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MICROBIAL CONTAMINATION OF SHELLFISH: Prevalence, Risk to Human Health, and Control Strategies

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ABSTRACT

There has been significant concern in recent times about the safety of molluscan shellfish for human consumption. Despite extensive efforts to assure a safe supply of molluscan shellfish, the number of cases of disease and death are still great enough to cause concern among the public. The number of cases of illness and death associated with the ingestion of shellfish falls in the lower end of the range of other similar microbial pathogen-related foodborne disease. Disease and deaths due to viruses and naturally occurring bacteria are now of greatest concern because they are the most often cited casusative agents. The greatest risk of disease or death due to shellfish consumption is among the population with underlying health conditions who choose to consume raw shellfish. Control strategies to limit shellfish-borne disease should focus upon disease and death caused by viruses and naturally occurring bacteria among at-risk populations.

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INTRODUCTION

Molluscan shellfish have held an important place in the diets of Americans since the birth of the United States. During colonial times, shellfish thrived in the estuarine environments and were a staple food. However, as the population grew and transportation systems improved, shellfish-borne disease also increased. Sewage discharges from population centers introduced a variety of human pathogens into coastal waters. Transportation improvements allowed shellfish to be introduced to inland markets, but the lack of adequate control during distribution resulted in reduced quality of shellfish upon arrival at the marketplace. It was not until the late 19th to early 20th century that public health agencies considered controls to reduce shellfish-borne disease (73). In February 1925, the Surgeon General arranged a conference with the Bureau of Chemistry (now the United States Food and Drug Administration) and the Bureau of Commercial Fisheries (now the National Marine Fisheries Service) to establish sanitary controls for the oyster industry. At this conference the agencies resolved to control "the beds on which shellfish are grown" and "the plants in which shellfish are shucked" (73).

Shellfish safety issues continue to revolve around these two categories: the quality of the waters in which shellfish are grown, and the conditions under which shellfish are harvested, processed, and distributed. Significant strides have been made in creating a safer food, but many problems nevertheless remain. We examine first the magnitude of the shellfish-borne disease in terms of its prevalence and the risks associated with shellfish consumption. We next address the issues of water quality, harvesting, processing, and distribution as they relate to shellfish-borne disease, and present strategies to minimize the risk of disease. Sanitary controls have focused upon edible bivalve mollusks, including oysters, clams, mussels, and scallops, of the class Pelecypoda since they are filter feeders and concentrate pathogens from the water (46). We therefore limit our discussion to these edible bivalves.

SHELLFISH-BORNE DISEASE RATES

The most comprehensive inventory of shellfish-related disease has been compiled by Scott Rippey of the Northeast Technical Services Unit (NETSU) of the US Food and Drug Administration (58). The Centers for Disease Control and Prevention (CDC) also maintain surveillance data on outbreaks of shellfish-borne disease (14, 58). While NETSU includes reports of outbreaks (two or more persons who become ill after consumption of a common food during a common time window) and individual cases, the CDC data base includes only outbreaks. Additionally, the CDC data are collected exclusively through submission of outbreak forms from state public health departments, whereas

the NETSU report is a compilation of both case and outbreak data reported in written form, most of which are confirmed verbally by the state public health directors. The NETSU data base is therefore more inclusive and precise than the CDC data base for bivalve molluscan shellfish disease and death rates.

The prevalence of shellfish-borne disease over the past ten years, the various disease agents or types of disease involved with disease, the type of shellfish, and the geographic regions from which the shellfish in question originated can all be determined from the NETSU data base. Examination of these data allows risk to be quantified and rates of disease and death to be compared with the rates of other ingestion-related diseases. Additionally, the data can identify areas of focus in formulating control strategies.

Although both the CDC and NETSU have compiled the best available data, only an estimated 5–10% of all cases of seafood-borne disease are actually reported (13). Findings by the Institute of Medicine on seafood safety indicate that it is possible to identify "the source of much of the acute illnesses associated with the consumption of seafood" but that the dimensions of the problem are very difficult to derive from the CDC and NETSU data bases (1). The NETSU data therefore probably reflect only a small percentage of the disease magnitude.

Prevalence

The NETSU data in Table 1 reveal that the largest number of disease cases are of unknown etiology. The greatest percentage of known death (95%) is caused by non-cholera vibrios. Non-cholera vibrios also account for the second highest number of cases of shellfish-borne disease. Norwalk, Norwalk-like viruses, and *Vibrio cholerae* are the second highest causative agents of disease. Of the various diseases caused by shellfish over the past 10 years, 86% were of unknown agents or were caused by non-cholera vibrios, Norwalk, Norwalk-like viruses, and *Vibrio cholerae*.

The next question of interest is what type of shellfish caused the majority of disease and death. Information in Table 2 shows that oysters account for the highest proportion of cases of disease (49%) and death (97%). Clams present the second major health hazard, and account for 38% of the cases of disease and 2% of the deaths. In some instances, illness is associated with the ingestion of more than one type of shellfish. Mixed consumption of shellfish accounts for 12% of the cases of disease and 1% of the deaths. Scallops and mussels account for 2% and 3%, respectively, of recorded cases of disease, although none of these cases resulted in death.

Establishing the geographic source of contaminated shellfish illustrates the distribution of shellfish disease and death. There are three designated coastal regions: East, the Atlantic states except Florida; Gulf, states bordering the Gulf

Table 1 Shellfish-borne disease: cases and deaths

Year	Cases	Deaths		Disease or agent										
				Non-Cholera Vibrio	Hepatitis A	Norwalk and Norwalk-like Viruses	Cholera	Salmonella	Shigella	Plesiomonas	Aeromonas	*E. coli*	Campylobacter	Unknown
1984	496	6	Cases	36	3	0	34	0	0	16	13	2	0	392
			Deaths	6	0	0	0	0	0	0	0	0	0	0
1985	238	7	Cases	22	0	3	14	0	0	0	0	0	0	199
			Deaths	7	0	0	0	0	0	0	0	0	0	0
1986	359	9	Cases	66	0	0	31	0	71	4	0	0	0	187
			Deaths	9	0	0	0	0	0	0	0	0	0	0
1987	118	12	Cases	47	0	0	11	0	0	2	0	0	0	58
			Deaths	12	0	0	0	0	0	0	0	0	0	0
1988	142	14	Cases	48	69	0	14	0	0	0	0	0	0	11
			Deaths	14	0	0	0	0	0	0	0	0	0	0
1989	858	9	Cases	52	22	270	14	4	1	0	0	0	5	490
			Deaths	7	0	0	[redacted]	0	0	0	0	0	0	0
1990	242	11	Cases	58	4	0	[redacted]	4	4	0	0	0	6	157
			Deaths	10	0	0	[redacted]	0	0	0	0	0	0	0
1991	33	4	Cases	22	0	0	5	0	0	0	0	0	0	6
			Deaths	4	0	0	0	0	0	0	0	0	0	0
1992	99	15	Cases	34	0	4	8	0	0	0	0	0	[redacted]	52
			Deaths	13	0	0	2	0	0	0	0	0	0	2
1993	210	9	Cases	21	0	156	0	0	0	1	0	0	0	32
			Deaths	9	0	0	0	0	0	0	0	0	0	0
TOTALS	2795	96	Cases	406	98	333	140	8	76	23	13	2	12	1573
			Deaths	91	0	0	4	0	0	0	0	0	0	1

Table 2 Shellfish-borne disease: types of shellfish and location of harvest

Year		Type of Shellfish						US Coastal region of harvest			
		Clams	Oysters	Scallops	Mussels	Multiple	Unknown	West	East	Gulf	Unknown
1984	Cases	265	206	0	0	25	0	3	239	99	155
	Deaths	0	6	0	0	0	0	0	0	1	5
1985	Cases	164	73	0	0	1	0	0	128	17	93
	Deaths	0	7	0	0	0	0	0	0	0	7
1986	Cases	65	292	0	0	2	0	0	82	100	177
	Deaths	0	9	0	0	0	0	0	0	1	8
1987	Cases	4	113	0	0	1	0	0	0	9	109
	Deaths	0	12	0	0	0	0	0	0	4	8
1988	Cases	1	136	0	0	5	0	5	3	66	68
	Deaths	0	14	0	0	0	0	0	0	9	5
1989	Cases	390	184	2	3	279	0	16	241	115	486
	Deaths	0	9	0	0	0	0	0	0	3	6
1990	Cases	159	70	0	0	3	10	1	1	36	204
	Deaths	0	11	0	0	0	0	0	0	11	0
1991	Cases	3	30	0	0	0	0	0	0	3	30
	Deaths	0	4	0	0	0	0	0	0	0	4
1992	Cases	24	74	0	0	1	0	13	0	32	54
	Deaths	2	12	0	0	1	0	0	0	2	13
1993	Cases	1	184	0	0	25	0	4	4	167	35
	Deaths	0	9	0	0	0	0	0	0	8	1
TOTALS	Cases	1076	1362	2	3	342	10	42	698	644	1411
	Deaths	2	93	0	0	1	0	0	0	39	57

of Mexico including Florida; and West, Pacific states. Shellfish harvested from waters along the Gulf Coast states accounted for 23% of all reported cases of shellfish-borne disease and 41% of resultant deaths during the ten-year period, 1984–1993. Twenty-five percent of all cases of shellfish-related disease originated from East Coast states, but had no associated deaths. Shellfish from West Coast waters yielded 5.5% of cases of disease with no associated deaths. The remaining cases (50%) resulted from shellfish in which the location of harvest could not be identified.

Shellfish from the East and Gulf Coasts are essentially equally likely to

cause disease. Most molluscan shellfish illnesses on the East Coast are from outbreaks associated with virally contaminated clams, whereas on the Gulf Coast they are due to individual cases involving oysters with non-cholera vibrios.

In general, the NETSU data indicate that in the late 1800s and early 1900s most outbreaks involved cases of typhoid or hepatitis resulting from sewage contamination of waters where shellfish was grown. From the late 1970s to the present, increased incidence of disease associated with non-cholera vibrios indicates a rapidly emerging problem with naturally occurring environmental pathogens (58). Rippey noted that while nearly 25% of all shellfish-borne disease outbreaks in the NETSU data were cases of typhoid fever, the last such recorded outbreak occurred in 1954 (58). Similarly, cases of hepatitis A associated with the consumption of shellfish have steadily decreased over the same time period, while cholera is sporadically reported. Beginning in the early 1980s, outbreaks associated with Norwalk and Norwalk-like viruses have increased. Many of cases of unknown agents reported during this time are similar in nature to symptoms associated with Norwalk and Norwalk-like viruses.

IDENTIFYING THE POPULATION AT RISK

Both the CDC and NETSU data show that of all the shellfish-borne disease agents, none produces heat-stabile toxins, and that all, except for possible human enteric viral agents in the unknown categories, are deactivated by varying degrees of heat under most conditions (9, 32). Research results suggest that a wider heat range is needed to kill viruses than bacteria (48, 54). Heating molluscan shellfish to an internal temperature of 85–90°C for one minute completely inactivates viruses (48) and thus eliminates risk due to viral or bacterial agents.

However, the preference of many people for raw shellfish poses the greatest risk from bacterial or viral agents. This risk is greatly enhanced in individuals with underlying health conditions and predisposes them to illness and/or prolonged illness and death. For most diseases caused by the consumption of raw shellfish, higher infection rates occur most frequently in immunocompromised hosts—patients who have neoplasia of the immune system, a hematopoietic disorder, liver disease or alcoholism, chronic renal failure, acquired immune deficiency syndrome, or who are receiving pharmacological immunosuppression for neoplasia or transplantation of an organ (6, 34). Additionally, the risk of infection is higher for patients with diabetes mellitus, individuals with naturally low levels of gastric acid, or those taking prescription or over-the-counter medication to reduce stomach acidity (6, 41). Individuals with hepatic disorders and iron metabolism dysfunction are at much higher risk of progres-

sive *Vibrio vulnificus* infection, often resulting in death (64). The elderly, the debilitated, the malnourished, and young children also are more susceptible to disease and death from the ingestion of raw shellfish (6).

Since the risk is highest for consumers of raw or partially cooked shellfish, this specific population should be defined. However, there are no national statistics to provide this information (21, 72). The best estimate of raw shellfish consumption is obtained from surveys performed in Virginia and Florida. A 1992 Commonwealth Poll estimated approximately 850,000 raw shellfish consumers in the State of Virginia [18% of the population aged 18 or older] (37). The 1988 Florida Behavioral Risk Factor Survey estimated that approximately 3 million adults in Florida consume raw oysters [23% of the population aged 18 or older] (23). Large numbers of people are thus at risk of disease and death via raw oyster consumption in both Virginia and Florida. It is not known how these rates of consumption in Virginia and Florida translate to other areas of the country. However, it can be assumed that the consumption of raw molluscan shellfish is more popular in coastal areas of the East Coast than in inland states, based upon an informal survey of local sales of shellstock oysters (74).

Of the estimated 850,000 raw shellfish consumers in Virginia, 93,000 (11%) have at least one high-risk characteristic: liver disease, stomach disorders, diabetes, immune system disorder, or immune suppressant drug therapy. In Florida, 71,000 (2.5%) of these raw oyster eaters have liver disease, a high-risk characteristic (23). The larger number of at-risk raw shellfish consumers in Virginia is likely to be partially due to the more inclusive definition of who is considered to be at risk.

Table 3 indicates that the relative risk for raw oyster eaters with liver disease in Florida of contracting a *Vibrio vulnificus* infection is approximately 92 times greater than for a raw oyster eater without liver disease, and 120 times greater than for a nonraw oyster eater. The relative risk of death for a raw oyster eater with liver disease in Florida is 190 times greater than for a raw oyster eater without liver disease and 345 times greater than for a nonraw oyster eater. In Virginia, the relative risk of contracting a *Vibrio vulnificus* infection is approximately 13 times greater for a raw oyster eater with at least one high-risk condition than for a raw oyster eater without any high-risk conditions, and 60 times greater than for a nonraw oyster eater.

Non-cholera vibrios, Norwalk, Norwalk-like viruses, and *Vibrio cholerae*, are the top three shellfish disease-causing agents, respectively. Non-cholera vibrios and *Vibrio cholerae* occur naturally throughout the marine environment within US coastal waters (28, 38, 50, 68–70). Norwalk virus is associated with human fecal contamination either in the shellfish-growing waters or through postharvesting contamination (27, 55). The remaining diseases identified with the ingestion of molluscan shellfish are associated with fecal pollution of the marine environment or with postharvesting contamination during processing

Table 3 Relative risk data; Florida and Virginia

Florida 1981–1993*	
Nonraw oyster eaters	
.6 illnesses/1 million adults	(95% C.I. .57–.64)
.131 deaths/1 million adults	(95% C.I. .124–.139)
Raw oyster eaters	
.8 illnesses/1 million adults	(95% C.I. .7–1)
.236 deaths/1 million adults	(95% C.I. .196–.297)
Raw oyster eaters with liver disease	
74.1 illnesses/1 million adults	(95% C.I. 37.8–215.9)
45.3 deaths/1 million adults	(95% C.I. 23.1–1320.7)
Virginia 1974–1993	
Nonraw oyster eaters	
.483 illnesses/1 million adults	(95% C.I. .466–.502)
.0402 deaths/1 million adults	(95% C.I. .0380–.043)
Raw oyster eaters	
2.2 illnesses/1 million adults	(95% C.I. 2.03–2.40)
.191 deaths/1 million adults	(5% C.I. .176–.208)
Raw oyster eaters with at least one high-risk characteristic	
28.9 illnesses/1 million adults	(95% C.I. 25.4–133.6)
2.51 deaths/1 million adults	(95% C.I. 2.15–62.86)

**Source:* GW Hlady (30).

(55, 73). Enteric pathogens account for 80% of reported shellfish-borne disease. Naturally occurring bacteria account for 20% of shellfish-borne disease but 99% of the deaths. Therefore, enteric pathogens pose a greater risk of disease through the ingestion of raw or partially cooked molluscan shellfish, whereas naturally occurring bacteria pose a greater risk of death.

The number of cases of microbial pathogen-related food-borne disease, calculated from CDC data, for all age groups reveals that the rate of disease is ~36 cases per 100,000 per year for the period from 1983 through 1987 (12). The prevalence of microbial pathogen-related shellfish-borne disease, calculated from the NETSU data for the same period, was ~9 cases per 100,000 (58). Prevalence rates for other ingestion-related diseases such as amebiasis, botulism, hepatitis A, salmonellosis, and shigellosis are described in Table 4. The data indicate that shellfish-borne disease is exceptionally low in relation to other similar diseases with the exception of botulism. The death rates for shellfish-borne disease are not significantly different from those for amebiasis

Table 4 Disease and death rates per 100,000 for shellfish-borne and related diseases 1983–1991, 1992.

	Shellfish-borne disease	Amebiasis	Botulism	Hepatitis A	Salmonellosis	Shigellosis
Disease rate per 100,000 1983–92	.127	1.74	.047	11.79	20.91	10.26
Death rate per 100,000 1983–1991	.0043	.0035	.011	.031	.036	.0043

and shigellosis. The death rate for botulism is significantly less, while the rates for hepatitis A and salmonellosis are significantly greater ($p \leq .01$). The death rate for shellfish-borne disease falls in the middle of the range of death rates identified for the diseases.

CONTROL STRATEGIES

Food safety is a value judgment of how much risk an individual or a community is willing to accept (5, 42). Of the food groups implicated in outbreaks of food-borne illness in the U.S. from 1977–84, seafood was most frequently associated with disease (~25%) (2, 15). Of these cases, 28% were related to shellfish, and of these, 22% were associated with a bacterial or viral agent (4). Control strategies to minimize shellfish-borne disease associated with viruses or bacteria could reduce food-borne disease in the U.S. by more than 6%.

Naturally Occurring Pathogens

The naturally occurring pathogens of concern that cause shellfish-borne disease are those of the family *Vibrionaceae*, *Plesiomonas shigelloides* and *Aeromonas hydrophilia*. These organisms vary seasonally (i.e. temperature sensitivity) and geographically (i.e. salinity sensitivity) in the marine environment.

Bacteria from the family *Vibrionaceae* cause the majority of identifiable illness and death from shellfish consumption. Patterns in their environmental distribution may provide a basis upon which to develop an effective disease control strategy. The species of this family associated with shellfish-borne disease are *Vibrio cholerae*, *V. vulnificus*, *V. parahaemolyticus*, *V. mimicus*, *V. hollisae*, and *V. furnissi*.

Toxigenic strains of *V. cholerae* are of public health concern. These strains of *V. cholerae*, identified by two groupings, serotype 01 and non-01, are found in greater concentrations during the warmer months of the year, with significantly higher incidence of disease occurring during this same time period (44).

Both strains of *V. cholerae* are adapted to waters with lower salinities (4 ppt to 17 ppt) (3, 61).

Vibrio parahaemolyticus has been found in marine environments in higher concentrations during warm weather periods (29, 53). This organism exists in the upper-salinity regimes of the marine environment (18).

A number of studies indicate a strong correlation between temperature, salinity, and the presence of *V. vulnificus* in seawater and oysters (36, 39, 51, 52). Although *V. vulnificus* has been isolated from waters with a wide range of temperatures and salinity, the highest concentrations of the organism are more frequently isolated from waters with temperatures of 17° to 31°C and salinities of 15 ppt to 25 ppt (52). Tamplin's study found significant associations ($p \leq 0.0001$) between salinities from 10 ppt to 20 ppt and numbers of *V. vulnificus* organisms (66). Additionally, there were high populations of *V. vulnificus* when water temperatures increased from 20° to 30°C (66).

The influence of temperature on the geographic distribution of *V. vulnificus* in the U.S. can easily be observed. Tamplin's study shows that the lowest concentrations of *V. vulnificus* for all sample sites in the United States (<100 MPN/g) occur in northern East Coast waters and all West Coast waters (66). Concentrations of *V. vulnificus* in oysters increased from Virginia south to Texas, with oysters from Texas sometimes exceeding 1 million MPN/g (66). Tamplin derived a predictive model predicated on the data from this study that estimates concentrations of *V. vulnificus* based upon temperature and salinity levels in specific geographic areas (65).

Tamplin's research examined the concentrations of virulent (opaque) and weakly virulent (translucent) strains of *V. vulnificus* at various sample sites in the Gulf of Mexico throughout a two-year period. The mean concentrations of virulent strains of *V. vulnificus* in oysters were 56.57 MPN/g (S.D. 214.21) during cold weather months (November to March), while during warm weather months (April to October) the concentrations were 7204.76 MPN/g (S.D. 34810.87) (66). Concentrations of weakly virulent strains during cold weather months were .289 MPN/g (S.D. 0.269), and during warm weather months they were 79.81 MPN/g (S.D. 246.10) (66). There is a significant ($p \leq .05$) increase in the number of virulent strains of *V. vulnificus* during periods of warm weather. Furthermore, there is also a significant increase in weakly virulent strains in warm weather. It may be possible to use the concept of seasonal or geographical distribution of strains and variable degrees of pathogenicity as a basis for identifying harvest areas that pose the greatest risk to consumers of infections from *V. vulnificus* (65).

Concentrations of *V. mimicus* vary seasonally, with higher concentrations present during warm weather periods (18). The organism persists in a wide range of salinities, but prefers salinities common to brackish water environments (7, 18).

The seasonal distribution and ecology of *V. hollisae* is not well understood because the organism is difficult to isolate (55). *V. furnissi* is found in greater concentrations during periods of warm weather, as are the other pathogenic members of the family *Vibrionaceae*. This organism has been isolated from a wide variety of salinities, ranging from fresh to brackish water environments (59).

Both *P. shigelloides* and *Aeromonas hydrophilia*, like some *Vibrionaceae*, are found ubiquitously in both fresh and saltwater environments. Both organisms exhibit higher natural concentrations in water during warm weather conditions (75).

Concentrations of naturally occurring pathogenic bacteria are distributed in the shellfish-growing coastal environments based upon temperature and salinity. These pathogens are distributed over a wide range of salinities with different genera and species thriving in relatively narrow ranges. Common to all of these pathogens is their increase in numbers with temperature. Since there is a definite relationship between temperature and the concentrations of these organisms in the environment, a twofold strategy to reduce death and disease is suggested. The first would limit harvesting of molluscan shellfish to cold weather months (November to March) in areas where these pathogens are known to exist in significant concentrations. This restriction would, in turn, necessitate an extensive monitoring program to determine when harvesting could be permitted.

Salinity preferences vary; many pathogens are able to grow throughout a wide range. Furthermore, salinities change constantly in the shellfish-growing environment. Thus a strategy to limit harvest based upon salinity alone, although possible, would be difficult to implement effectively.

The Institute of Medicine Food and Nutrition Board's Committee on Evaluation of the Safety of Fishery Products suggests that shellfish-growing waters be monitored during periods of warm weather for *Vibrio* species and that other means be investigated and implemented to eliminate or reduce the potential for disease from naturally occurring pathogenic bacteria through the ingestion of molluscan shellfish (1). Monitoring shellfish-growing areas for *Vibrio* species would not be a feasible proposition for public health agencies. More promising is a harvest-control strategy supported by a validated geographic model that predicts concentrations of *V. vulnificus* based upon temperature and salinity. If this model could be coupled with data on the identification and ecology of virulent strains, it would be possible to predict when harvesting areas should be closed to minimize risk. Such a model would work well for steady state conditions. However, the typically large fluctuations of salinity and temperature over small periods of time in estuarine environments would limit its usefulness, and alternative strategies would be needed.

The second component of this disease-reduction strategy—consumer education—holds greater potential for success. Individuals who consume raw

shellfish, especially those with underlying risk factors, should be adequately apprised of the risks by health care providers and warnings should be posted at establishments where shellfish is purchased and/or consumed (76). In most instances the health care providers are the first to discover that an individual has an underlying risk factor, and should therefore be made aware of the importance of informing these patients that their condition requires abstinence from raw or partially cooked molluscan shellfish in order to avoid serious illness or possible death. If an individual is unaware of the personal risk, a health warning attached to the shellfish package or posted at the establishment where shellfish is sold will not prevent consumption.

Public warning notices should be provided both by health care providers and at the point of sale. Point of sale warnings should alert consumers to the increased risk of infection associated with the consumption of raw molluscan shellfish if they have neoplasia of the immune system, a hematopoietic disorder, liver disease or alcoholism, chronic renal failure, or acquired immune deficiency syndrome (34, 41). Also included are patients receiving pharmacological immunosuppression for neoplasia or transplantation of an organ or diabetes mellitus, individuals with naturally low levels of gastric acid, and those taking prescription or over-the-counter medication to reduce stomach acidity. Any warning system, to be effective, must contain language that clearly conveys potential risk and should be posted at all points of sale of molluscan shellfish if it is to reduce the incidence of disease and death.

Cooking the oyster to an internal temperature of 85–90°C will destroy both viruses and bacteria of public health concern in molluscan shellfish. Control strategy would require that consumers be advised to cook oysters during periods of warm weather.

Enteric Bacteria Associated with Contamination

Enteric bacteria and viruses can also contaminate shellfish either in the growing waters or during harvesting, processing, and distribution. Pathogens of concern that have been associated with disease from consumption of contaminated molluscan shellfish include human enteric viruses; hepatitis A, non-A, non-B enteral hepatitis (hepatitis E), unclassified viruses; and such bacteria as *Salmonella, Shigella, Camplyobacter jejuni*, and pathogenic *Escherichia coli* (14, 55, 58). The group of unclassified viruses includes the Norwalk, Norwalk-like virus, Snow Mountain agent, and small round structured virus. Although human viruses are inert outside of their host and therefore do not multiply in other organisms, they are resilient and persistent in the environment and in molluscan shellfish (22, 24, 47, 54). These viral and bacterial enteric pathogens are of public health concern because of their link with disease caused by fecal contamination of the waters from which molluscan shellfish are harvested and of the environment in which they are processed (12, 14, 17, 31, 54, 56).

Other pathogenic bacteria (*E. coli, Yersinia enterolytica, Listeria monocytogenes, Clostridium botulinum*, and *Staphylococcus aureus*) that are not exclusively of enteric origin can also potentially contaminate molluscan shellfish, both in their natural environment and through processing and distribution (45).

Prevention of shellfish-borne disease caused by these enteric related pathogens should focus upon strategies to increase sensitivity in detecting contamination of shellfish, avert the entry of pathogens into areas open to shellfish harvesting, and eliminate pathways by which pathogens could contaminate shellfish through their harvesting, processing, and distribution. A National Indicator Study sponsored by the National Oceanic and Atmospheric Administration is currently under way to identify better indicators of fecal pollution than either total or fecal coliforms (49). This study seeks to identify an organism or series of organisms that will provide a more specific mechanism to detect polluted shellfish-growing areas. Total or fecal coliforms are limited as indicators because they cannot be correlated with the presence of enteric viruses (25, 33). This limitation is especially important in light of the significant 10-year increase in viral enteric shellfish-borne disease (14, 56). Fecal coliforms do not differentiate well between human and nonhuman pollution sources (63). Once the best available indicator(s) is identified, the regulatory community should implement a classification system of shellfish-growing areas based upon such indicator(s).

The United States Food and Drug Administration has proposed to mandate a quality assurance program to regulate molluscan shellfish safety based on the Hazard Analysis Critical Control Point (HACCP) concept (71). Currently, the molluscan shellfish industry is regulated by the National Shellfish Sanitation Program. Although this voluntary framework has been effective, the adoption of a HACCP-based program will provide a system of preventive controls and corrective actions to be implemented by molluscan shellfish processors and handlers and monitored by regulators to insure that conditions under which shellfish are harvested, processed, and distributed minimize the risk from contaminated shellfish reaching the consumer.

A recent outbreak of shellfish-borne disease—oyster-related Norwalk-like virus gastroenteritis—occurred in November 1993, and was associated with fecal contamination from fishing boats (16). This incident suggests that similar sporadic cases of pollution, which are very difficult if not impossible to trace, could potentially have been responsible for some of the many unidentifiable cases of shellfish-borne disease. Comprehensive education for users of the waterways on the importance of proper sewage disposal and imposition of stiff penalties for improper disposal of fecal material could reduce such sporadic discharges into approved shellfish harvest waters.

Likewise, harvest areas adjacent to sewage treatment facilities with point

source discharges should be more closely evaluated, especially for the presence of viruses. Conventional sewage treatment facilities do not reduce numbers of enteric viruses in their discharges to low concentrations (40, 43). Outbreaks of disease associated with Norwalk virus have increased, and many cases where the agent is unknown are similar to those associated with this virus (58). Areas that receive discharges from a sewage treatment facility and that also support resources of molluscan shellfish that have been approved for harvesting must be carefully evaluated for the presence of viruses. Improvement in the technology of sewage treatment is needed to eliminate viruses in these areas.

Oysters have a persistent microbial flora in the gut region. Controlled purification involves the supervised processes of depuration and relaying. Depuration requires placing of molluscan shellfish in recirculating seawater tanks where the water is continuously disinfected. The circulation of water in these tanks stimulates molluscan shellfish to feed, which thus facilitates defecation of the bacteria and viruses populating the gut into the tank water, where they are inactivated by disinfection. Under most holding conditions, this depuration process does not successfully remove *V. vulnificus* or lower concentrations of enteroviruses in shellfish (26, 43, 57, 67). Depuration will not produce oysters free of *V. vulnificus* or viruses and therefore will not predictably reduce the risk of disease or death.

Relaying is the transfer of molluscan shellfish from contaminated growing areas to approved areas (i.e. with no contamination) so that the gut will be naturally purged of pathogenic organisms. This strategy has been shown to be effective in reducing total numbers of organisms in shellfish (10, 11, 62). *V. vulnificius* as part of the natural microflora of the gut of oysters does not depurate in an artifical environment. Since relaying can be thought of as depuration in the natural environment, the elimination of *V. vulnificius* through this process has not been considered to be effective. However, recent research suggests that in the natural environment, if the waters to which the shellfish are to be relayed are free of *Vibrio vulnificus*, the numbers of these organisms will be reduced over time in cold water conditions (35).

Irradiation has been proposed as a means of killing or inactivating the *V. vulnificus* organism without killing the oyster. The United States Food and Drug Administration and the United Nation's World Health Organization have determined that there is no health risk associated with foods irradiated by approved commercial procedures (20). However, the FDA has yet to approve commercial irradiation procedures for shellfish. The potential for such approval appears encouraging; Dr. George Hoskin, associate director of FDA's Office of Seafood, described the process as "promising for control of pathogens including vibrios" (60).

Processes such as rapid chilling and mild heat treatment of oysters can

limit the growth of *V. vulnificus*—and actually reduce its concentration over time—in oysters that are not shucked (8, 19). The National Shellfish Sanitation Program has taken the first step toward implementation of strict time-temperature controls, which are technologically feasible and attainable. However, these measures fall short of what will reduce or limit the growth of the organism. Intensive rapid chilling, cold storage, and heat treatment (which does not change the protein nature of the shellfish) can significantly reduce *V. vulnificus*. Thermal processing is also lethal to several other pathogens. Both processes are not an inclusive control strategy for all pathogens of concern.

The most effective control strategy would be to ban the sale of raw molluscan shellfish either totally or at food service facilities, although this proscription would not eliminate consumption resulting from the recreational harvest or from illegal sales. However, such an extreme measure is unlikely for political reasons, and it would be virtually impossible to adequately enforce. To estimate the risk reduction, it would be necessary to calculate the magnitude of the illegal market and recreational catch and the risk factors of those who would consume such product.

Strategies to control shellfish-borne disease should focus upon illness caused by bacteria of the family *Vibrionaceae* and upon viral illness since the majority of cases and deaths (86%) are a result of these agents. The strategies that have been outlined focus upon minimizing all types of shellfish-borne disease with an emphasis upon maximizing the reduction of risk from *Vibrionaceae* and viral disease and death. If these strategies are fully implemented, the risk of shellfish-borne disease and death can be significantly reduced.

The disease and death rates from eating raw shellfish are small in relation to other similar risks and consumers appear willing to bear this risk in order to enjoy the food. However, steps can be taken to increase the safety of raw shellfish, and consumers should be warned of the risks. The control strategies presented here provide various levels of potential risk reduction. A determination of which strategies to use should be based upon the level of risk that is considered acceptable, the costs to the shellfish industry, and the costs to the consuming public (in deaths and disease). Risk can be eliminated by prohibiting the consumption of raw or partially cooked shellfish. If lesser reductions of risk are desired, consumer education, seasonal harvest restrictions, strict time-temperature controls, changes in indicator organisms, and the inclusion of viruses in evaluation of shellfish growing areas can be selected.

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