

ISSC Vp Subcommittee Meeting Report
Orlando, FL
March 10, 2004

Subcommittee Participants

Paul Comar (Chair)	Jennifer Tebaldi	Kirk Wiles
Lori Howell	Mike Hickey	David Heil
Don Kraemer	Kathy Brohawn	Robin Downey
Bill Hastback	Bill Kramer	Eric Feerst (for Bob Connell)
Angela Ruple (for Spencer Garrett)		

Other Participants

Andy DePaola	Brett Bishop	Rob Wittman
Bill Watkins	Paul DiStefano	

In its four hour session, the subcommittee followed an agenda (attached), concentrating on three areas that encompass the subcommittee's charges: 1) *Vp* illness reporting, 2) *Vp* research prioritization, and 3) identifying and evaluating control strategies other than the current *Vp* Interim Control Plan to reduce sporadic cases of *Vp*. In a brief review of results from the 2003 ISSC Biennial Meeting, it was acknowledged that the 2003 recommendation to evaluate alternative control strategies was the most significant charge and a change beyond the objective of the *Vp* ICP that was implemented to help control *Vp* outbreaks, such as those occurring in 1997 and 1998.

Vp Illness Reporting

1. Comar acknowledged the *2002 State-Based Illness Reporting Table*, largely done prior to the 2003 meeting, was not completed with all final state reports as recommended. Comar will work with the ISSC Executive Office to complete and forward to the subcommittee by March 24, 2004.
2. It was agreed that *harvest date and harvest location* would be data fields added to the table for the current illness reporting data call. Paul Comar will work with the ISSC Executive Office to modify the table and instructions with minor edits by March 18 to be re-issued, if possible, to the states in the current *Vp* reporting effort.
3. FDA will review the *Vp reporting procedures* recommended in 2003 to help ensure to the extent possible that states report *Vp* illnesses and that FDA specialists then forward those reports to the ISSC consistent with timelines recommended.
4. It was acknowledged that *Vp reporting by states varies*; some states currently require it, others do not. Also, the quality of reporting is influenced by a variety of factors. Gathering these data from non ISSC-member states may be more challenging. The ISSC will continue to work toward the most complete reporting possible.

5. FDA was asked to assist in reviewing *CDC's vibrio surveillance report*, comparing and evaluating it against annual ISSC *Vp* reporting data to determine if the CDC report improves our quantification of *Vp* cases.
6. A request was made to determine which *Vp* cases were linked to *recreational harvest and triploid oysters*, both of which the state of Washington indicated it could provide to ISSC and FDA. Since these data and their impact on risk modeling seemed to be applicable mostly to the state of Washington, FDA noted they would be willing to run additional risk modeling for WA considering these variables.

Research

At the 2003 meeting, the subcommittee produced an un-prioritized list of 8 *potential research areas*. At the current March 10 meeting, the FDA provided the subcommittee an additional list from the revised, unreleased *Vp* Risk Assessment. FDA noted that research undertaken on the Risk Assessment-based list would improve the accuracy of assumptions used in the report, therefore decreasing uncertainty and improving the risk assessment itself. There was also a *Vp* research proposal handed out to the subcommittee for consideration of funding by the ISSC Executive Office, which has in the range of \$50K reserved for *Vp* research.

One key point made by FDA was that a sensitivity analysis of the Risk Assessment indicated the two primary *factors influencing the Risk Assessment* were total number of *Vp* consumed and percentage of those *Vp* that are pathogenic. Thus, research improving these estimates is needed to improve the Risk Assessment. Another of several data improvements desired is a better estimate of the percentage of harvested oysters that are eaten raw. Survey data of raw consumption in four states will be presented during the *Vv* discussion and will be reviewed for application in the revised *Vp* Risk Assessment.

In looking over all potential research items, the subcommittee categorized them under three headings Enumeration, Environmental Factors, and Mitigation, all three of which can play a role in better quantifying and reducing risk from Vp. Another item discussed, but not enough to reach consensus, was considering research as short vs. longer term. Short term might be more related to some potential mitigation or risk reduction strategies, at least as empirically considered. For example, what measures might the industry implement and test which are likely to reduce levels of *Vp* at consumption? Longer-term research that could also provide useful information might be more related to environmental factors effecting *Vp* levels.

Without time to consider both the previous and new list, subcommittee members agreed to review a table developed after the meeting and “vote” for research in a prioritized manner. Comar and Bill Kramer agreed to collate information and send a composite priority list back out to the subcommittee for a *final analysis and prioritization* before then sending to the ISSC Executive Office.

The subcommittee was asked to provide comment to the ISSC by March 24 on the specific proposal received (from the Pacific Shellfish Institute). The Executive Office may provide a means for responding quickly and efficiently, likely through access to a page on the ISSC website.

Control Strategies Alternative to the *Vp* ICP

FDA's Don Kraemer and Andy DePaola led the review and discussion of the FDA's Discussion Paper on *Vp* Control distributed at the 2003 meeting, and Kraemer distributed some highlights of the revised but unreleased *Vp* Risk Assessment report. Kraemer emphasized that the Risk Assessment is still draft and that those pages and information handed out must be kept in the subcommittee. A March 2004 two-page report from CDC was also distributed, indicating the basis for the new CDC estimate of 2790 cases of *Vp* per year caused by raw oyster consumption. It was noted in discussion that where oysters and another potential source of *Vp* were both consumed, the CDC likely attributed the case to oysters. Also, recreationally harvested oysters linked to illnesses were also included in the CDC estimates. This new, lower estimate of annual *Vp* cases linked to raw oysters (2790 vs. 4750 previously) is being used in the revision of the Risk Assessment.

Since the Risk Assessment is still draft, there will be no description of that information in this *Vp* meeting report. However, two conclusions shared by the FDA were that 1) there is a very good correlation between *Vp* levels found at retail [in a 330 market-sample conducted by FDA] and *Vp* levels predicted by the Risk Assessment and 2) there is a very good correlation between CDC's new estimates of *Vp* cases by region/season and *Vp* cases by region/season predicted using the Risk Assessment. The FDA strongly encouraged state dialogue and participation with FDA modelers in running risk reduction scenarios that should also help improve those models.

The final *Vp* Risk Assessment has a new target release date of May 2004. The subcommittee requested that FDA provide pre-release copies to *Vp* subcommittee members to help in their understanding of the assessment process and conclusions being drawn. It should also assist some states in beginning a dialogue with FDA of control measures that might be considered and their potential to reduce risk from *Vp*. FDA will consider the request, and Kraemer was hopeful of a positive response. The subcommittee also requested that FDA provide copies of the five economic-based reports cited in David Zorn's one page "Impacts of Eliminating Shellfish Hazards" summary at the 2003 meeting. FDA agreed to act on that request.

Discussion followed on how the subcommittee should proceed relative to making a recommendation on alternative control strategies for the 2005 biennial meeting. The core of much of that deliberation centered on the public health significance of sporadic *Vp* cases, better understanding the number of those cases (actual vs. estimates), understanding how to measure the effectiveness of any control strategy implemented, and the economic effects on the industry of implementing one or more selected control strategies. Basically, the subcommittee must consider the March 2004 CDC *Vp* case estimates, the *Vp* Risk Assessment and its conclusions and risk models when provided, and the economic impact assessments completed to date.

One additional point raised in the follow-up Vibrio Management Committee meeting was the need to determine an end point *Vp* maximum for post-harvest treatment designed to decrease the number and therefore risk of *Vp* illness. It was proposed that this determination might be best considered through participation with those developing similar criteria for *Vv*.

The *Vp* Subcommittee requests the ISSC Executive Office reserve 1½ days for its deliberations at the *Vibrio* Committees / Executive Board meeting considered for the first week in August. Preparatory work will be conducted as determined through e-mail and possibly through information sharing enabled on the ISSC website.