How did Work follow up? SSA + NDI? or just NDI?

info to New Study Director

SCOPE OF WORK

UPDATE OF MORTALITY AMONG VINYL CHLORIDE WORKERS

The Chemical Manufacturers Association (CMA) is interested in receiving proposals to update the mortality experience among an established cohort of workers employed in the vinyl chloride/polyvinyl chloride (VC/PVC) industry. This cohort was previously studied and reported on by Tabershaw and Gaffey (1974), Cooper (1981), and Wong et. al. (1991).

The Scope of Work for this project is outlined below and includes some key elements which should be addressed in any proposals submitted.

As you will note, CMA is interested in receiving two major work products at the conclusion of the project: 1) a written technical report summarizing an epidemiologic evaluation of the mortality experience of the cohort through 1992; and, 2) a manuscript which is suitable for publication in the peer-reviewed scientific literature.

Background

The original records which formed the basis for prior reports on the mortality experience of this cohort are currently in the possession of ENSR Health Sciences, located in Alameda, California. If a different study group is awarded the contract to conduct the update study, CMA will arrange for the transfer of all pertinent records from ENSR to that contractor. However, ENSR did make confidentiality agreements with some states (see attached list) precluding direct transfer of death certificates for some cohort members. Therefore, submitted proposals will need to indicate how other contractors would proceed to obtain such death certificates for persons dying prior to 1983, the end date for follow-up in the most recent update. — resubmit to NDI for those states where confidentiality agreements were signed

Projected Scope of Work

All proposals submitted in response to this request should address the following issues:

1) Verification of the completeness of the database, in comparison with the results of the most recent update (see Wong et. al., 1991, attached).

2) How to obtain death certificates for employees dying before 1983 which could not be transferred directly from ENSR to a different contractor.

3) Ascertainment of vital status for cohort members who survived through the end of the previous update period (i.e. as of 12/31/92).

4) Obtaining death certificates for employees determined to have died after 1982 and assigning a nosologically valid underlying cause of death to each.

5) Conduct of a Standardized Mortality Ratio (SMR) analysis comparing the cause-specific mortality experience of the cohort with age-, gender-, and period-specific mortality rates for the U.S. male population and individual state male populations. The analyses conducted should consider at least the following factors:

- Age at first exposure;
- Year of first exposure;
- Type of plant (VC monomer or PVC);
- Length of exposure;
- Elapsed time since first exposure.

In addition to these points, any proposal should also include the investigator's thoughts on the feasibility and technical merit of the following:

- Updating the exposure histories of surviving cohort members from 1982 through 1992;
- Performing internally standardized mortality analysis using such methods as Poisson regression for comparing SMR's or Proportional Hazards modeling of time to death;
- Using race-specific comparison mortality rates in the epidemiologic analyses, which has not been done previously due to small numbers of non-white cohort members;
- Updating uniform coding of all death certificates according to the Eighth or Ninth Revision of the International Classification of Disease (in all previous updates certificates were uniformly coded to the Seventh Revision).

Technical Criteria

You may be interested in the criteria which the CMA Vinyl Chloride Panel Research Coordinators will use to evaluate proposals received. These are listed below for your consideration in the preparation of your response. The criteria are not listed in any particular order and should not be viewed as having equal weight.

1) The curriculum vitae for each of the scientists who will participate on your project team;

2) Your proposed approach to each of the technical items listed in the projected Scope of Work;

3) Your proposed schedule for completion of the required deliverable work products listed below;

4) Your description of the technical and physical resources at your disposal for completion of this project.

Required Deliverable Work Products

The deliverables expected by CMA include the following:

1) A series of timely progress reports addressing the following:

   - Verification of the completeness of the existing database against the tables presented in the 1986 report to CMA prepared by Wong et. al. (see attachment).
   - Outcome of efforts to ascertain vital status of cohort members through 1992.
   - Outcome of efforts to obtain death certificates for workers dying after 1982, and for employees dying before 1983 if necessary.

2) A detailed technical report summarizing the epidemiologic analysis, submitted to CMA for review and commentary by participating member companies.

3) A manuscript suitable for publication in the peer-reviewed scientific literature, submitted to CMA for review and commentary by participating member companies.

Timing

Investigators wishing to submit proposals should do so by August 1, 1994. CMA would like to receive proposals in two separate documents -- one containing the technical proposal and the other containing the cost and time schedule proposals. This will allow us to evaluate the technical merits of the proposal independently of cost and time schedule considerations. Please supply one original unbound copy of the technical proposal, and one original unbound copy of the cost/time schedule proposal.

Additional Information

Please contact Dr. Has Shah of CMA at (202) 887-1192 if you have any questions about this request or about contract administrative details. Our lead scientist for this effort is Dr. Jonathan Ramlow of The Dow Chemical Company. You may contact him at (517) 636-1276 with questions about the scientific aspects of this Scope of Work.

Attachments

1986 Final Report: An Update of An Epidemiologic Study of Vinyl Chloride Workers, 1942-1982

1989 ENSR Reassessment of Liver Cancer Among Vinyl Chloride Workers

1991 An Industry-Wide Epidemiologic Study of Vinyl Chloride Workers, 1942-1982

1993 Letter to the Editor, Diagnostic Bias in Occupational Epidemiologic Studies (H. Shah)

1993 Response to Letter to the Editor, Diagnostic Bias in Occupational Epidemiologic Studies: An Example Based on the Vinyl Chloride Literature (O. Wong)

Status of ENSR Confidentiality Agreements with Individual States

ENSR had to enter into agreements with different states to obtain death certificates. In some states there were no restrictions concerning with whom we could share the certificates, while with others there were variable restrictions. The following summarizes the status of agreements with the states as we understand them at this time: — date?

└ Hawaii about at the time the agreements were signed

Group A: States that will allow ENSR to give the death certificates to individual companies or CMA as long as we document what is being transmitted.

This group includes the following states: Alaska, California, Connecticut, Washington, D.C., Illinois, Iowa, Maryland, Massachusetts, Minnesota, Nevada, Ohio, and Washington.

Group B: States that will allow ENSR to provide state file numbers, dates of death, and deceased names to companies or CMA.

This group includes the following states: Colorado, Georgia, Idaho, Indiana, Kentucky, Louisiana, Maine, New Mexico, New York, Oregon, Rhode Island, South Carolina, West Virginia, Wisconsin, and Wyoming.

Group C: States that require both ENSR and the companies or CMA to write and request the death certificates based on the study follow-up data. This involves completing application forms for each state (not identical for each), entering the state file numbers, and communicating with each company or CMA.

This group includes the following states: Alabama, Arizona, Arkansas, Delaware, Florida, Kansas, Michigan, Missouri, Mississippi, Montana, New Hampshire, New Jersey, New York City, North Carolina, North Dakota, Oklahoma, Pennsylvania, South Dakota, Tennessee, Utah, Virginia, and Puerto Rico.

We are still investigating the process in three states: Hawaii, Nebraska, and Vermont. They have not as yet responded to multiple inquiries. — Why do they need to respond? If no Corp. agreements were signed why not transmit the certificates?

1. Who will request & State records (death certificates) + all other data included in this study?

2. Who is signing the NDI request?

3.

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Evaluation Matrix For VCM Industry-Wide Cohort Study Update Proposals

	Proposal		
Criterion	Applied Health Sciences	Applied Epidemiology	New York University
Verify dataset completeness	OK rapid MI	? can CMA expedite? could save 6 months M1-4	? can CMA expedite
Obtain death certificates from previous update	OK - rapid access likely M1	? can CMA expedite? not expected to be major problem M1-10	will run thru PBI + NDI again
Follow-up vital status ascertainment to 1992	depend on CMA, M1-4 companies, will verify for living members	depend on CMA - companies M6	depend on CMA + companies cohort/recap study
Obtain death certificates through 1992	NDI plus DMF (DMF optional 15K) M3-10	NDI plus DMF (DMF optional)	NDI plus PBI (@MF)
Mortality analysis completeness	OK - OCMAP M10-12	OK - analysis based on ProQuest DB system + data files M18-22	OK OCMAP adjust expecteds by % PC follow-up
Update employment history to 1992	Yes - depend on CMA + companies	NO - not used	Yes - similar to [illegible] why did it - apply Cox regression in case control design
Apply regression modeling	Cox modeling for covars suggested in SMR analysis	maybe - will use Kaplan-Meier analysis to evaluate M20-22	yes Poisson regression will apply to exposure intensity
Update coding of cause of death	4-H cancers only QA on a 10% sample for death > 1982 ↓ to establish NAK SMR	yes, all cancers to 9th or 10th M12 ↓ compare IT ?	QA DC's yes all cancers to 9th OCMAP includes comp. check

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Evaluation Matrix For VCM Industry-Wide
Cohort Study Update Proposals

	Proposal		
Criterion	Applied Health Sciences	Applied Epidemiology	New York University
Use state and local mortality rates	for causes of death known to have regional variation	yes - weighted comparison rates independent of OCMAP	yes, for 8-state subset
Include race-specific analysis	NO	will look at race distribution in all deaths as a cue	will try to estimate % - total potential impact = interested in Asians too
Prepare written protocol	NO	Yes - use GEP's M3	Yes - use GEP's
Time frame for study	14 months	~~[illegible]~~ 29 months	42 months
Total study cost	290K	399K	1,455K post-doc, programmer, 2 project assts. & clerk plus indirect
Other	Final report M12-13 R Doll as consultant epidemiologist (5K)	expert panel wanted (22K)	are planning add-on studies, i.e. case-cohort & ascertainment study only
Overall	willing to consider fixed price contract basic, no frills	very professional very high quality + epi insights	very professional, very high quality, good epi insights