of the outbreak. If the outbreak appears to be limited and no more cases are calling in, it is actually preferable for the food service to stay open. Routine operations can then be observed and more clues may be found regarding the source of the outbreak.

The manager should be asked again if any reports of illness were received by the food service establishment. If so, names and phone numbers must be obtained. They should also be asked if any customers were ill in the restaurant around the time of the alleged meal or if any employees were ill during that time. Employee work attendance records should be checked by the manager and any employees reporting ill during the week prior to and the week of the suspect meal should be reported to the Sanitarian. These employees will be interviewed to determine if their illness meets the case definition or if they may be a possible source.

Specific information about the meal should be obtained, including number of meals served of the suspected food. If any of the food is left from the suspect meal, the food items will be tagged or labeled to identify it as a specimen and must remain refrigerated. The manager must be notified that this is a hold order for possible delivery to the MDCH laboratory. A written notice must be left with the owner or manager.

The inspection of the facility must be tailored to the type of food service and the foods initially implicated in the outbreak. There are some elements of investigation that should always be included:

1. Check personal hygiene of food handlers. Observe hand washing practices, if they are wearing bandages or have any open sores, etc.
2. Check the producer and supplier of the suspect food product. Record any information that may be important if a trace back is required.
3. Check food handling and preparation practices of the suspect food product from delivery to actual service to the customer.
4. Check time/temperature relationships of the following: thawing, preparation, cooking, display, storage, cooling, reheating. Pay close attention to foods implicated in outbreak.
5. Check if there were any problems with refrigeration or power outages at the time of the complaint.
6. Check for food additives used.
7. Check for contamination by vermin such as mice or cockroaches.

8. If the facility has an on-site sewage disposal system or well, these must be evaluated. A water sample must be taken for bacterial and chemical analysis if there is a well.

After the inspection is completed, the manager must be provided with a complete report documenting the investigation. If necessary, the field Sanitarian or Nurse may call a lead person back at the office to report any pertinent findings or information that would be useful immediately instead of waiting to return to the office.

Section VI

Section VI states that active surveillance including area ambulatory health care centers and emergency rooms may be necessary depending on the scope of the outbreak at the discretion of the Medical Director.

Section VII

Section VII describes the activities involved with the summary report of the investigation. The format to follow for the final report is included in the appendix of the protocol. The lead persons of the investigation from both CD and EH will collaborate in the writing of this report. The scientific format includes four sections: Introduction, Methods, Results and Discussion. The Department of Agriculture has requested this specific format and would like it to be approximately 2-3 pages of narrative and 2-3 tables or graphs.

The Introduction will give a brief description of the outbreak. It will explain why the investigation was done and who was involved in the investigation.

The Methods section will be of more detail and will include epidemiological methods and field investigation methods. In this version of the protocol the laboratory methods are included in the field methods. Under Epidemiologic Methods the following will be summarized: Case definition, Study Design, Case and Control selection techniques, Questionnaire procedures, Interview technique and analysis methods. Under Field Investigation Methods the following will be summarized: Food sampling technique, Client specimen collection technique, Laboratory methods used, Scope of food service inspection and employee interview technique.

The Results section will include only the following pertinent data: Graphs and tables including the epidemic curve graph, an attack rate table, a food-specific attack rate table and/or any other important visual aid. It should also include a description of findings from interviews, the field investigation, laboratory results and the data analysis.

The Discussion will explain the data, draw conclusions and make recommendations for prevention of foodborne illness. Rarely do all the lab results and field investigation results positively confirm a causative link between a food item and illness. Conclusions must be made with the information available.

After the draft copy is completed, corrections are made and the draft is circulated to the other team members for review. The comments are collect and final changes made. The Final report is than filed in the food service establishment's official file in the EH Division. All confidential interview information and laboratory reports will be filed in the CD Division. Copies are also distributed to the following people: Medical Director of ICHD, Health Officer of ICHD, EH and CD supervisors, Michigan Department of Agriculture and the Michigan Department of Community Health.

CHAPTER 4

AN OUTBREAK OF FOODBORNE ILLNESS

Introduction

The Ingham County Health Department (ICHD) was notified on May 5, 1998 by Michigan State University (MSU) Department of Public Safety (DPS), Safety and Public Health Division of a potential foodborne illness outbreak. A woman who worked at an MSU dormitory cafeteria reported directly to the MSU Registered Sanitarian at DPS that her boyfriend and her brother became ill after eating a meal for a banquet at the Kellogg Center on May 3, 1998. Supervisory personnel for the MSU dormitory cafeterias have benefited greatly from the good rapport with the Department of Public Safety Sanitarians. In addition to providing a regulatory oversight service the DPS sanitarian regularly offers training sessions for food service personnel. The cafeteria employee who reported the illnesses therefore knew to report the illnesses to DPS. Kellogg Center was contacted by the sanitarian to request booking information for banquets held that day. A banquet meal for 190 of MSU Minority Affairs staff and students was served at Kellogg Center on May 3, 1998 at 4:30 p.m. When the Office of Minority Affairs was contacted to obtain the guest list, the sanitarian was informed of an employee of the department had also become ill after attending the banquet. The initial report to Ingham County Health Department included these three unrelated persons ill with enteric symptoms who ate the banquet meal. The definition of an outbreak was met (Two or more unrelated persons having the same clinical features as well as a time, place or person association).

Supervisors of the Environmental Health Division and the Communicable Disease Division were notified. The investigation process was initiated. Several meetings were held including members of all three agencies in a teamwork approach to accomplish the tasks described below using professional, efficient and well-organized methods.

Methods

Environmental Investigation Methods

A joint environmental inspection was performed by staff from MSU Public Safety and ICHD Environmental Health Division in the afternoon of May 5, 1998. The executive chef of Kellogg Center was consulted. The menu and recipes for the banquet meal were provided. Chicken was the main entrée for the banquet. The chef indicated that two servings of the chicken AuGratin were leftover and available. These were marked and held under refrigeration until they could be picked up for delivery to the Michigan Department of Community Health (MDCH) laboratory for testing.

The environmental investigation was performed by two Registered Sanitarians. Accompanying them were the executive chef and sous chef of Kellogg Center. General operational procedures were reviewed with the chef, including hot and cold holding temperatures, food handling and storing practices. Employee hygiene practices were reviewed including proper hand washing. The specific food preparation procedures used for this particular banquet meal were studied. In addition, a list of employees who were absent from work due to illness within the previous two weeks was obtained from the executive chef.

Epidemiological Methods

Case Definition

During the first outbreak meeting on May 6, a "working" case definition was formulated. A case was any person who consumed the meal served at the Kellogg Center Banquet for MSU Minority Affairs on May 3, 1998 who had onset of abdominal cramping and diarrheal illness within 36 hours of the suspect meal or laboratory confirmation of an enteric condition within 36 hours of the meal.

Interview Process

The MSU Minority Affairs Office was contacted by MSU DPS and a guest list was provided for the May 3 banquet and faxed over to ICHD Communicable Disease Division. A questionnaire was developed by members of both ICHD divisions based on the menu provided by Kellogg Center. It was determined that the team would attempt to interview all of those people attending the banquet in order to find both ill and well people (cases and controls). Telephone numbers for the attendees were provided by the MSU DPS and included local and home town (when listed) numbers. The interview process was delegated to four public health nurses from the Communicable Disease Division and one registered Sanitarian who worked as a team to contact and interview all attendees of the banquet. The interviewers were provided with a standard and uniform methodology for conducting the interviews. The data obtained from the interviews was designed to be entered into the Epi-Info (version 6) statistical analysis program from Centers for Disease Control.

Employees who had been ill were interviewed in order to ascertain whether or not they had any enteric illness during the two weeks prior to the outbreak. All persons interviewed were asked if they would be willing to submit stool specimens.

By the fourth day of the investigation a total of 69 of the 190 attendees of the banquet were interviewed. Local campus telephone numbers as well as home town numbers were used. Attempts to reach the remainder of the students failed. No further attempts were made once the team determined that we had enough ill and well people to continue with the investigation.

Analysis Methods

Epi-Info (6) software was utilized to calculate frequencies, attack rate, chi square and statistical significance of results for a case-control study. Generally, for foodborne illness outbreaks a case-control approach is used when all of those at risk cannot be identified or only a proportion of ill persons and well persons can be interviewed about their exposures. A cohort study would be done if the entire group at the event is known and interviewed about illness and exposure.[27] Only 69 out of the 190 attendees could be reached for an interview, so the case-control study was chosen. All attendees interviewed that were well became the controls.

Laboratory Investigation Methods

Stool Specimen Collection and Testing

After studying the onset times as well as the symptoms of the cases, it was decided that testing for *Clostridium perfringens* and *Bacillus cereus* be conducted along with the standard enteric pathogen testing so the necessary forms were completed for this special request. Patient mailable specimen kits were utilized. Instructions for collection

were provided in the kits along with the laboratory request forms. Ten cases had agreed to submitting stool specimens by May 6. MSU DPS staff delivered specimen kits to these people during the afternoon of May 6, 1998. They would then mail them to MDCH laboratory for analysis. None of the ill people had required medical attention and no specimens were obtained from them prior to this point. Standard plate counts were conducted for *C. perfringens, B. cereus* and the standard enteric panel.[38,39]

Food Specimen Collection and Testing

The food samples were also delivered by MSU staff to MDCH laboratory for analysis on May 6. Testing for *B. cereus* and *C. perfringens* was requested in addition to the standard enteric testing. For *C. perfringens* a standard plate count on tryptose-sulfite-cycloserine (TSC) agar plates is conducted.[39] An isolation of 10^5/gm is required for confirmation.[27] In addition, a test to detect *C. perfringens* enterotoxin is performed.[50] This is a reversed passive latex agglutination test. This technique enables soluble antigen such as the diarrheal enterotoxin to be detected in an agglutination assay. In a standard agglutination assay, soluble antibody reacts with particulate antigen such as bacterial cells.

For *B. cereus* a standard plate count on mannitol-egg yolk-polymyxin (MYP) agar plates is conducted.[38] The same number of cells (105/gm) are required for confirmation of *B.cereus*.[27] In addition, a test to detect the *B. cereus* enterotoxin is done. This is also a reversed passive latex agglutination test.[49]

Results

Environmental Investigation

General Practices

The field inspection on May 5 performed by two Sanitarians (one from ICHD, one from MSU) took approximately 1½ hours. Both the Executive Chef and the Sous Chef attended.

Temperatures of refrigeration units appeared to be acceptable with temperatures reading 38-44° F. The baine-marie for hot food holding was set at 190° F. and the foods held in the unit were above 140° F.

Storage practices of cold foods and temperatures were monitored. Individual portions of cooked food items placed in single layers on sheet trays in walk-in coolers was noted. This is an acceptable cooling practice.

The potential for cross contamination was noted with raw beef stored below raw chicken and raw sausage patties stored on top of cooked potatoes. Open containers of sheet trays of chicken breast were noted with parchment paper or toweling on top of them.

Inadequate cooling of food products prior to cold storage in a large container was observed. A five gallon container of chicken minestrone soup was marked 5-5-98 as a preparation date with no time given. The temperature of the soup was from 50-60° F. The chef indicated that ice baths are commonly used to cool soups but no cooling wands were used (ice filled plastic stirring wands). He estimated that the soup was prepared late that morning.

Proper hand washing was found to be an issue. At least two sinks were blocked by carts, empty boxes or clean dish racks. Hand wash sinks were supplied with paper towel and liquid hand soap. The use of the hand wash sinks was questionable. No food preparation employee was observed washing their hands during the inspection. One of the sanitarians observed employees rinsing their hands at food preparation sinks several times. He also observed am employee lick his fingers and use a common towel to wipe his face, then lay the towel back down on the preparation area at the grill station. The employee failed to wash his hands prior to continuing food preparation. Plastic gloves are used by food preparation employees regularly. However, some bare-hand contact of food was noted. Strict personal hygiene was discussed with the chefs, including the importance of thorough hand washing.

Practices Specific to the Outbreak

There was a set menu for the banquet. The choices included either a Chicken AuGratin entrée or a Vegetarian Strudel entrée. The recipes for the meal and specific procedures for the Chicken AuGratin were scrutinized. Chicken breasts were seasoned and sauteed lightly on both sides and then placed on sheet trays to cool in the walk-in cooler the day before serving. The vegetable mixture of mushrooms, leeks, red peppers and green peppers were cut up the day prior to serving. The parmesan cream sauce consisting of whipping cream, white wine, parmesan cheese, bay leaf, salt, pepper, roux, cayenne pepper and chopped fresh basil was prepared the day prior to service as well. The four gallon batch was then cooled in the walk-in cooler. The chef indicated that it should have been quickly cooled in a water bath, but no temperature record was kept. He could not be sure that the sauce was properly cooled. On the day of service the chicken

breasts were taken out of the cooler and baked for approximately 25 minutes at 325° F. until the internal temperature reached 165° F. The vegetables were sauteed and placed on the cooked chicken, topped with warmed parmesan cream sauce, parmesan cheese/bread mix and briefly broiled just before serving.

Epidemiological Results

Of the 69 attendees that were contacted, 35 met the case definition. They had all attended the banquet on May 3, 1998 and had onset of cramping and/or diarrhea within 36 hours of the meal. The remaining attendees interviewed who were not ill became the controls for the study. The breakdown of symptoms was as follows: Diarrhea: 91.7%, Cramping: 63.9%, Vomiting: 5.6%, Fever: 2.8%. The median onset time was 10 hours with a range of 2-24 hours. (See Figure 6)

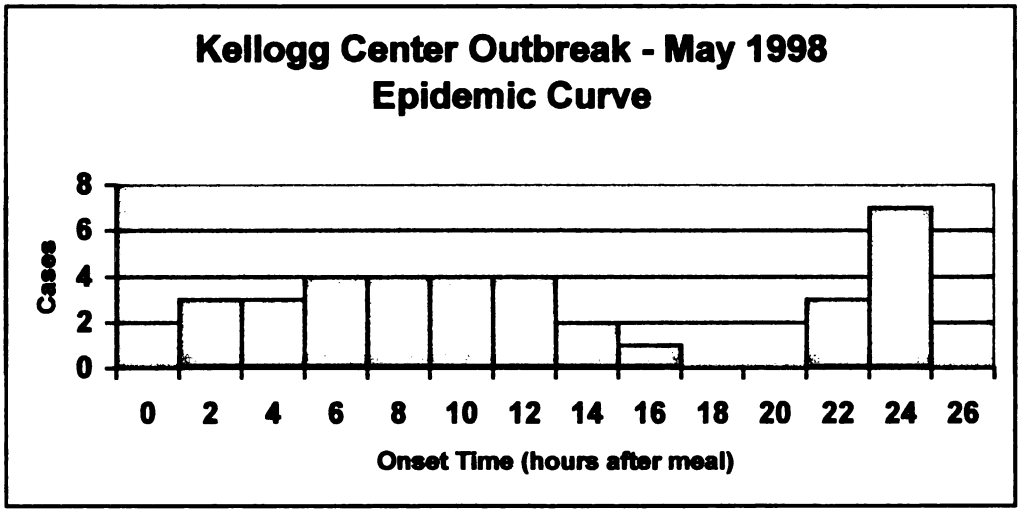

Figure 7. Epidemic Curve

Table 4. Summary of Food Specific Attack Rates, Odds Ratios, X^2 and p-values Kellogg Center Outbreak – May 1998

Food	ILL	Ate Total	AR %	Did Not Eat ILL	Total	AR %	OR	95%CL	X^2	p
Chicken	35	64	55	0	5	0			5.6	.025
Veg. Strud	3	7	43	32	62	52	0.7	.11,4.2	0.19	.483
Potatoes	33	63	52	2	6	33	2.2	.31,19	0.80	.323
Gr. Beans	27	50	54	8	19	42	1.6	.49,5.4	0.78	.377
Rolls	28	57	49	7	12	58	0.69	.16,2.9	0.34	.562
Red Pepper	3	9	33	31	59	52	0.45	.08,2.4	1.15	.238
Salad	30	58	52	5	11	45	1.3	.30,5.7	0.15	.703
Ranch Dr	22	43	51	13	26	50	1.05	.35,3.1	0.01	.925
Italian Dr	8	13	61	27	56	48	1.72	.43,7.1	0.75	.387
Cheesecake	31	61	51	4	8	50	1.03	.19,5.6	0.0	.63
Water	34	63	54	1	6	17	5.86	.59,143	3.0	.09
Soft Drink	19	40	47	16	29	55	0.74	.25,1.9	0.40	.529
Tea	3	4	75	32	65	49	3.09	.26,83	1.00	.318
Coffee	3	14	21	32	55	58	0.2	.04,.90	6.0	.014
Milk	0	1	0	35	68	51			1.0	.493

The overall illness attack rate was 50.7% (35/69). See Table 4 for food-specific attack rates. Notable was the attack rate for those who ate the chicken entrée which was 55% (35/64). The attack rate for those who did not eat the chicken entrée was 0%.

Using Epi-Info software, the only food item with a positive association with illness was the chicken entrée with a p-value of .025 (Fisher's Exact Test). The odds ratio could not be calculated due to the fact that one cell in the table was 0 (0 people were ill who did not eat the chicken). The chi-square value is also not accurate due to low cell counts. Therefore the Fisher's Exact probability test was recommended.

Laboratory Results

Stool Specimen Results

Five of the cases returned a stool sample to MDCH laboratory. All of them tested negative for the foodborne pathogens tested for. The specimens were all collected 3-4 days after the meal was consumed.

Food Specimen Results

Two complete chicken entrees were tested. *Bacillus cereus* was found at a level of 10^3/gm. There was no way to separately test the sauce and chicken so this is the result of the homogenation of the two. In addition, *Clostridium perfringens* was found, but only after enrichment. The test for *Bacillus cereus* enterotoxin was negative.

Disscussion

Limitations

The duration of the illness was short, about 24 hours, and the symptoms were not severe. None of the cases required medical attention. No initial stool specimens were collected. The college student population during this week of final exams was transient. These factors contributed to the low response rate of stool specimen collection and the inability to interview a greater percentage of the attendees of the banquet. However, 69 of the 190 attendees were interviewed (36%), including 5 of the 20 vegetarian attendees, a large enough number to produce statistically significant results.

All the stool specimen test results were negative for all organisms tested. The specimens were collected after acute illness was over. Some pathogens such as *C. perfringens* remain in the intestinal tract only for a few days after onset of the illness.[27] It would have been preferable to collect the specimens during acute illness but this was not practical considering the short duration of symptoms. The collection time was most likely past the prime "shedding time" when an adequate number of organisms or level of toxins in the stool can be detected by culturing or toxin testing.

Conclusion and Discussion

The results of the statistical analysis show that the most likely source was the chicken entrée. Considering attack rates, none of the attendees who ate only the vegetarian entrée (which were those who did not eat any chicken entrée) were ill compared to 55% of those eating the chicken entrée were ill. The Fisher's exact p-value was <.05 which tells us that this difference is significant. No other food item stood out with any significant results.

Bacillus cereus was found in the chicken entrée specimen submitted (10^3/gm) but not at a definitive level. IAMFES Procedures to Investigate Foodborne Illness states that to be confirmation of the cause it must be found at a level of 10^5/gm in the epidemiologically implicated food. *C. perfringens* was found only after enrichment and was therefore not definitive. To be considered confirmation it would also have to be found at a level of at least 10^3/gm of epidemiologically implicated food. No other enteric pathogens were found. The sample included chicken with sauce and the laboratory could not test the two separately. It is unusual to find two different pathogenic organisms in a food sample, even at these lower levels. *C. perfringens* would most likely have originated from the fresh chicken and the *B. cereus* from the sauce ingredients, but there is no way of determining this without extensive testing of the food items in the same lots as the original meal ingredients.

Inadequate cooling procedures in the sauce preparation would allow for germination of surviving bacterial spores and subsequent growth. Inadequate cooling procedures were found in this kitchen for an unrelated food item during the environmental inspection, making this scenario more plausible. The partial cooking of

the chicken breasts the day prior to serving may also have allowed survival of pathogenic organisms that would grow if not quickly cooled. The environmental inspection report highlights the need for improved employee hygienic procedures and possible cross-contamination in the walk-in cooler.

Although positive stool cultures would have been desirable, positive food specimen results (although not high enough to be conclusive), the clinical features of the illness, including incubation period and the statistical significance of the attack rates all support the following conclusion: The outbreak was caused by ingestion of the chicken entrée that had been naturally contaminated with the pathogenic organisms. The ingredients were heated and then cooled slowly, allowing germination of spores of one or both of these two organisms and subsequent toxin formation in the intestines which in turn caused the illness.

A similar outbreak occurred in Napa, California in 1989.[42] A wedding reception including 140 guests was catered by a local restaurant. The outdoor buffet included Cornish game hens, Kentucky Fried Chicken and various side dishes. The guest list was obtained and 56% of the group (79/140) were interviewed. Of those interviewed, 70% (55/79) met the case definition. The overall attack rate was at least 39%(55/140). The median incubation period was 12 hours and the median duration was 19 hours.

The statistical analysis showed that consumption of the Cornish game hen was highly associated with illness (OR=29.33, p=.0001) Fecal samples were only collected from two guests. These were only tested for the common enteric bacteria and were not tested for *B.cereus* or *C. perfringens*. However, both *B. cereus* and *C. perfringens* were found in the Cornish game hen sample. *B. cereus* was found at 14 million per gram of

food. *C. perfringens* was present at 99,000 per gram. The plate count for *B. cereus* was sufficient as confirmation of causative organism. The *C. perfringens* was not at a high enough level for confirmation, although the investigators left open the possibility that some of the illness may have been caused by *C. perfringens*. The actual dosage could have been high enough in the Cornish hens eaten to cause illness.

In this outbreak bacterial multiplication was facilitated at several points during the preparation and transportation of the food:

1. The main refrigeration unit used in the catering operation was only holding temperatures of 48° F.-50°F.;
2. The birds were probably thawed incompletely, resulting in inadequate cooking at the center;
3. Cross-contamination occurred when the same brush was used for basting both before and after cooking without being washed; and
4. On the day of the event, when the outdoor temperature reached 90°F., the hens were held for approximately 4 ½ hours in an unrefrigerated van while a delivery was made elsewhere in the county.

Like the MSU outbreak, this outbreak resulted from improper temperature control that was conducive to the growth of both *B. cereus* and *C.perfringens* and resulting toxin formation. In addition to the onset times and symptomology being similar, the fact that these two organisms grow under the same conditions should lead investigators to test for both of these organisms and toxins when one of them is suspected.

Recommendations to the Foodservice Establishment

Good employee hygiene is always stressed in the prevention of foodborne illness. It is recommended that employee training be increased in this area and reviewed frequently. This food service estabishment is one of the more well-trained facilities in Ingham County. The new Food Code requires that employers have an employee hygiene training policy in place. In fact, the MSU DPS Registered Sanitarian offers regular training for MSU employees. All full time employees working for the food services at MSU are required to attend a ½-day food service sanitation class that includes basic HACCP principles. The chefs and other managers are required to be certified with Serv-Safe or an equivalent course, including the chef at Kellogg Center at the time of the outbreak.

The Hazard Analysis Critical Control Point (HACCP) system is used as a method of ensuring safe food processing "from the farm to the table". Developed in the 1970's for the National Aeronautics and Space Administration (NASA) for the astronauts' foods, it is now applied at all levels of the food industry. The HACCP system emphasizes the quality of all ingredients and all processing steps on the premise that the resulting product will be safe if these steps are properly controlled. The system addresses all of the leading causes of foodborne illness listed earlier. A "critical control point" (CCP) is any point in a specific food system where control can be exercised and a hazard can be minimized or prevented.[29] The essential elements of HACCP are:

1. Assess hazards and risks of the food process.
2. Determine the critical control points to ensure control of or minimize a hazard

3. Establish critical limits (prescribed tolerances that must be met to ensure that a CCP effectively controls a microbiological hazard. An example is to cook a hamburger to at least 155°F. for 15 seconds.)
4. Establish procedures to monitor CCP's, such as charting temperatures of refrigeration units.
5. Establish corrective actions to be taken when deviations occur in CCP monitoring.
6. Establish effective record-keeping to document the HACCP plan.
7. Establish procedures for verification that the HACCP system is working correctly.

The recipes used at Kellogg Center are not HACCP recipes. The principles are usually incorporated into the recipes, but there is no requirement for the recipes to be in HACCP style. However, the dormitory food service cafeterias are in the process of changing their recipes to reflect good HACCP procedures. Figure 7 shows the actual recipe used for the banquet and Figure 8 shows the recipe converted to a HACCP style recipe. The inspection process for the food services has also evolved into a HACCP inspection, from the point of delivery to the point of service at the cafeteria line.

Breast of Chicken AuGratin- Recipe used in May, 1998

6 oz. chicken breast
½ oz. mushrooms
½ oz. leeks, sliced
½ oz. red peppers
2 oz. cream sauce
½ oz. grated parmesan
½ oz. bread crumbs

- 6 oz. Chicken breast sauteed lightly on both sides, season with salt & pepper.
- Place chicken breast on sheet tray.
- Cook for 25 minutes at 325°, until internal temp reaches 165°.
- Saute mushrooms, leeks, green and re peppers.
- After chicken is cooked, top each breast with 2 oz. of vegetable mixture.
- Sprinkle 1 oz. of Parmesan bread mixture on top of chicken, vegetables and cream sauce.
- Place chicken under broiler for 5-10 seconds to brown off Parmesan mixture.

Parmesan Cream Sauce- Recipe used in May, 1998

4 qt. Whipping cream
½ qt. White wine
4 bay leaves
salt and pepper
16 oz. roux (mixture of butter and flour)
1 t. cayenne pepper
1 T. dry basil, chopped

- Heat together wine and bay leaves. Reduce to ½.
- Add cream and simmer for about ½ hour on low-med. Heat.
- Thicken with roux to a smooth consistency.
- Add seasoning and hold in bay.

Figure 8. Recipes for chicken augratin entrée served at banquet, May, 1998

Breast of Chicken AuGratin- Suggested HACCP-based Recipe

Cream Sauce

4 qt. Whipping cream- held at 41° F. or below
½ qt. White wine
4 bay leaves
salt and pepper
16 oz. roux (butter and flour)
1 t. cayenne pepper
1 T. dry basil, chopped

- In a pot heat together wine and bay leaves. Reduce to ½.
- Add cream and simmer for about ½ hour on low-med heat.
- Thicken with roux to a smooth consistency.
- Add seasoning.

If using immediately:

- **CCP**: Immediately transfer to hot-holding unit and hold at 140°F. or higher until chicken entrees are assembled.

If using the next day:

- **CCP**: Cool quickly down to 70° F. or lower within 2 hours using an ice bath and ice paddles for stirring. Continue cooling to 41°F. or lower within another 4 hours using the same procedure or transfer sauce to shallow containers and store in walk-in cooler. Monitor temperature.

Chicken Entree

6 oz. chicken breast held frozen in freezer, then thawed in walk-in cooler in drip-proof container.
½ oz. mushrooms
½ oz. leeks, sliced
½ oz. red peppers
2 oz. cream sauce prepared as described above
½ oz. grated parmesan
½ oz. bread crumbs

- Saute chicken breast lightly on both sides. Season with salt and pepper.
- Place chicken breast on sheet tray.
- **CCP**: Cook for about 25 minutes at 325° F. oven temperature until internal temperature of chicken breast reaches 165° F.
- **CCP**: Hold at 140°F. or higher until entrees are assembled.
- **CCP: If assembling and serving the next day**, cool quickly to 70° F. or lower within 2 hours and to 41° F. or lower within another 4 hours by chilling in coldest part of walk-in cooler in single layers on trays. Monitor temperature.

If serving immediately:

- Sauté mushrooms, leeks, green and red peppers.
- Top each breast with 2 oz. of vegetable mixture.
- Pour 2 oz. of hot cream sauce on top of chicken and vegetable mixture.
- Sprinkle 1 oz. of parmesan bread mixture on top of chicken, vegetables and cream sauce.
- Place chicken under broiler for 5-10 seconds to brown off parmesan mixture.
- CCP: Hold entrees at 140° F. or higher until served.

If assembling and serving the next day:

- **CCP**: Heat cream sauce and chicken portions to 165°F. or higher prior to assembling with vegetables as described above.
- **CCP**: After assembling, hold at 140°F. or higher until served.

Figure 9. HACCP-based recipe for Chicken Entrée served May, 1998 Indicating Critical Control Points (CCP)

The practice of cooling cooked foods was reviewed. In order to prevent sporulation and subsequent growth of organisms surviving the cooking stage, the foods must be cooled quickly, within four hours to 45°F or below based on the 1979 FDA Code. The new 1999 FDA code requires cooling to a temperature below 70°F. within 2 hours and then to 41°F. or below within another 4 hours.

Sauces prepared ahead of time should be cooled in a water bath and stirred with an ice-filled stirring paddle or transferred to shallow pans to bring the hot sauce down to proper temperatures within the safe time requirements. Water bath use with ice paddles is the standard operating procedure for cooling soups and sauces at this food service establishment. However, it appears that during this unusually busy period this practice was not completely followed or documented.

The cooperative effort of staff members in the bureaus of Communicable Disease and Environmental Health and Michigan State University was instrumental in the quick response and thorough investigation of this outbreak. Notable also was the highly professional attitude and total cooperation of the management of this highly respected food service. This allowed for the most complete investigation possible and resulted in a valuable learning experience for all parties involved.

CONCLUSION

The 1998 foodborne illness outbreak described is an example of many investigations that have been done in the last few years at ICHD. The protocol has helped to make the process more efficient. Every outbreak is unique and it is helpful to have a guide to follow in order to be sure steps are not missed. More outbreaks are discovered and investigated each year in Ingham County. The information gained by thorough investigation is valuable not only to the particular food service establishment, but at the state and federal level, as it is tabulated into the appropriate surveillance systems. These surveillance systems, both active and passive, are improving in their capabilities to more accurately measure the burden of foodborne disease and its causes. The FDA has used this information to update the FDA Food Code, the 1999 version being the most recent. This updated version is an outstanding improvement, having incorporated public health interventions designed to address the most frequent causes of foodborne illness. As the epidemiology of foodborne illness continues to change, public health policy will also change to more effectively prevent foodborne illness. To accomplish this goal, the importance of foodborne illness surveillance and outbreak investigation must become a priority at the national, state and local levels.

APPENDIX

BACKGROUND INFORMATION ON *CLOSTRIDIUM PERFRINGENS* AND *BACILLUS CEREUS*

Background Information on *Clostridium perfringens*

Clostridium perfringens is an anaerobic, gram-positive, spore-forming rod. It is widely distributed in the environment and is commonly found to inhabit the gastrointestinal (GI) tract of humans, domestic livestock and other warm-blooded animals. Spores of the organism persist in soil, sediments, and areas subject to human or animal fecal contamination. Meats become contaminated during the slaughtering process and poultry during line processing. The organism can then grow on the food surfaces. Cooking usually kills the vegetative cells but heat-stable spores survive. Then if the food is held at improper temperatures the spores can germinate and proliferate in the food. The most frequently implicated foods include roast beef and gravy, turkey, dressing and gravy, casseroles containing meat/poultry, stews, Mexican foods, sauces, salads, and pork.[40,41] The illness is a relatively mild, self limiting disease characterized by diarrhea and abdominal cramps 6-24 (usually 10-12) hours after ingestion of the contaminated food. The illness usually resolves within 12-24 hours.

C. perfringens has been recognized as a cause of foodborne illness for more than 50 years.[34] *C. perfringens* can cause other diseases such as gas gangrene and at least 13 different toxins have been identified from the organism. Any individual strain will produce only a few of the toxins. The production of four certain major toxins ($\alpha,\beta,\epsilon,\iota$) is the basis for subtyping into five toxigenic types (A,B,C,D and E).[34] The toxin associated with foodborne illness is termed the *C. perfringens* enterotoxin (CPE) and can be present in any of these. Foodborne illnesses due to *C. perfringens* are almost always

caused by serotype A. Ingestion of a large number of vegetative organisms (>=10^5) is followed by sporulation of the bacterial cells in the small intestine with the production of the enterotoxin. CPE synthesis is increased by sporulation. Sporulation is also required for CPE release from the cell. This second sporulation may occur in the food during reheating, but most likely occurs when the bacterial cell reaches the low pH of the stomach. The pathogenesis of CPE involves binding to the tips of the villi of the epithelial cells of the ileum, insertion into the cell membrane and a formation of a complex which causes pore formation, alteration in permeability and ion fluxes, inhibition of cell metabolism, cytoskeletal disintegration and ultimately cell lysis.[34] The result of this process is cramping and diarrhea.

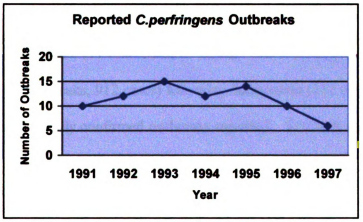

Figure 10. Outbreaks of *C. perfringens* in the U.S.[4,11,17]

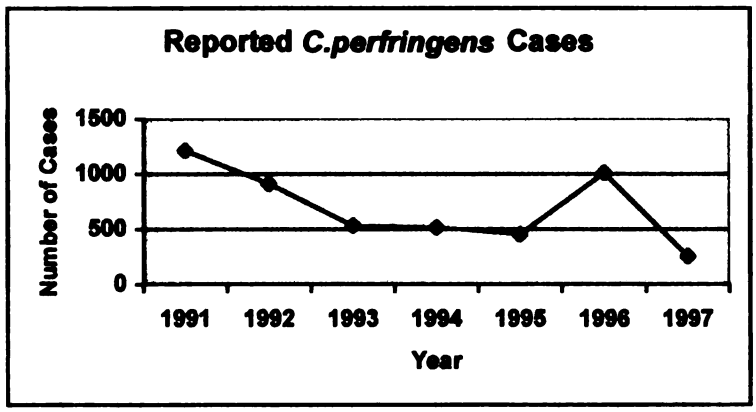

Figure 11. Cases of *C. perfringens* in the U.S.[4,11,17]

During 1991, 528 outbreaks involving 14,876 cases of foodborne disease were reported to CDC. Only 214 (41%) were of confirmed etiology. Of those 214 outbreaks, 173 were from bacterial pathogens. Of the bacterial pathogens Figure 12 shows *C.perfringens* was third in number of outbreaks (10 outbreaks, 1,213 cases). *Salmonella* caused most of the confirmed outbreaks (122 outbreaks, 4,146 cases) and second was *C.botulinum* (11 outbreaks, 25 cases).[4] In 1992 *C. perfringens* jumped to second place (12 outbreaks, 912 cases) following *Salmonella* (117 outbreaks, 4,156 cases) of etiologically confirmed outbreaks reported. For both years *C. perfringens* claimed more cases than any other bacterial pathogen except for *Salmonella* (Figure 13)

The number of reported illnesses due to *C. perfringens* has dropped in recent years. It still remains the third in number of outbreaks caused by bacterial pathogens from years 1993, 1994, 1995,1996 and fifth in 1997. The number of reported cases due to outbreaks has dropped also.[17]

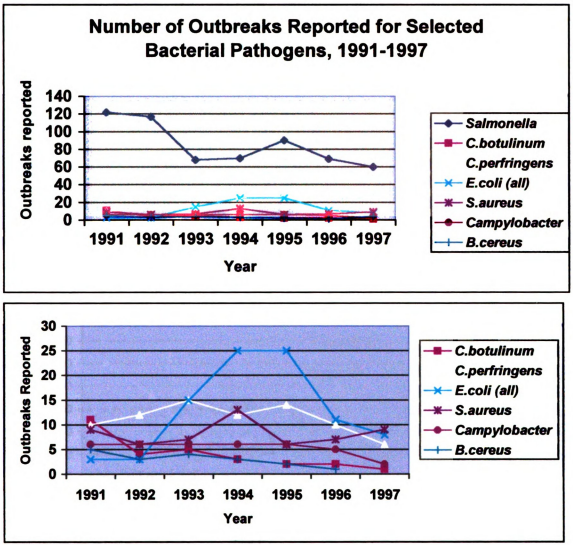

Figure 12. Number of Outbreaks of Selected Bacterial Pathogens, 1991-1997 (Lower graph is of smaller scale, excludes *Salmonella* to magnify the remaining pathogens.)[16,17]

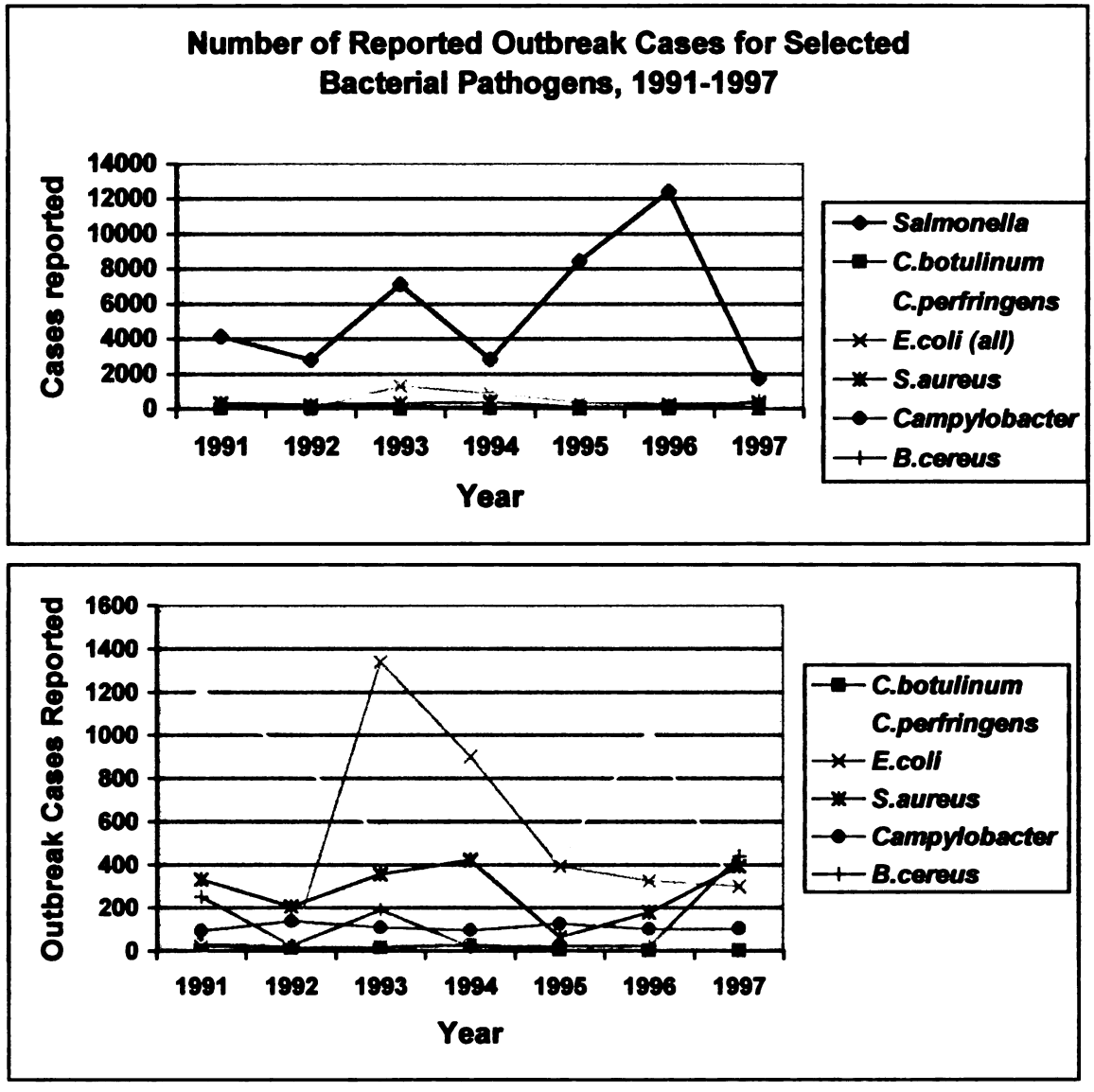

Figure 13. Number of Reported Cases of Selected Bacterial Pathogens, 1991-1997. (Lower graph is smaller scale, *Salmonella* deleted, to magnify remaining pathogens.)[16,17]

Standard bacteriological culturing procedures are used to detect the organism in implicated foods and in fecal samples from patients. Serological assays are used for detecting enterotoxin in the feces of patients and for testing the ability of strains to produce toxin. The criteria used for confirmation of a case or outbreak include:[27]

a. Isolation of the same serotype of *C. perfringens* from specimens from most ill persons but not from controls; or

b. Isolation of the same serotype of *C. perfringens* from ill persons and epidemiologically implicated food; or

c. Fecal spore count of $>10^6$/g *C. perfringens* in most ill persons examined within a few days of illness; or

d. Isolation of $>=10^5$ *C. perfringens* in epidemiologically implicated food; or

e. Demonstration of toxin in feces by reverse passive hemagglutination, flourescent antibody or other techniques.

(Methods c, d, and e are the most frequently used methods.)

A confirmed outbreak of *C. perfringens* occurred in Ingham County in November 1990.[41] Thirty-two of forty two (76%) of attendees of a cake decorator's conference became ill with gastroenteritis and a median incubation period of 6.5 hours (range 1.5-15 hours). Ill persons were five times more likely to have consumed minestrone soup than were those who were not ill (relative risk=4.92, 95% confidence interval 1.23-∞). *C. perfringens* ($>10^5$organisms/g) was isolated from 11 of 12 stool samples collected. *C. perfringens* (10^7organisms/g) was isolated from the minestrone soup. The environmental investigation found that the soup was cooked two days prior to serving and was slowly cooled before refrigeration. On the day it was served it was briefly reheated. The lack of time and temperature controls during the cooling and reheating of the soup most likely allowed for the proliferation of the *C. perfringens* in the soup and subsequent toxin formation. The relatively short incubation period (median 6.5 hours, range 1.5-15 hours) suggests that sporulating cells or preformed toxin may have been ingested.

Background Information on *Bacillus Cereus*

Bacillus cereus is an aerobic or facultatively anaerobic, gram-positive spore-forming rod. It is commonly found in soil, air, dust, water and in many raw and processed foods. *B. cereus* may be isolated from rice, dairy products, meat, spices and eggs. The bacterium is capable of surviving different environmental stresses, making it very difficult for the food industry to control.

B. cereus causes two different types of foodborne illness: diarrheal and emetic. The diarrheal type of illness is caused by complex, heat labile enterotoxins produced during vegetative growth of *B.cereus* in the small intestine. This type of illness is considered an infection. For the diarrheal type the incubation period is from 8 to 16 hours. The emetic toxin causes vomiting and is produced in the food by growing cells. The incubation period for the emetic type of illness is from ½ hour to 6 hours. The toxin is injested while in the food and the resulting illness is considered an intoxication. This toxin is resistant to heat and is therefore not inactivated by reheating of foods.[20] For both types of illness the duration is usually less than 24 hours.

In both types the food involved has usually been heat-treated. The surviving spores then produce either the enterotoxins or the emetic toxin. *B.cereus* grows well after cooking and cooling. The heat treatment (cooking) causes spore germination and subsequent growth. Different strains of *B.cereus* produce different amounts of enterotoxin. The infectious dose appears to range from $10^5 - 10^8$ viable cells. Factors contributing to foodborne outbreaks include: Storing cooked foods at room temperature; storing cooked foods in large containers in refrigerator; preparing foods several hours

before serving; inadequate reheating of leftovers. The emetic type of illness has most often been associated with boiled or fried rice, cooked cornmeal dishes, cooked cereals and pasta. The diarrheal type has been associated with cereal product, soups, custards and sauces, meatloaf, sausage, cooked vegetables, reconstituted dried potatoes and refried beans.[2,27]

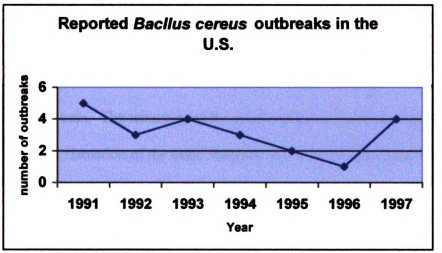

Figure 14. Reported *B. cereus* Outbreaks in the U.S.[4,17]

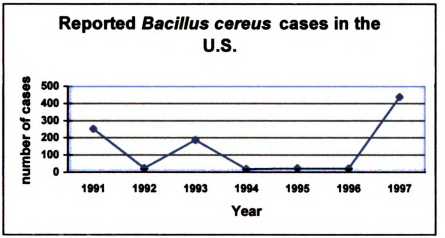

Figure 15. Reported *B. cereus* Cases in the U.S.[4,17]

Cases of *B.cereus* foodborne illness are not routinely reported (Table 1). No more than 5 outbreaks per year have been reported to the CDC from 1991-1997 (Figure14). Those outbreaks accounted for as few as 22 cases in 1996 to a high of 438 in 1997 (Figure 15). Because it is a mild illness, it is considered to be highly underreported and has been estimated by the CDC to actually be 27,360 cases per year in the U.S.(Table 1).

Standard bacteriological culturing procedures are used to detect the organism in implicated foods and in fecal samples from patients. Serological assays are used for detecting enterotoxin in the feces of patients and for testing the ability of strains to produce toxin. The criteria used for confirmation of a case or outbreak include:

a. Isolation of the same serotype of *B. cereus* from stool specimen from ill person(s) but not from controls; or
b. Isolation of >=10^5 *B. cereus* per gram from epidemiologically implicated food;or
c. Detection of enterotoxin by ligated rabbit ileal loop, vascular permeability reaction, immunogel-diffusion, aggregate-hemagglutination, reverse passive latex agglutination; or
d. Detection of emetic enterotoxin by monkey feeding, Hep-2 cell, or other test.

REFERENCES

1. Albrecht J. Food safety knowledge and practices of consumers in the U.S.A. J Consumer Studies and Home Economics 1995;19:119-34.

2. Andersson A, Ronner U, Granum P. What problems does the food industry have with the spore-forming pathogens *Bacillus cereus* and *Clostridium perfringens*? Internat J Food Microb 1995;28(1995):145-155.

3. Angulo F, Voetsch A, Vugia D, et al. Determining the Burden of Human Illness from foodborne diseases: CDC's Emerging Infectious Disease Program Foodborne Disease Active Surveillance Network (FoodNet).[Online] Available http://www.cdc.gov/ncidod/dbmd/foodnet/pub, 1998.

4. Bean N, Goulding J, Lao C, et al. Surveillance for Foodborne-Disease Outbreaks—United States, 1988-1992. MMWR 1996;45(SS-5):1-55.

5. Bryan F. Hazard Analysis Critical Control Point (HACCP) Systems for Retail Food and Restaurant Operations. J Food Protection 1990;53(11): 978-983.

6. Bryan F. Risks Associated with Vehicles of Foodborne Pathogens and Toxins. J Food Protection 1988;51(6):498-508.

7. Bryan F. Risks of Practices, Procedures and Processes that Lead to Outbreaks of Foodborne Diseases. J Food Protection 1988;51(8):663-673.

8. Centers for Disease Control (CDC). Appendix B Guidelines for Confirmation of Foodborne-Disease Outbreaks. MMWR 2000;49(SS01):54-62.

9. CDC. *Bacillus cereus* Food Poisoning Associated with Fried Rice at Two Child Day Care Centers-Virginia, 1993. MMWR 1994;43(10):177-178.

10. CDC. Epi-Info (Version 6) Statistical Software package.

11. CDC. Foodborne Disease Outbreaks, 5-Year Summary, 1983-1987. MMWR 1990;39(SS01):15-23.

12. CDC. Healthy People 2010 Chapter 10 Food Safety. [Online] Available http://www.health.gov/healthypeople/Document/HTML/Volume1/10Food.htm. 2001.

13. CDC. Incidence of Foodborne Illnesses: Preliminary Data from the Foodborne Diseases Active Surveillance Network (FoodNet)—U.S., 1998. MMWR 1999;48(9):189-194.

14. CDC. Preliminary FoodNet Data on the Incidence of Foodborne Illnesses—Selected Sites, United States, 1999. MMWR 2000;49(10):201-5.

15. CDC. Preliminary FoodNet Data on the Incidence of Foodborne Illnesses—Selected Sites, United States, 2000. MMWR 2001;50(13):241-6.

16. CDC. Surveillance for Foodborne-Disease Outbreaks—United States, 1988-1992. MMWR 1996;45(SS-5):1-55.

17. CDC. Surveillance for Foodborne Disease Outbreaks—United States, 1993-1997. MMWR 2000;49(SS01):1-51.

18. Chin J. Control of Communicable Diseases Manual, 17th Edition. Washington, D.C., American Public Health Association, 2000.

19. Crane J. Preformed Bacterial Toxins. Clinics in Laboratory Medicine 1999;19(3):583-599.

20. Dufrenne J, Soentoro P, Tatini S, et al. Characteristics of *Bacillus cereus* related to safe food production. Int J Food Micro 1994;23:99-109.

21. FSIS. Reducing the Risk of *Listeria monocytogenes* Joint Response to the President, Executive Summary. [Online] Available http://www.foodsafety.gov/~dms/lmriplan.html. 2001:1-10.

22. Frewer L, Shepherd R, Sparks P. The interrelationship between perceived knowledge, control and risk associated with a range of food-related hazards targeted at the individual, other people and society. J Food Safety 1994;14:19-40.

23. Granum PE, Lund T. *Bacillus cereus* and its food poisoning toxins. FEMS Microbiology Letters 1997;157:223-228.

24. Gregg M. Field Epidemiology. New York: Oxford University Press, 1996:92-131.

25. Ingham County Health Dept. Foodborne Illness Investigation Protocol 1998.

26. Ingham County Health Dept. Press Release: An Outbreak of Salmonella enteriditis in Ingham County, Aug. 21,1997.

27. International Association of Milk, Food and Environmental Sanitarians, Inc. (IAMFES). Procedures to Investigate Foodborne Illness Fifth Edition. Des Moines, Iowa: IAMFES 1999.

28. Jackson L, Wenger J. Listeriosis: a foodborne disease. Infections in Medicine 1993;10:61-66.

29. Jay J. Modern Food Microbiology. New York, N.Y.: International Thomson Publishing 1996: 408-417.

30. Knabel S. Role of Home Food Handling Practices. Food Technology 1995; 49(4): 119-131.

31. Last J. A Dictionary of Epidemiology Third Edition. New York: Oxford University Press, 1995.

32. Lindsay J. *Clostridium perfringens* Type A Enterotoxin (CPE): More Than Just Explosive Diarrhea. Crit Rev Microb 1996;22(4):257-277.

33. Mead P, Slutsker L, Dietz V, et al. Food-Related Illness and Death in the United States. Emerg Inf Dis 1999;5(5):607-625.

34. Meer R, Songer G, Park D. Human Disease Associated with *Clostridium perfringens* Enterotoxin. Rev Environ Contam Toxicol 1997;150:75-94.

35. Michigan Department of Agriculture, Food and Dairy Division. 1998 Year-End Summary Foodborne Illness Surveillance. Oct 1995.

36. Michigan Department of Agriculture, Food and Dairy Division. 1999 Year-end Summary Foodborne Illness Surveillance. Sept 2000.

37. Michigan Department of Agriculture, Food and Dairy Division, Food Service Sanitation Section. Minimum Program Requirements- A manual of food Service Sanitation Regulatory Minimum Program Requirements. August 2000.

38. Michigan Department of Community Health Bureau of Laboratories, Division of Infectious Diseases. Foodborne Illness and Poisoning: *Bacillus cereus* Colony Count (Procedure) 1998.

39. Michigan Department of Community Health Bureau of Laboratories, Division of Infectious Diseases. Foodborne Illness and Poisoning: *Clostridium perfringens* Colony Count (Procedure) 1998.

40. Reed G. Foodborne Illness (Part 3) *Clostridium perfringens* Gastroenteritis. Dairy, Food and Environmental Sanitation 1994;14(1):16-17.

41. Roach R, Sienko D. *Clostridium perfringens* Outbreak Associated with Minestrone Soup. Am J Epidemiol 1992;136(10):1288-1291.

42. Slaten D, Oropeza R, Werner S. An Outbreak of *Bacillus cereus* Food Poisoning—Are Caterers Supervised Sufficiently? Pub Health Reports 1992;107(4):477-480.

43. Sondik E. Healthy People 2000 Progress Review, Food Safety (Part 2) [Online]. Available http://www.cdc.gov/nchs/aboutotheract/hp2000/foodsafety/foodcharts.htm. 1999.

44. State of Michigan, Michigan Compiled Laws, Act 92 of 2000 sections 289.3103-289.3139.

45. State of Michigan, Michigan Compiled Laws, Act 368 of 1978, Mich Public Health Code P.A. 1978.

46. Taormina P, Beuchat L, Slutsker L. Infections Associated with Eating Seed Sprouts: An International Concern. Emerg Inf Dis 1999;5(5):626-634.

47. Tauxe R,Vandepitte J, Wauters G. *Yersinia enterocolitica* infections and pork: the missing link. Lancet 1987;1:1129-32.

48. Tauxe R. Emerging Foodborne Diseases: An Evolving Public Health Challenge. Emerg Inf Dis 1997;3(4):425-434.

49. Unipath Limited. Oxoid Toxin Detection Kits, PET-RPLA *Clostridium Perfringens* Enterotoxin Test Kit. 1990.

50. Unipath Limited. Oxoid Toxin Detection Kits, BCET-RPLA *Bacillus Cereus* Enterotoxin (Diarrhoeal type) Test Kit. 1990.

51. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Food Code-1999 Recommendations of the U.S. Public Health Service Food and Drug Administration. 1999.

52. United States Food and Drug Administration, Center for Food Safety & Applied Nutrition. Foodborne Pathogenic Microorganisms and Natural Toxins Handbook.

53. Yang S. FoodNet and Enter-net: Emerging Surveillance Programs for Foodborne Diseases. Emerg Inf Dis 1998;4(3):457-8.

54. Yang S, Leff M, McTague D. Multistate Surveillance for Food-Handling, Preparation and Consumption Behaviors Associated with Foodborne Diseases: 1995 and 1996 BRFSS Food-Safety Questions. MMWR 1998;47(SS-4):33-54.