

Correspondence

Regarding distance of residence in 1984 may be used as exposure surrogate for the Bhopal disaster - further observations on post-disaster epidemiology

Sir,

We appreciate Dr De's comments on our correspondence published in December 2012¹. We agree that there would be recall bias on using memory-dependent exposure surrogates such as duration of exposure, use of protective measures, and activity at that time more than two decades after the disaster. However, distance of residence is an objective datum which is easily verified and was shown to be correlated with the objective measure of lung function². Dr De states that the $FEF_{25-75\%}$ is a variable parameter to assess small airway function¹. While this parameter is more variable than FEV_1 and FVC in individual clinical testing, epidemiological research deals in aggregate data, so we believe that such a finding needs to be explored, particularly when other studies have demonstrated associations with this parameter². Animal and human studies have shown that methyl isocyanate, being moderately soluble in water, is toxic throughout the lung to the upper large airways as well as the lower mid to small airways³.

Dr De found no difference in prevalence of lung function abnormalities among patients assigned to the satellite health centers of Bhopal Memorial Hospital which he used as a surrogate for distance of residence^{1,3}. While the satellite health clinics were originally supposed to serve gas-affected victims who live nearby, it is our understanding that this has not necessarily been the case. In a recent conversation with a leader of the victim's organization, we were told that the original aim of registering and serving nearby residents was never implemented to the intended extent⁴ (*Bhopal Gas Peedith Mahila Udyog, Sanghatana*,

personal communication, March 2012). The clinics do not necessarily register residents in the area, with the result that any local resident can attend any of the clinics. The Hospital is apparently no longer dedicated only for Carbide victims but provides care for any Bhopal resident who seeks it. This variability of patient registration precludes the use of satellite health clinics as a surrogate exposure marker in the assessment of differences in lung function.

Dr De also suggests that a community-based study will be required to determine the true association of MIC and lung function abnormalities. Twenty eight years after the disaster, there will have been significant migration into and out of the area such that many of the exposed victims will no longer be present in the area and a viable community-based study will not be possible.

As long-term observers, investigators, and former members of the International Medical Commission on Bhopal, we would like to take the opportunity to highlight some aspects of post-disaster epidemiology which, in our opinion, have served as obstacles to the conduct of scientific and valid epidemiological investigation:

The original cohort registered by the Indian Council of Medical research (ICMR) was chosen on the basis of health effects rather than any true measure of gas exposure. Instead, the cohort of 96,000 individuals was selected based on severe, moderate, and mildly affected areas based on death rates⁵. Prior versions of the technical report characterized the area as 'affected' but later versions contained confusing and contradictory terms such as 'exposed

and affected', 'exposed but unaffected' and the term 'affected' was used interchangeably with 'exposed'. In epidemiological studies, it is well known that not all subjects in an exposed area are affected. As early as in 1987, a dispersion model was available which delineated the exposed areas but was never used⁶.

The selected cohort ratio was heavily skewed toward the severely affected area (75%) and such a selection would have introduced bias in the results and an incomplete understanding of the health effects in the population. The non-random cluster of deaths sample selection approach instead of randomized selection using a sampling frame had the potential for interviewer bias due to prior knowledge of potential health effects. Persons migrating out were excluded rather than treated as lost to follow up thereby shrinking the sample size available for analysis.

Operational problems with such a large cohort included inadequate staffing and equipment - only 20 research assistants were available for monitoring the 96,000 person cohort⁵ and we estimate that one research assistants would have had the herculean task of interviewing 40 families daily⁷.

The six monthly morbidity and mortality prevalence data have not been consistently published since the cohort was formed. There may be some internal reports but these are not available to the wider scientific community or even the general public. Timely publication of epidemiological data is vital to understanding the spectrum of gas-related disease and provision of health services. ICMR's comprehensive reports appeared late thereby limiting their utility in health planning.

We are aware that the Bhopal medical community was faced with (i) the urgent health care needs of the affected community, (ii) the non-availability of toxicological and accident-related information, (iii) the extreme sensitivity of local and national government bodies toward all aspects of the disaster, (iv) lack of expertise, and (v) the lack of funds available to independent researchers to conduct investigations. Faced with lawsuits and the prospect of bankruptcy, Union Carbide's efforts to keep open channels of communication were highly inadequate to address these issues. In addition, the transnational political and legal ramifications served to throw a veil of secrecy around the disaster, thus impeding

the discovery of essential pieces of information. Medical, toxicological, and accident-analysis data were not made public, thereby frustrating the efforts of the medical community to understand the linkage between exposures and health effects and devise appropriate treatment strategies. As an example, the lack of information about whether MIC could thermally decompose to hydrocyanic acid led to years of contentious debate on the merits of treating the gas victims for cyanide poisoning⁸ and an unfortunate violation of patient confidentiality⁹.

Koplan *et al*¹⁰ indicated that post-disaster epidemiologic studies should accurately estimate exposure to enable correct dose-response relationship modelling. These data are needed for identifying ill and exposed persons, determining long-term effects, and linking exposure and effects for use in litigation and to determine compensation. In the absence of the above modelling, studies on Bhopal victims will suffer from the limitation that the link between exposure and health effects cannot be easily made. For various reasons, Bhopal clinical and epidemiological studies have had relatively small sample sizes, thus limiting the ability to infer exposure-response relationships. Dr De's study has the largest number of subjects we have seen and, therefore, is particularly important to reanalyze this dataset to search for definitive exposure-response. We respectfully offer the above critique in an effort to better understand the suffering of the Bhopal gas victims as well as to offer a roadmap for investigation and prevention of future disasters.

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