

National Education Program to Influence Consumption Behavior of High-Risk Individuals Regarding Raw Molluscan Shellfish - Phase III Final Report

I. Abstract

Since 1996, the National Marine Fisheries Service (NMFS) Saltonstall-Kennedy Grants Program has funded the Interstate Shellfish Sanitation Conference (ISSC) to conduct educational programs aimed at reducing illness from *Vibrio vulnificus* infection. This grant, *A National Education Program to Influence Consumption Behavior of High-Risk Individuals Regarding Raw Molluscan Shellfish-Phase III*, is the third in a multi-part effort to develop educational strategies, materials and partnerships to realize this goal.

Until recently, *V. vulnificus* disease reduction efforts were voluntary and carried out primarily by the ISSC. In July 2001, however, the ISSC formally adopted Issue 00-201 with confirmation by the U.S. Food and Drug Administration (FDA). The National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish now requires states to develop and implement a *Vibrio vulnificus Risk Management Plan* if there are two or three *V. vulnificus* cases associated with raw or undercooked oysters originating from the waters of that state.

The collective goal of these risk management plans is to reduce rates of *V. vulnificus* illness by 40 percent for 2005-2006, and 60 percent for 2007–2008. Illness reduction rates will be determined using case reports collected by FDA's Southeast Regional Office. Issue 00-201 also identifies the regulatory consequences should core states' efforts fail to meet these illness reduction goals. These new guidelines prompt states to implement effective education and prevention measures to avoid regulatory actions which would significantly affect the shellfish industry.

Since the passage of Issue 00-201, four states have developed *Vibrio vulnificus Risk Management Plans*: Florida, Texas, Louisiana, and Alabama. The NSSP Guide requires that all risk reduction plans include consumer education programs targeting consumers at increased risk of *V. vulnificus* infection. During Phase III, the ISSC

provided financial and technical assistance to states required to develop risk management plans. The ISSC assisted these states, along with California and Mississippi, in designing education programs, selecting priority audiences, and linking media activities to these audiences. The ISSC also supplied informational materials to many other state and federal agencies.

During Phase III, the ISSC developed several new educational materials (e.g., a video press kit, a consumer brochure in Spanish, and several articles for high-risk audiences, and a health care provider kit) and updated others (e.g., the consumer brochure and physician fact sheet). In addition to material development and dissemination, the ISSC furthered collaboration with voluntary organizations serving those at risk, such as the American Liver Foundation (ALF). The ALF's relationship to Veteran Administration hospitals and Hispanic community groups opened new doors to reaching high-risk communities.

A survey of raw oyster consumers was among Phase III's most important accomplishments. Issue 00-201 charged the ISSC's Vibrio Management Committee with evaluating state educational efforts using a consumer survey. Members of the ISSC's *Vibrio vulnificus* Education Subcommittee drafted the questionnaire. The ISSC contracted Clearwater Research Inc. to collect and analyze the data. This information serves as a baseline measure of consumer awareness, attitudes and behavior. It also provides a basis for assessing changes in consumer knowledge and behavior over the next several years.

Over the course of this project, the ISSC implemented six principal interventions:

1. Surveyed raw oyster consumers to establish their current risk awareness and behavior;
2. Developed partnerships with organizations with direct links to persons at risk;
3. Disseminated consumer brochures and fact sheets to agencies and individuals involved in *V. vulnificus* education;
4. Provided funds for core and other states to conduct educational activities;

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5. Inserted articles on *V. vulnificus* in magazines or other media reaching those at high-risk; and
 6. Developed and disseminated *V. vulnificus* press kits to all ABC, NBC, CBS, and FOX media outlets in three core states.

II. Executive Summary

In 1996, the National Marine Fisheries Service (NMFS) Saltonstall-Kennedy Grants Program funded the first ISSC educational effort to reduce illness and death from *V. vulnificus* bacterial infection. The current grant, *A National Education Program to Influence Consumption Behavior of High-Risk Individuals Regarding Raw Molluscan Shellfish-Phase III*, is the third program to reduce illness by educating those at risk.

During Phase I, the *Vibrio vulnificus Model Education Campaign*, the ISSC developed and disseminated new educational materials to state health departments and healthcare providers. This project sought to reach high-risk individuals through doctors, nurses, and nutritionists. During Phase II, the ISSC tried an alternative approach—disseminating materials primarily through organizations serving those at risk. Through collaborations with groups like the American Liver Foundation, the ISSC utilized existing organizational networks (such as newsletters, conferences and providers) to reach high-risk individuals with prevention messages. During Phase II, the ISSC also produced the first analysis of ten years of illness data collected by the FDA. The data linked the majority of *V. vulnificus* cases to product from a few states in the Gulf of Mexico. This realization shifted the project's emphasis away from a broad, national educational effort, to a focus on oyster-producing states in the Gulf.

Phase III coincided with the passage of ISSC Issue 00-201, requiring certain states to implement *V. vulnificus* education programs and making disease reduction activity mandatory for several states. Consequently, the ISSC became more involved in supporting state education efforts. To this end, the project provided additional financial, technical, and material resources to the Gulf States and California.

In the course of Phase III, the ISSC developed several new educational materials. They included a video press kit, a consumer brochure in Spanish, several articles for high-risk audiences, and an educational video for health care providers. The project also revised earlier materials, such as the English consumer brochure and physician fact sheet. In addition to material development, the ISSC continued to collaborate with agencies serving those at risk, such as the American Liver Foundation.

The survey of raw oyster consumers was Phase III's major undertaking. Since Issue 00-201 required that state education programs be evaluated using survey data, the ISSC developed this survey and contracted Clearwater Research, Incorporated to collect the data. These data statistically capture current consumer beliefs and behaviors and will enable states to measure the impact of educational efforts in the years ahead.

III. Project Purpose

The ISSC developed this consumer education project to reduce the number of illnesses and deaths resulting from consumption of raw molluscan shellfish containing *V. vulnificus*. Millions of Americans have liver disease, diabetes, weakened immune systems or other risk factors for *V. vulnificus* infection, yet few are aware of the risks of eating raw shellfish. While increased awareness is the first step toward behavior change, the project's ultimate purpose is to persuade those at risk to stop consuming untreated raw oysters.

Extent of the Problem

While millions of people eat raw shellfish with no ill effects, each year about 30 people report serious illness from *V. vulnificus*. About half of those who become seriously ill die. Individuals with liver disorders, diabetes and those with weakened immune systems are at highest risk for infection, illness, and death.

Vibrio vulnificus is a bacterium that can cause severe illness or death in health-compromised people who eat raw shellfish, particularly oysters. Between 1989 and 2000, the FDA collected 282 reports on *V. vulnificus* illnesses. About half of these cases

resulted in death. Because of the limitations of *V. vulnificus* reporting, the U.S. Centers for Disease Control and Prevention (CDC) considers these numbers to comprise only twenty percent of the actual cases.

V. vulnificus is a naturally occurring bacterium commonly found in coastal waters. It is not the result of pollution and can be found in waters approved for shellfish harvesting. *V. vulnificus* does not change the taste, appearance, or odor of shellfish. Although it is widespread in coastal waters, research shows that these bacteria are most abundant during the warm weather months of April through October.

V. vulnificus usually has little effect on healthy individuals, although diarrhea, nausea, vomiting, abdominal cramps, and fever have occasionally been reported. Certain health conditions, however, greatly increase an individual's vulnerability to illness. These conditions include liver disorders, alcoholism, diabetes, gastric disorders, hemochromatosis, AIDS/HIV and any condition or medication that compromises the immune system.

Infection in vulnerable individuals usually occurs within 24 hours after eating raw or undercooked shellfish. These infections progress rapidly to primary septicemia, which results in a fifty percent mortality rate. Because *V. vulnificus* infection in those at risk can result in death within two days, it must be promptly diagnosed and aggressively treated. For those at risk, prevention is the best medicine. Vulnerable individuals should never eat raw shellfish. If they eat shellfish, it must be thoroughly cooked or treated with an effective post-harvest process. Proper cooking, or post-harvest treatment, destroy the bacteria and eliminate the risk of infection.

IV. Project Objectives

Phase III sought to increase awareness and prevent illness among those at risk of from *V. vulnificus*. The ISSC *Vibrio vulnificus* Education Subcommittee has established a 24-month goal to: 1) Increase high-risk consumer awareness of the risks of eating raw shellfish thirty percent above baseline levels; and, 2) Increase the proportion of high-risk consumers who refrain from eating raw oysters for health reasons by fifteen percent.

The consumer survey provides a starting point for measuring changes over the next several years.

By educating those at risk, the project contributes to other *V. vulnificus* prevention efforts, such as post-harvest refrigeration and treatment. Preventing illness and death from *V. vulnificus* infection is the shared goal of all these efforts.

V. Project Approach

The project conducted six principal interventions which are discussed in detail below.

1. Establish baseline consumer awareness and behavior levels.

The purpose of the survey was to quantify consumer knowledge about *V. vulnificus* and its prevention before source states began implementing educational activities.

Specifically, the baseline survey provides a snapshot of:

1. Consumer knowledge that eating raw oysters can be dangerous for people with certain health conditions;
2. High-risk consumer knowledge that eating raw oysters can be dangerous to people with specific health conditions;
3. Consumer exposure to prevention messages delivered by television, radio, health care providers, etc.
4. Changes in raw oyster consumption, especially among those at risk, 24-months after the initial survey.

Shifts in consumer knowledge, concerns about illness and raw oyster consumption all reflect the effectiveness of educational efforts. Since behavior change is a gradual process, survey data is especially valuable because it can capture a *range* of changes. This information is a better measurement than counts of *V. vulnificus* cases alone. Survey data reflect progress toward preventing illness. With prevention in mind, Issue 00-201 defined the success criteria for state education activities as:

1. Among raw oyster consumers, increase awareness of risk by forty percent;
2. Among at-risk raw oyster consumers, reduce high-risk behavior by fifteen percent.

V. vulnificus Education Subcommittee members drafted a series of questions for the survey. The entire Subcommittee reviewed and approved the final survey before including it in a request for bids sent to five survey research firms. In July 2001, the contract was awarded to Clearwater Research, Incorporated.

By January 2002, Clearwater had telephoned over 62,000 households in four states-- California, Louisiana, Florida, and Texas. By February, Clearwater had completed 1,975 interviews with raw oyster consumers. This was below the anticipated 4,800 completed interviews. Clearwater contended that it had underestimated the number of calls necessary to complete a single interview.

Key Survey Findings

A large proportion of all respondents (38 percent) reported eating oysters less often over the past year. The difference between states was noteworthy, with 39 percent of respondents in California & Texas reporting eating oysters less frequently, compared to 30 percent of Florida & Louisiana respondents.

Health concerns (26 percent) and availability (26 percent) were most frequently cited for decreased oyster consumption. In individual states, however, the impact of health concerns on consumption ranged from a low of 22 percent in California to a high of 46 percent in Florida.

More than any other group, individuals with liver disease reported decreasing consumption of raw oysters for health reasons (58 percent). A large proportion of other immunocompromised persons (44 percent) also reported eating raw oysters less often because of health concerns.

About half of all respondents (51 percent) felt “somewhat” to “very concerned” about raw oysters and their health. Some 15 percent were “very concerned”, 36 percent “somewhat concerned”, and 48 percent “not at all concerned”.

Respondents with liver disease or weakened immune systems were more than twice as likely to be “very concerned” about raw oysters and their health. Some 34 percent of those with liver disease and 40 percent of the immuno-compromised reported being “very concerned”. Only 24 percent of those with weak immune systems reported being “not at all concerned”.

Most respondents had taken no action to reduce their risk of illness. A few reported eating fewer oysters, some now eat only cooked oysters. Consumer responses also suggest confusion about when oysters are “in-season” and presumably safe.

Two-thirds of those with liver disease or weakened immunity (66 percent) mentioned their provider as their source of information on raw oysters and risk. This compares with just 16 percent of diabetics and 26 percent of all respondents.

Respondents frequently cited mass media (newspapers, 49 percent; television, 40 percent; and magazines, 41 percent) as sources of information on raw oysters and risk. Radio was mentioned much less often (16 percent).

About a third (32 percent) of all respondents also mentioned “posted notices” as a source of information on risk. This proportion varied greatly by state, ranging from just 25 percent in Texas to 48 percent in Florida.

About half (47 percent) of all respondents reported that it had been a year or more since they had heard/read about the risk of eating raw oysters. More respondents from Florida and Louisiana (40 percent) had heard or read about this issue in the last six months than those in California or Texas (29 percent).

A table of responses for all respondents and each state are summarized in Attachment A.

2. Earmark funds for core states to use in conducting *V. vulnificus* education activities.

Phase III allocated \$100,000 to support educational activities in source states and California. The dollars complement funding provided by FDA’s Gulf of Mexico Program (GOMP) and the National Sea Grant Program. Core states needed new funding to conduct mandatory *V. vulnificus* prevention activities. The ISSC also provided technical assistance and guidance to states interested in applying for these funds.

State risk management plans were required to satisfy core state educational criteria defined by the Vibrio Management Committee. Florida, Alabama, Texas, Louisiana, Mississippi, and California all have submitted work plans to the ISSC. As of June 1, the

ISSC has finalized contracts with Florida and Louisiana and is providing non-contractual assistance to several other states.

3. Develop partnerships with organizations with direct links to persons at risk.

By collaborating with the National Office of the American Liver Foundation (ALF), the ISSC reached over 50,000 vulnerable individuals via direct mail. The ALF's National Office operates a 24-hour telephone hotline to respond to callers' questions about liver disease. Through this operation, the ALF has sent over 20,000 brochures to these callers. The ALF also included an article on *V. vulnificus* and liver disease in their newsletter *Progress* reaching about 35,000 high-risk households. At its medical advisory committee meeting, the ALF also provided ISSC fact sheets to 3,000 participating physicians, gastro-enterologists and other health care providers.

The **American Liver Foundation, Gulf Coast Chapter** recently completed their second contract with the ISSC. The ALF has reached thousands of Gulf Coast residents who have liver disease with information about the risks of eating raw oysters. The Gulf Coast Chapter conducted an intensive information campaign to reach veterans, supplying six Veteran Administration hospitals with brochures, conducting mailings to 127 veteran's organizations and publishing an article on *V. vulnificus* prevention in the *Veterans' Post Newsletter*. By including the ISSC brochure in their quarterly chapter newsletter, the ALF reached another 2,500 households—in addition to distributing thousands of brochures to liver transplant centers, local health departments, and Hispanic community groups.

In December, the San Diego Chapter completed their second contract with the ISSC. The Chapter distributed 4,500 consumer brochures in their fall newsletter and distributed another 700 brochures to local liver disease support groups. The ALF continued supplying brochures to two local transplant centers--the San Diego Veterans' Administration Medical Center and the Balboa Medical Center. Through community health fairs and local events like the "California Liverwalk", the ALF reached another 500 community members. The ALF also disseminated over 500 ISSC brochures through

the San Diego Veteran’s Council and associated Veteran organizations including the Disabled Vets, American Legion, and Veterans of Foreign Wars.

4. Disseminate consumer brochures & fact sheets to agencies and individuals interested/involved in *Vv* education.

With input from the *Vibrio vulnificus* Education Subcommittee, the ISSC revised both the consumer brochure and fact sheet for health care providers. The brochure now speaks to the target audience on the cover, with the headline “The Risk of Eating Raw Oysters: Advice for persons with liver disease, diabetes or weakened immune systems”. Both the brochure and fact sheet now feature the American Liver Foundation’s logo and endorsement, giving these materials added credibility. The attractive new design and colors draw attention and interest. The ISSC also created a Spanish version of the consumer brochure. The Spanish brochures are particularly useful in states with large Hispanic populations, such as Florida, Texas, and California.

During Phase III, the ISSC fulfilled requests for a total of 110,290 brochures in English and 51,250 in Spanish, and 17,800 fact sheets. Material requests have come predominantly from state agencies (57 percent); followed by federal agencies (14 percent), partner organizations (23 percent) and industry (2 percent). This distribution pattern is entirely different from that in Phase II, when partner organizations alone accounted for 71 percent of all requests, followed by states (17 percent), federal agencies (10 percent) and industry (1 percent). States’ increased demand for print materials parallels their growing involvement in education and prevention activities. A complete list of material recipients is in Attachment B.

The project also supported the creation of a *V. vulnificus* education catalog to make it easy for states to obtain educational materials from the ISSC. This catalog contained samples of ISSC materials such as brochures, fact sheets, reference materials, the *V. vulnificus* education exhibit, the *V. vulnificus* public service announcement, the video press kit, the *Clinician’s Guide to Vibrio vulnificus Infection and Treatment*, the Saltonstall-Kennedy Grant Phase I Final Report and the Saltonstall-Kennedy Grant Phase II Interim Report. It also included several excellent journal articles on *V.*

vulnificus, and materials order form. The ISSC recently provided twenty catalogs to core state agencies.

While not part of the original grant, the ISSC collaborated with the Florida Department of Health and Department of Aquatic and Consumer Services to create a *Clinician's Guide to Vibrio vulnificus Infection and Treatment* from Florida's Department of Health and Department of Aquaculture and Consumer Services. The guide includes all the essentials for physician education—a 60-minute video on *V. vulnificus*, a collection of pertinent journal articles, fact sheets, and brochures. Physicians who attended the Florida Medical Association's 2001 Annual Meeting received the Clinician's Guide and continuing medical education units (CME's). The guide was so well received in Florida, the ISSC adapted and reproduced it for other states to use in their clinician education programs. To date, the ISSC has disseminated 277 copies of the guide.

5. Insert articles on *V. vulnificus* in 2-4 magazines or other media reaching those at high-risk.

The ISSC contracted with a science writer to create several articles on *V. vulnificus*. Three articles were produced each targeting a different audience, specifically:

- ❖ Individuals with diabetes
- ❖ Individuals with liver disease, and
- ❖ Individuals with diabetes, liver disease and/or seriously weakened immune systems

The articles address different risk groups for circulation to appropriate publications. The project identified and contacted dozens of publications including magazines for diabetics, veterans, Gulf State newspapers, and organizations serving those at risk. *Diabetes Digest Online* included the diabetes article on their website, reaching an estimated 30,000 diabetics. *Progress*, a national publication of the American Liver Foundation, also included an article on the risk of *V. vulnificus* for those with liver disorders. The FDA also included an article in one of their newsletters,

The ISSC has encouraged states to copy or adapt these pieces to support their own education efforts. Both Texas and Florida have used these articles for *V. vulnificus* prevention efforts.

6. Develop and disseminate press kits to major media outlets in 1-2 core states.

The ISSC conceived the press kit as a means of shaping television coverage of *V. vulnificus*. Most local television stations have limited resources for research and production. By providing media outlets with pre-recorded interviews and other relevant video footage, press kits make it easy for local news stations to present accurate information on *V. vulnificus*. The program emphasizes prevention, especially for immuno-compromised adults. The video featured:

- ❖ A fully-produced 2 ½ minute story;
- ❖ Script and footage for locally adapted news stories;
- ❖ Bullet points summarizing the most important ideas; and
- ❖ Color graphics and Images without sound.

The video includes interviews with Glen Morris, PhD, Director of the Department of Epidemiology at the University of Maryland. Dr. Morris spoke as an expert on *V. vulnificus* in a segment explaining the nature of the bacteria and its consequences for persons at risk. In the second interview, with Dr. George Hoskin of FDA's Office of Seafood, Dr. Hoskin explained how those at-risk can avoid infection.

The ISSC has encouraged states to include local statistics on illness and a list of local experts for reporters to contact when developing their stories. The ISSC has distributed kits in Florida, Louisiana, and Texas. The distribution included all ABC, NBC, CBS and FOX affiliates in those states.

7. Strengthen evaluation component of PSA for possible broadcast in high-risk locations.

During Phase II, the ISSC developed a public service announcement (PSA) on *V. vulnificus*. The spot was broadcast extensively in Louisiana, Florida, and Texas. The impact of the announcement, however, was not assessed. Before purchasing additional

broadcast time, the *Vibrio vulnificus* Education Subcommittee suggested that the PSA be carefully evaluated.

At the ISSC's Annual Meeting, however, the *Vibrio vulnificus* Education Subcommittee suggested developing an alternative piece for informing at-risk consumers. Rather than focusing on the risks of eating raw oysters alone, this video would emphasize that raw oysters are healthful for most people, but point out that people with specific health conditions should avoid them. The *Vibrio vulnificus* Education Subcommittee formalized this recommendation at the ISSC Annual Meeting and the ISSC is seeking funding for developing this PSA.

VI. Project Management

The ISSC was responsible for project management and implementation. The Executive Director provided oversight on all aspects of project execution, with the Project Coordinator responsible for carrying out most day-to-day activities. The ISSC office in Columbia, South Carolina provided administrative support and financial monitoring. Each quarter, the ISSC submitted Progress Reports to Susan Linn, Project Officer at NOAA/NMFS.

The ISSC formalized partnerships with other agencies with signed, contractual letters of agreement. Final payments were contingent on successful completion of all project activities and submission of a final report.

VII. Evaluation

Process evaluation was most useful for assessing information delivery during Phase III. Several tracking measures were used:

- Materials inventory—periodic counts of printed literature, videos and other materials distributed.
- Distribution list—records of organizations and individuals requesting materials from ISSC; follow-up telephone calls for re-supply.

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- Agency work plans—tables of activities, timelines, and materials to be disseminated.
 - Agency final reports—verifying completion of work plan activities.

The consumer survey will provide an excellent long-term outcome evaluation measure in states conducting educational activities.

From 1996 to 2002, the ISSC has been the primary source of *V. vulnificus* education efforts. The organization will continue to play a central role in data analysis, educational material

development and as a forum for discussion. States will begin playing a pivotal role in education, however, as they begin implementing required disease reduction programs. State involvement in a collective illness reduction program will have profound implications for the success of *V. vulnificus* prevention efforts in the years ahead.