Distorted Lives

Women's Reproductive Health and Bhopal Disaster

medico friend circle
October 1990

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A community based epidemiological study of the effect of the toxic gases on the menstrual pattern and pregnancy outcomes in women affected by the Bhopal gas leak disaster

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Contribution
Rs. 20/-

THIS STUDY IS DEDICATED TO THE GAS - AFFECTED WOMEN OF BHOPAL WHOSE SPECIAL SUFFERINGS HAVE BEEN NEGLECTED AND WHO CONTINUE TO SUFFER SILENTLY.

CONTENTS

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PREFACE

The Bhopal gas tragedy, the biggest and the worst man-made disaster in the history of human kind, has not as yet taken its complete toll. Thousands are still going through the hell of incapacitating health problems created by this poisonous gas leak. It was argued by Union Carbide circle as well as some local medical experts that the gases that leaked on the night of 2nd December, 1984 produced only local irritant effects on the skin, eyes and the lungs; that MIC (methyl iso cyanate) as a chemical cannot produce systemic effects. There has been mounting evidence to give a lie to this claim. The present study is one more significant addition to this evidence. It shows that the gas leak considerably altered the menstrual pattern of the gas exposed women and significantly increased the incidence of spontaneous abortions and still births. This study has not only brought forward the neglected aspect of the health problems of gas affected people, but has used the sensitive indicator - spontaneous abortions - to assess damage to the pregnancies, compared to other less sensitive indicators used in the ICMR studies. The increase in spontaneous abortions also point out to the possible mutagenic effect of the gas leak.

It must be made clear that this study covers only the reproductive health of gas-affected women in Bhopal and that they also suffer from many other health problems related to other systems of their bodies.

It is hoped that serious implication of this study would be appreciated.

We have no words to apologise for the inordinate delay in the publication of this study.

Anil Pilgaokar

Convenor

Medico Friend Circle

THE STUDY TEAM

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Most of the above participants represented one of the following orgnisations :

Medico Friend Circle, ARCH (Mangrol), Sabla Sang, Action India, Ankur, Saheli and Jagori, (All from Delhi), Prayas (Rajasthan), Mahila Mukti Morcha (Sewapuri), Nari Atyachar Virodhi Manch (Bombay), Sahiyar (Baroda).

Further details of this study are available with

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BACKGROUND

In February 1985, three months after the gas leak disaster in Bhopal, a fact finding team of four doctors observed that women have suffered from abortions, still births, diminished fetal movements, suppression of lactation, abnormal vaginal discharge and menstrual disturbances (1). Later, based on the information on women from two affected bastis attending Gynaecological Clinic, two women doctors reported the presence of a large number of menstrual and gynaecological disorders. The clinical conditions were pelvic inflammatory disease, endocervicitis, excessive menstrual bleeding and suppression of lactation (2). While the fact finding team's observations were based on unstructured interviews, and the clinic based survey on a self-selected sample and therefore needed to be interpreted with caution, they were both indicative of an important area of morbidity that required detailed and sustained epidemiological investigation.

In March 1985, a study, done between 104-109 days after exposure, organized by the Nagarik Rahat Aur Punarvas Committee, Bhopal, showed that out of the 198 women examined, 100 had persistent gynaecological symptoms. Leucorrhoea or excessive vaginal discharge was the commonest symptom noticed both in groups from severely exposed area and mildly exposed area. Majority of these had no local or pelvic factor responsible for this symptom. In 26.5% of women from the severely exposed area the examination of cervical smear showed presence of inflammatory cells with evidence of dysplasia in a small number of them. Of the 38 women pregnant at the time of the disaster, 29 had first or second trimester abortions (3). The study organized by NRPC was cross sectional, community based, using random sampling. However, this study had to be interpreted with caution because of the clinic nature of the survey which expected the surveyed people to "walk" upto the clinic thus introducing self-selection into the sample.

In the same month, a socio-medical survey carried out by the medico friend circle (mfc), focused on the continued effects of the toxic gases in Bhopal (4). The study showed that between 50-70% of the ambulatory population in the severely exposed areas of Bhopal continued to have one or more serious symptoms implicating different body systems. Among women in the reproductive age group, a significant alteration in the menstrual cycle had taken place. The alteration was in the form of shortened cycles, abnormalities in the menstrual flow, dysmenorrhoea, leucorrhoea, and lactation suppression. The mfc study was a population based, cross sectional survey comparing a severely exposed area with a mildly exposed one through a pre-designed questionnaire with defined parameters and the use of random sampling. The findings of this study were therefore of greater epidemiological significance. However the number of women in the sample was too small to comment on the effect of toxic gases on pregnancy outcomes.

Although, the above mentioned studies/surveys were not designed to systematically explore the effect of the leak on the menstrual pattern of women and on the pregnancy outcomes, they had, in a way, corroborated the experience of social activists working in these bastis and had underlined the urgent need to systematically study this important aspect of the health status of the gas exposed women.

Despite this urgent need, there was no indication that the official established research institutions were planning to respond in an adequate and appropriate manner. Under the sponsorship of the Indian Council of Medical Research (ICMR), several research studies had been launched in Bhopal to look into the effects of the gases on the different systems. However, none of the studies was designed to explore the effect of the toxic gases on the menstrual health of the women. Further, the preliminary findings of the study on pregnancy outcomes, at least upto May 1985, indicated that there had been no adverse outcomes following the disaster. This seemed to contradict the popularly held impressions of an increase in spontaneous abortions in the post gas leak period and it was not possible to assess the authenticity of the data because of the Official Secrets Act imposed on all matters concerning the disaster.

There was thus a need for an independent study that would assess the effect of the toxic gases on pregnancy outcomes and on the menstrual health of the women in Bhopal and mfc decided to undertake this task.

Since to study the effect of the gas leak on the overall gynaecological morbidity and pregnancy outcomes was beyond the financial and other resources capacity of mfc, it was decided to limit the objectives to a study of menstrual patterns, spontaneous abortions and still births in the period following the gas leak.

Once the decision was made, letters announcing the proposed study were sent to several women's organisations for help with the carrying out of the survey. The overwhelming response of women activists to this announcement indicated that the survey was a realistic and feasible proposition.

CHAPTER I

SURVEY DESIGN & METHODOLOGY

STUDY POPULATION AND CONTROL

Our study set out to find answers to three questions.

1. what was the effect of the toxic gases on the menstrual cycle of the non-pregnant women?
2. what was the effect on the spontaneous abortion and still birth rates of the women pregnant at the time of disaster?
3. what was the effect on the spontaneous abortion rate of the women conceiving after the disaster?

It was decided to undertake a retrospective study of the gas exposed population for this purpose. For the purpose of "control", it was decided to study the same population for a period of one year before the toxic exposure took place.

The reasons for selecting this form of historic control were:

1. The studies carried out earlier on the gas exposed population, both by governmental and non-governmental institutions had used distance from the Carbide factory as an indicator of the differential exposure and had selected population from the low socio-economic strata residing 8-10 kms from the Carbide factory as the control population. The selection also seemed to be justified by the differential mortality rates in these areas. However, the results from the

both the mfc & NRPC studies had revealed significant symptoms of gas exposure in the control population as well. In fact, the mfc study had concluded that "a control population selected like Anna Nagar (colony 10 kms from Carbide factory) is not strictly speaking a `non-exposed' population as it should be but serves as a control population by virtue of being minimally exposed in comparison to JP Nagar (colony across the road from Carbide factory). This also implies that even in our control population one would expect to observe some of the disabilities or debilitating morbidities in a higher proportion of the population than would be the case in an unexposed contorl area. Actually this is what we did observe" (5). Thus, it was not possible to find a socio-economically matched, control population within Bhopal as all such colonies were situated down-wind to the Carbide factory and therefore could not be considered `non-exposed'

2. Selecting a control population outside of Bhopal would have created the important problems of logistics and resource availability. The survey was being carried out with the help of unpaid volunteers and with limited financial support. To sutdy two large samples in two different cities would have stretched the organisation's resources beyond a limit.
However, while the problem of matched control could be resolved by studying the same population before and after the gas leak, the potential disadvantage of this survey design was the problem of differential recall. It will be discussed later.

The time-scale of the study design could be represented diagramatically as follows:

1st December 1983	3rd December (Gas Leak) 1984	22-29 September 1985 Survey
12 months	Gas exposed women (Study Population)	10 months

Of all the abnormal outcomes of pregnancy, only spontaneous abortions and still births were selected since the population to be covered could not be too large. Further, of the different pregnancy outcomes, spontaneous abortion rates are considered to be both a specific and sensitive indicator of chromosomal anomalies (6). In order to asses the effect of the gases on menstrual pattern, it was decided to study the changes in cycle length, menstrual flow and to study the occurrence of delayed and missed periods.

Sampling the study population:

On the basis of post gas leak morbidity and/or mortality rates, three areas adjacent to the Carbide factory were chosen for the study. These figures were available to us from a study carried out in January 1985 by the "Centre of Social Medicine and Community Health", Jahawarlal Nehru University JNU which covered a population of 68,000 in 29 mohallas through a systematic random sampling of 6.66% households (7). The areas selected for the study were:

JP Nagar	-	mortality rate 65.3/1000
		morbidity rate 66%
Kazi Camp	-	mortality rate 46.7/1000
		morbidity rate 54.60%
Kenchi Chola	-	mortality rate 35.7/1000
		morbidity rate 91.9%

The three areas selected for the study fell into Municipal ward 13, one of the officially recognized severely exposed wards in Bhopal.

Each of the three areas selected consisted of more than one basti but were given area codes and were identified by the name of the largest basti in that area by the Indian Council of Medical Research.

Thus,

JP Nagar	(area code 01) consisted of JP Nagar, Risaldah Colony, Chola Naka, Shakti Nagar and Rajgarh Colony.
Kazi Camp	(area code 02) consisted of Kazi Camp, Old Sindhi Colony, Phoota Maqbara & part of Chola Road upto the Nallah.
Kenchi Chola	(area code 07) consisted of Kenchi Chola & houses along the North of the railway track (Bhopal-Delhi line) upto Nishad Pura Yard.

Each household in these gas exposed areas has an ICMR plate and using this ready made list of houses, the random sample for the study could be drawn. Since random selection of the individual women was not possible, it was decided to select random households and cover all the women in the reproductive age group in the selected household. The number of households in each were (according to the ICMR sample framework) JP Nagar area-1998, Kazi Camp - 1950 and Kenchi Chola - 1300. The total population in these areas was between 31,000 to 35,000 (8). This formed our study population.

Sample Size :-

A review of literature shows that there are very few population based studies on pregnancy outcomes. Even in the few studies available, estimates of spontaneous abortion rate vary widely both because of the definition selected and because of the methodology adopted. The data obtained in Khanna study in rural Punjab through prospective field observations over a period of 3-5 years from the village population of roughly 12,000 indicated an overall rate of 100 abortions per 1000 pregnancies (9). Another study on pregnancy wastage in a rural community near Delhi between December 1983 & May 1984 showed that of the 3351 pregnancies reported by the respondents, 2.09% ended in still births & 8.12% in spontaneous abortions (10).

For the purposes of our study we assumed the "normal" rate of spontaneous abortion in the community to be 10% of all pregnancies. To detect a two fold increase in the rate of spontaneous abortions i.e., 20%, with an error of 5% and error of 10%, 260 pregnant women needed to appear in the sample. Assuming a birth rate of 35/1000 population, with the period of observations for the post gas leak period being 10 months, the size of the sample population that would yield the required number of pregnant women would be 9000. A random sample, using the random numbers table, of 30% of the total households yielded the necessary number of 1586 households. Keeping in mind the high non-response rate of 29% in the earlier study of mfc in Bhopal (11) another 10% of households were selected randomly and the interviewers were specifically instructed in the criteria of replacement should the need arise. Thus the number of households from each area selected was : JP Nagar - 596, Kazi Camp - 585 and Kenchi Chola - 390 households.

METHODOLOGY

The World Health Organisation defines **spontaneous abortion** as any non-deliberate interruption of an intra-uterine pregnancy before the twenty eighth week of gestation in which the fetus is dead when expelled. According to embryological evidence, the greatest loss is during the week following implantation. Since these early losses are not associated with any clinical signs or symptoms, they remain largely unrecognized as spontaneous abortions. Since no previous study has been reported concerning the possible incidence of this event, an **occult abortion** is defined as a pregnancy which aborts so soon after its implantation that its existence is not clinically suspected except by a few days, delay in the onset of an otherwise normal menstrual period. The data of Block SK indicate that approximately 37.5% of those cycles which would otherwise have been thought to represent a prolonged luteal phase, were actually occult abortions (12). In this study, spontaneous abortion was defined as fetal loss occuring between 8 weeks and 28 weeks of gestation, signified by the passing of products of conception with or without abdominal cramps. Since there is no equivalent in Hindi for the term "products of conception", descriptions such as "pieces of blood", "pieces of tissue", or the experience of something "expelled" were taken to signify products. All fetal loss after 28 weeks of gestation was defined as still births.

By taking a cut off point of 8 weeks i.e., two missed periods as the lower margin of gestation, we were missing out on the early occult abortions of gestational period of less than 8 weeks. This was inevitable, because to diagnose occult abortions, history alone is insufficient. Further, no authentic information was available to help with the estimation of occult abortion among those reporting secondary amenorrhoea following the gas leak. Hence secondary amenorrhoea of less than 8 weeks was tabulated and analysed separately from recognized spontaneous abortions. A delayed period was defined as one missed period while only if two periods were missed (without the history of spontaneous abortion) it was termed a missed period. In order to asses the changes in the menstrual pattern following the gas leak, changes in the duration of menstrual flow, alteration in cycle length, and the regularity of cycle were studied; here irregularity was defined as unpredictability of cycle.

For the purpose of analysis of spontaneous abortions, both fetal death ratio (FDR) and cumulative incidence rate have been used. FDR is defined as the number of spontaneous abortions per 100 pregnancy outcomes (live birth + still birth + spontaneous abortion). Incidence rate has been calculated as number of spontaneous abortions per 100 conceptions. Induced abortions have been removed from all the tables.

By its very timing to the gas leak, our study had to be based on retrospective data. In such a study, immediately three methodological problems become aparent. Firstly, since it is retrospective, it has to rely on the memory recall of the population studied; secondly, it has to rely on histories' with no supportive objective data; and thirdly, determination of Last Menstrual Period (LMP) becomes crucial. These aspects are discussed below with reference to spontaneous abortions, one of the important variables in the study. In studies using recalled data, several factors relating to recall failure have been identified. These include time elapsed since the event, gestational age of the fetus at the time of abortion, the timing of the abortions to a particular event in a woman's life, the total number of births and spontaneous abortions in a woman's life, a woman's age at the time of pregnancy, medical treatment and hospitalisation related to abortion and the social class and the educational level of the women (13 & 14).

These factors have been identified in long term studies where the length of time elapsed since the abortion have played a crucial role in recall of the event. The period for recall in our study was only 21 months,which was not considered long enough to affect recall appreciably. This also meant that the total number of births and spontaneous abortions in a woman's life and her age at the time of pregnancy would not have formed major factors affecting recall. However, in these 21 months, an unforgettable incident of the gas leak disaster had taken place and unlike in the period prior to the disaster, women were more likely to be hospitalised in the post gas leak period. Therefore a relatively more accurate reporting of spontaneous abortion in the post gas leak period could not be ruled out.

A final methodological problem of recall was that relating to the **respondents' motivation** in answering the proforma. In surveys of this kind which consists of questions of intimate nature, the women respondents feel embarrassed or more importantly wonder how the collection of such information will be of benefit to them. Often this reluctance is expressed in the form of "inability of recall". While this was not considered a major constraint in the context of the disaster, the real problem was of possible exaggeration because of incorrect association with individual compensation. Care was therefore taken to explain through a Hindi pamphlet,the need for accuracy. Further, the random nature of the selected houses together with the decision of not giving a copy of the proforma to the respondents helped in disassociating the survey from the process of assessing monetary compensation for the individuals affected by the disaster.

With regard to the determination of the **last menstrual period**, efforts were made to make the dates as accurate as possible. The population in the selected bastis consisted of both Hindus and Muslims who follow different indigenous yearly calendars. Using the different phases of the moon, the Hindu & the Muslim calendars, and the different festivals, a `local events' calendar was prepared. To be doubly sure that the mistakes in assessing LMPs were kept to the minimum, the survey team was asked to write down all the relevant dates (LMP, date of abortion, date of delivery) in the same words as that of the respondent. After the survey was completed, these dates were converted into the English months and dates, using the local events calendar., and transferred into the box provided for it in the proforma. (A sample of the clendar is annexed. (Annexure - I).

History Taking:

A pre-designed, pre-tested proforma in Hindi consisting of five sections was administered to the eligible members in the sample. Section I containing family composition and income levels could be administered to the head of the family. Section II was to be specifically administered to all married women in the reproductive age group in the sample. Section III, IV & V were to be administered depending on whether a woman had aborted or delivered in the post gas leak period or was currently pregnant at the time of the survey. (See Annexure II for a copy of the proforma).

Section I:- This included the following information about each household: composition of the family, history of exposure to the gas, dead or missing members in the family since gas leak, and the income of the family before the gas leak.

Section II:- This was to be administered to all the married women in the households selected who were in the reproductive age group. It included details of the menstrual history in the year preceding the gas leak as well as in the period following the gas leak. Specific questions related to the number of times the menstrual period had been delayed or missed. The question were formulated in such a way that it led to the least amount of confusion and yet enabled the survey team to get accurate information. For instance to determine regularity of menses the proforma contained six questions.

The section also included information on the past obstetrical history of the women i.e., number of conceptions, number of abortions, still births, live births and the number of children alive at the time of the survey. The family planning status and the changes in libido were also recorded.

__Section__ III:- This was for those women who had aborted after the gas leak. Both spontaneous abortions and induced abortions were included. Activity during pregnancy, the last menstrual period date of abortion, description of abortion (onset, symptoms), changes in fetal movements after gas leak in those who aborted after 20 weeks of gestation as well as reasons for induction in case of induced abortions were recorded.

__Section__ IV:- This was for women who had delivered a child live or still birth) after the gas leak. It included details of the antenatal, delivery and post natal period. Special attempts were made to find out if any significant changes had been noticed by the women after the gas leak (e.g. changes in fetal movement) and significant changes between this delivery and previous deliveries.

__Section__ V:- This was for women who were currently pregnant during the time of the survey. Although the proforma intended that at least a minimum of physical examination be carried out, it was not possible to do so because the majority of the survey team consisted of people not trained in such skills.

The data for the study were collected between the 22nd and 29th of September, 1985. Throughout the survey, a constant check was maintained to assess the coverage of the sample population and to reduce non response to a minimum. A non-respondent was considered to be a person/household that could not be contacted even after two repeated visits. If only the woman respondent was not contactable, information was taken from other members of the family (husband, mother-in-law, sister-in-law). This information was however not used for the purpose of analysis.

Apart from the door to door survey of the selected population, a **gynaecological-clinic** with facilities for internal examination was run in the bastis by qualified gynaecologists from our team Women reporting gynaecological/symptoms, whether part of the sample or not, were referred to the clinic. A report of the findings in the women attending the clinic is annexed (Annexure III).

Training of the survey team:

The survey team consisted of two types of women, the majority belonging to the working class who had undergone training in Community Health and were working as health workers for the last three years; the other group consisted of middle class women with or without medical background but with experience in data collection. All the members were literate but most were conversant with only Hindi, and therefore the proforma was prepared in Hindi. The team members had volunteered for the survey and were not paid any remuneration for their participation in the survey.

About a month prior to the survey, the proforma was explained to the health workers and was tested out on them. The initial scepticism gave way to a somewhat realistic assessment of the ability to recall. The proforma was then administered to several households in the slums of Delhi and Bhopal and necessary changes were made. The first day of the survey period was spent in briefing the participants and in giving practical experience in administering the proforma in the bastis in Bhopal. During the briefing, each question was explained, the need to fill every column emphasised and the survey team was asked to write out on the reverse side of the proforma any other information that they felt was relevant but which could not fit neatly into the columns provided. The concept of random sampling was explained and emphasis was placed on the fact that on no account were the sample numbers to be changed.

CONSTRAINTS IN THE STUDY:

As a consequence of the political climate prevailing in Bhopal after the disaster, the study was constrained by several factors. Although these did not affect the overall quality of the data, they need to be stated to emphasis the tensions under which the survey team had to function.

To begin with, it was impossible to get any information from the medical establishment in Bhopal. This conspiracy of secrecy was extended to such ridiculous lengths that even innocuous information such as the ICMR maps of the bastis was treated like classified documents. It was only at the intervention of ICMR's head office in Delhi, that we were finally able to get some help from the various department of Gandhi Medical College and hospital.

The survey was first to have been conducted in July 1985. However, the dates had to be postponed because on June 25, 1985, in a sudden move, the MP Government arrested the doctors and activists working in the Jana Swasthya Clinic (People's Health Clinic) of Bhopal and seized their medical records under preventive detention. These activists and doctors were branded as terrorists and the MP Government issued **strict warnings** against any `outsiders' entering the affected area. The atmosphere in the bastis following the arrests was extremely tense as local people from the slums had also been picked up. Even previously sympathetic doctors from the medical community of Bhopal refused help because of the media reports. The dates for data collection therefore had to be postponed. The change in dates and the repression by the MP Government led to a large number of drop outs from those who had agreed to participate in the survey. Thus the number of volunteers available during the survey was far less than that required.

Once the survey began, the third problem was the **constant harrassment** from the police. Since the safety of the proforma was of concern, every night after the day's work was completed,the filled proforma had to be spirited' away to some safe place. This resulted in the loss of some of the completed proforma.

CHAPTER II

OBSERVATIONS AND RESULTS

Non-Respondents

Out of the total 5248 households, a random sample of 1571 were selected for the study from the three areas viz., Kenchi Chola, JP Nagar and Kazi Camp. In order to compensate for the non-response rate, another 523 households were chosen as reserves'. Of the total 2094 households selected, 1632 responded giving a non-response rate of 22.06%. Table I gives the reasons for non-response.

TABLE I

Reasons for non-response (Figs. in parentheses % of total)

		Kenchi Chola	JP Nagar	Kazi Camp	Total	(%)
1.	House locked	34	70	49	153	(33.11)
2.	House not located	11	14	87	112	(24.24)
3.	Migrated/shifted out	13	26	10	49	(10.5)
4.	Form missing/incomplete	2	33	20	55	(11.9)
5.	Out of station	12	24	14	50	(10.8)
6.	Miscellaneous reasons (converted into sewing centre, temple, shop).	3	5	9	17	(3.67)
7.	Empty house	5	5	5	15	(3.24)
8.	Disappeared with ICMR plate	5	4	1	10	(2.16)
9.	Refused to be surveyed	-	1	-	1	(0.21)
10.	Total	85	182	195	462	(100)

A non-respondent household was one that could not be contacted even after two repeated visits. Approximately 30% of the respondents whose house was locked had gone out for work and could be contacted only very late in the evenings. In Kazi Camp, 87 households could not be located and about 50% of these households belonged to consecutive numbers. The reason for these missing households, as told to us by th ICMR field staff, was that while the houses were being numbered in Jan/Feb 1985, about 100-150 families had put up their huts in the vacant land (Khabar Khana) in Kazi Camp and after a few months, these families had shifted out of the area. Since these families moved in after the gas leak, their non-response would not affect the results. Proforma of 55 households were removed from the analysis because they were either missing or incomplete. As mentioned in the chapter on methodology, during the survey period, due to constant harrassment, the completed proforma had to be shifted every night to a safe place to prevent them being seized, thus leading to the misplacement of some. 10% of the non-respondent households had shifted out of Bhopal permanently after the gas leak and another 10% were out of Bhopal on social visits. Only one household refused to be surveyed.

A. GENERAL CHARACTERISTICS OF STUDY AND CONTROL POPULATION

A total population of 8165 in 1632 households was surveyed between the 22nd and 29th September, 1985. Of those exposed to the toxic gases on 2/3 December 1984, 253 (30.98/1000 population) individuals had died following the exposure. Of the 8165 individuals, only 43 individuals had moved into the area since the gas leak. Unlike the general slum' situations, the population in the area under survey is a stable population with a history of residence going several generations back. Even the residents of the relatively "new" basti JP Nagar, are settlers in this area for more than ten years and in April 1984, had received `patta' for their residential plots declaring them as permanent residents.

In the population covered in the survey, there were 1486 married women in the reproductive age group. 261 of these women could not be contacted during the survey as they were either out on work or had gone on a visit to the maternal home. Thus a total of 1225 married women formed our sample population. 59.76% of the women respondents were Hindus, 39.6% Muslims, and 0.65% belonged to religions other than these two. 7.2% of the respondents were between the ages of 15-19 years, 53.3% between 20-29, 30% between the ages of 30-39 years and 9.45% were more than 40 years of age.

373 of the women had a pregnancy outcome (livebirth, still birth or spontaneous abortion) in the year prior to the gas leak and 368 women had a pregnancy outcome (live birth, still birth or spontaneous abortion) in the period following the gas leak. The control period i.e., the period before gas leak (BGL) was from 1st December 1983 to 2nd December 1984, and the study period (AGL) was from 3rd December 1984 to 22-29 September, 1985.
<u>Table II</u> shows that the sample of women who had a pregnancy outcome in BGL period and in AGL period are comparable with reference to age, gravidity and religion. History of smoking was not considered an important variable although it is known that smoking is strongly related to spontaneous abortion rate (15). In our study population, there is strong taboo against women smoking and cultural factors are powerful enough to prevent women from smoking. Hence history of smoking was not enquired into.

TABLE II

Comparison of characteristics of women who had a pregnancy outcome (live birth, still birth, spontaneous abortion) before and after gas leak (Figs in parentheses are the % of the total)

Age	Before gas leak*	After gas leak**
	n = 373	n = 368
15-19	17 (4.56)	31 (8.42)
20-29	247 (66.2)	237 (64.4)
30-39	102 (27.34)	88 (23.9)
40+	7 (1.87)	12 (3.26)
Gravidity		
1 & 2	155 (41.55)	132 (35.86)
3 & 4	120 (32.17)	130 (35.32)
5 & 6	63 (16.89)	63 (17.11)
7	35 (9.38)	43 (11.68)
Religion		
Hindu	210 (56.3)	207 (56.25)
Muslim	163 (43.7)	161 (43.75)
Others	---	---

* The control period i.e. from 1st December 1983 to 2nd December 1984 from now on to be referred to as BGL. (Before Gas Leak)

** The study period i.e. from 3rd December 1984 to 22-29 September 1985 from now on to be referred as AGL. (After Gas Leak)

For the purpose of the study, the current marital status was not considered necessary because the number of women who had lost their husbands in the gas leak would not affect fertility status adversely as only ten months had passed since the gas leak. Contraceptive usage was enquired into as both tubectomies and IUCDs can disturb the menstrual pattern. In the period between January 1984 to September 1985, only 19 women had undergone tubectomy and only 4 had IUCDs inserted.

B. EFFECT OF THE GAS LEAK ON THE MENSTRUAL PATTERN:

In order to assess the effect of the gases on the menstrual pattern, only those women who were menstruating in the year prior to as well as in the period following the gas leak were taken so that the menstural histories could be compared between the period before and the period after the gas leak. 571 women (46.6 percent) of the woman respondents fitted this category and each individual women served as her own control. Detailed history in terms of regularity of the cycles, number of days menstrual flow lasted and the length of the cycle were taken. Table III describes the changes in the duration of menstrual flow before and after gas leak. The changes in blood flow in AGL is significantly different from that in BGL ($p < 0.01$).

TABLE III

Comparison of menstrual blood flow before and after gas leak:

Duration of menstrual blood flow	BGL	AGL
1 day	9 (1.57)	19 (3.32)
2-3 days	191 (33.45)	179 (31.34)
4-7 days	329 (57.61)	316 (53.34)
8+	17 (2.97)	33 (5.77)
Irregular	25 (4.37)	17 (2.97)
Stopped	---	7 (1.22)

Changes in blood flow significantly different between AGL & BGL ($p < 0.01$).

From each of the women, the length of the menstrual cycle was enquired into for the BGL and AGL period and changes in the length of the cycle in this group of women is shown in **Table IV.** This table has been computed on the basis of the alteration in cycle length of each individual woman after the gas leak keeping her cycle length bfore the gas leak as normal for her. 14% of women reported a shortening of cycle by 5 days or more which is significantly different from the BGL period ($p < 0.05$).

TABLE IV

Alteration in cycle length after gas leak

n = 571

Remained same	429 (75.13)
Increased by 5 or more than 5 days	21 (3.67)
Decreased by 5 or more than 5 days	80 (14.01)
Irregularly irregular	34 (5.95)
Stopped	7 (1.22)

Alteration in cycle length significant $p < 0.05$

Table V describes the cyclical regularity of the menstrual cycle.

In 11.56% women the menstrual cycle was irregularly irregular after gas leak as compared to 5.6% women before the gas leak.

TABLE V

Change in the cyclical regularity of the menstrual cycle gas leak

n = 571

	BGL	AGL
Cyclically regular	539 (94.39)	498 (87.21)
Irregularly irregular	32 (5.6)	66 (11.56)
Stopped	---	7 (1.22)

Change in the cyclical regularity significantly different ($p < 0.01$).

Menstrual histories also tried to ascertain the episodes of delayed and missed periods before and after gas leak. Table IV shows the number of women with at least one episode of missed/delayed periods.

TABLE VI

Women experiencing at least one episode of missed/delayed periods BGL & AGL

n = 571

	BGL	AGL
Delayed period*	11	52
Missed period**	10	62

* Delayed period - amenorrhoea of 5 to 7 weeks.

** Missed period - amenorrhoea of more than 8 weeks.

Difference is significant ($p < 0.001$)

C. EFFECT OF THE TOXIC GASES ON THE REPRODUCTIVE OUTCOMES:

1. **Still births:** Table VII shows that the number of still births in the AGL period is statistically higher than that in BGL ($p < 0.01$) period.

TABLE VII

Still births in BGL and AGL Population

	BGL	AGL
No. of live births	348	240
No. of still births	1	13

Difference is significant ($p < 0.01$)

2. Fetal Death Ratio

In studies that use retrospective case histories to assess the incidence of spontaneous abortions in populations, the measure of such an incidence is the fetal death ratio (FDR). Table VIII gives the overall fetal death ratio BGL & AGL. The increase in FDR, after gas leak is statistically significant.

TABLE VIII

Fetal Death Ratio before and after gas leak.

	BGL (n = 373)	AGL (n = 368)
No. of live births + Still births	349	253
No. of spontaneous abortions	24	115
Fetal death ratio*	6.43	31.25

$$* \quad FDR = \frac{\text{No. of spontaneous abortions}}{\text{No. of spontaneous abortions + Live births + Still births}} \times 100$$

Increase in FDR in AGL period is highly significant.

Table IX compares FDR for the same calendar month periods, like with like i.e., between January 1984 to June 1984 and 1985 to June 1985. The difference in FDR is significant between BGL and AGL periods.

TABLE IX

Comparison of FDR for similar periods in BGL and AGL

	Jan.1984-June 1984	Jan.1985-June 1985
Total No. of live births + still births	131	143
Total No. of spontaneous abortions	17	51
FDR	11.49	26.29

Difference in FDR significant ($p < 0.001$).

3. Cumulative Risk of spontaneous abortions in the exposed population.

Fetal Death Ratio is basically a ratio and the denominator does not belong to the same population and therefore the risk involved cannot be estimated. In order to work out the risk involved, the cumulative risk has been worked out in the exposed and unexposed population. This would also give the relative risk, measure the strength of casual relationship and the attributable risk which can help in measuring the magnitude of the problem in the exposed population.

For this purpose, the conceptions of Jan. 1984 to April 1984 are selected because they form a cohort whose outcome in the form of spontaneous abortion will not be modified or distorted by the occurrence of exposure on 3rd December 1984. Hence conceptions in this period forms a cohort for the unexposed population. The abortion rate in this period when compared to the abortion rate in the period following exposure January 1985 - April 1985, as shown in table X is significantly less, the **relative risk** is 1.94, the **attributable risk** is 7.44, and the **etiologic fraction** is 48.5% of all abortions occurring in conceptions conceived after the gas leak.

TABLE X

Cumulative incidence of spontaneous abortions BGL & AGL

Month of conception	Total no. of conceptions	Total No. of abortions	Cumulative incidence
Jan. 1984 - April 84	139	11	7.9%
Jan. 1985 - April 85	163	25	15.34%

Cumulative incidence calculated by

$$\frac{\text{No. of spontaneous abortions}}{\text{No. of conceptions}} \times 100$$

Cumulative incidence significantly different ($p < 0.05$)

CHAPTER III

DISCUSSION

The present study carried out ten months after the gas leak disaster in Bhopal, is community based in a randomly selected sample of families and focusses on the effect of toxic gases on the menstrual pattern and pregnancy outcomes in the gas exposed population. The same population one year prior to the gas leak has formed the control.

In the immediate aftermath of the disaster, the Union Carbide Corporation, USA, responsible for the disaster, had maintained that the effects of the gases were local, affecting only the eyes and lungs and that these effects were temporary. This attempt at minimizing the effect of the gases had been countered as early as March 1985 i.e., three months after the disaster on the basis of data obtained through epidemiological studies which showed the gases to have a multisystemic effect.

The results of the present study support the contention that the gases have affected organs other than eyes and lungs by indicating damage to the reproductive system also of the exposed women. The results also indicate that the effect was unlikely to be temporary as it could be discerned even ten months after the disaster. The results of our study show a significant alteration in the menstrual pattern in the form of decreased cycle length, increased duration of bleeding and in the disruption of the cyclical rhythm of the menstrual cycle. Significantly higher number of women have reported episodes of delayed and missed periods.

The effect of the toxic gases on the pregnancy outcomes studied have shown that both still births and spontaneous abortions are significantly higher in the post disaster period. The increase in spontaneous abortions is not confined to the immediate post gas leak period but the rates have continued to remain high even ten months after the disaster. Further, the increase in spontaneous abortions are not confined to only those pregnancies conceived before the gas leak but pregnancies conceived after the gas leak have also experienced a significantly higher termination as spontaneous abortions.

The more refined indicator of cumulative incidence shows that the exposed population is at a relative risk of 1.94, the attributable risk being 7.44. Of the spontaneous abortions in conceptions after gas leak, 48.5% are a result of exposure to toxic gases.

Thus, contrary to the hypothesis that the effects of the toxic gases are temporary and limited to the organs directly exposed to them, the results of the present study indicate a continuous systemic poisoning along with a direct toxic effect. In addition to this, the increase in spontaneous abortions suggests a strong possibility that the gases are potentially mutagenic.

Spontaneous abortions as an index for detection of mutagens:

In assessing hazards posed by chemical agents, of special concern are those agents that might cause cancer, birth defects, or gene mutation, since their defects may not be detected for years or even generations and the damage caused is usually irreversible.

Hence while assessing genetic risks, the rapidity with which mutation is detected and the ability of the system to detect small increases in the mutation rates are two important criteria for selecting the indicator. The review of epidemiologic procedures as aids in population studies for detection of mutagens conclude that monitoring population for fetal deaths is one of the most important surveillance methods in conjunction with more specific tests such as biochemical cytogenetic analysis.

Stein - et - al. have pointed out that "most inferences about the distribution of specific congenital anomalies and about their causes have relied on observation made at birth or later. We wish to emphasise that observations made at early stages of gestation are a valuable and largely untapped source of information about congenital anomalies. Observations on fetal deaths are essential to an understanding of congenital anomalies; to rely solely on data from birth can lead to a false view of their natural history... Infants born at term are the survivors of cohorts which have suffered morbidity and loss during the months since conception. The incidence of a defect at birth is thus a function of the incidence of that defect at conception or in early gestation and of the probability of fetal survival" (17).

Using the model of Stein - et - al., and by applying currently available estimates to the model, Buffler has shown that it is possible to evaluate the utility of monitoring for spontaneous abortions as an indicator of chromosomal anomalies in an exposed population (18). Current estimates of all chromosomal anomalies among live births are fairly consistent as are spontaneous abortions among recognized pregnancies. Using the probabilities of fetuses with anomalies aborting and of fetuses without anomalies aborting in a hypothetical series of 1000 pregnancies, Buffler has shown that 94.7% of defective fetuses would be detected or screened out of the population by spontaneous abortion, leaving only 5.3% of the estimated total infants with chromosomal anomalies to be detected at birth. Spontaneous abortion also appears to be highly specific in that only 6.6% of all fetuses without anomalies are aborted compared to an abortion rate of 94.7% for fetuses with anomalies.

Thus, spontaneous abortion rates, while indirect, are both sensitive and specific indicators for assessing the mutagenic potential of a hazardous chemical agent in the exposed population.

The results of our study would indicate that the toxic gases that leaked on the night of 2nd December 1984 from the UCIL factory in Bhopal are potentially mutagenic. This indirect evidence of increased spontaneous abortions in the exposed population, however, needs to be substantiated through biochemical, cytogenetic analysis. There is also need to monitor the exposed population for delayed long term effects for the next 20 or 30 years and spontaneous abortion rates could form one of the important surveillance methods.

Annexure : I

Sample from the indigenous calendar prepared for the survey

Indigenous Calendar	Their Equivalent in English Calendar
Amavas	3.1.84
Rabial awful	upto 4 Jan 84
Rabial akhir	5.1.84
Makar Sankranti	14.1.84
Purnima	18.1.84
Magh (month beginning)	19.1.84
Amavas	2.2.84
Jamadil awful	4.2.84
Basant Panchami	7.2.84
Purnima	16.2.84
Phalgun (month beginning)	17.2.84
Mahashivaratri	29.2.84
Amavas	29.2.84
Jamadil akhir	5.3.84
Holi	16.3.84
Purnima	16.3.84
Chaitin (month beginning)	18.3.84
Amavas	1.4.84
Rajat	4.4.84
Purnima	15.4.84
Baishaki	16.4.84
Amavas	30.4.84
Shabhan	3.5.84

<u>Annexure</u> : II

Study Proforma (Translated from Hindi)

Section I : Information regarding Household.

1. Date
2. Area/Basti
3. ICMR number
4. Head of household
5. Religion
6. Composition of family : (Start with the household head; Include members who are dead and missing since gas leak)

No	Name	Age	Sex	Marital status	Exposed to gas - yes/no	If ill, symptoms
1.						
2.						
3.						
4.						
10.						

7. Economic status before gas leak

No.	Name of the earning member	Daily wage	No. of days of work	If on regular salary monthly
1.				
2.				
3.				
4.				
10.				

Section II : Menstural History (All married women between 15 - 44 years)

1. ICMR No.

2. Woman's name

3. Did you have a period this month?

   a. If yes, how long did it last?

   b. If no, when was your last menstrual period?

   c. And how long did it last?

4. Did you have a period in __________ month? (Investigator to mention the month prior to the LMP)

   a. If yes, how long did it last?

5. Did you have a period in __________ month? (Investigator to mention the month prior to that in question 4)

   a. If yes, how long did it last?

6. Can you tell me, after how many days do you get your period ?

7. Does your period usually come after ______________ days? (Investigator to quote answer to question 6)

8. Has your period been ever delayed since the gas leak?

   a. If yes, how long was the delay?

   b. How many times did this happen?

9. Has your period been ever missed since the gas leak?

   a. If yes, how many times?

10. Did you get your period every month in the year before the gas leak?

11. In the year before the gas leak did you ever miss your period?

    a. If yes, how many times?

12. Was your period ever delayed in the year before the gas leak?

a. If yes, how long was the delay?

b. How many times did this happen?

13. Age of the youngest child?

14. Did you conceive after this child?

a. If yes, month and year of conception ________________

b. What was the result of the conception?

(Investigator to take complete information)

15. Please tell me the names of all your children who are living at this time; start with the oldest.

No.	Name	Age	Sex
1.			
2.			
3.			
4.			
10.			

16. Now I will read out to you the names of your children who are still living. Is anyone missing? (If yes, add the name to the list)

17. Tell me about the children who were born alive but died subsequently. If there were any, give details.

18. Have you ever given birth to a child that was dead at birth?

If yes, give details.

19. Did any of your conceptions end in an abortion?

(give details)

20. Family Planning status: Tubectomy ( ) Date

Vasectomy ( ) "

IUCD ( ) "

Other ( ) "

None

21. Has there been any change in the libido since the gas leak?

Yours/husband's

Signature of Investigator

Date

Section III :For those women who aborted after the gas leak.

1. ICMR No. Basti

2. Woman's name

3. Occupation

4. Were you engaged in heavy labour during your pregnancy? Yes/No

   a. Fetching water (Uptill which month)

   b. Fetching firewood (_____ "_____)

   c. Any other heavy work (_____ " _____)

5. The last menstrual period before the abortion

   ____

   (Write in the same way as the woman states)

6. When did you abort: date and month __________________

7. Did you abort spontaneously or was it induced?

8. If it was spontaneous, give details about the abortion

   (Complete information is to be taken)

9. If there were fetal movements before the gas leak, was there any change after the gas leak?

10. If the abortion was induced give reasons ______________

Where was it done and who performed it? ______________

Signature of Investigator

Date:

Section IV : For those women who delivered a live/dead child after gas leak.

1. ICMR No. Basti

2. Woman's name

3. Occupation

4. Were you engaged in heavy labour during your pregnancy?

Yes/No

a. Fetching water (uptill which month)

b. Fetching firewood (" " ") ______________

c. Any other (" " ") ______________

5. Last menstrual period ______________________

6. Date of delivery ______________________

7. Fetal movements:

	Same	Increased	Decreased	Remarks
Before gas leak				
During gas leak				
After gas leak				

8. Any problem/complaint after the gas leak?

9. Was there any difference between the labour in the delivery as compared to your previous ones? (Give complete information)

10. Delivery

a. Vertex

b. Breech

c. Forceps

d. Caesarean

11. End result : a. Live child

b. Dead child (Fresh)

c. Dead child (Macerated)

12. Single / Twins

13. Did the child cry immediately after birth?

a. How long was it after birth ?

b. Colour of the skin

c. Other reflexes

14. Any problem in breast feeding?

15. Any congenital deformity?

16. Sex of the child

a. Female

b. Male

c. Indeterminate

17. If it was a live birth,

a. Is the child still alive and well?

b. If ill, give details

c. If dead, give cause of death

18. Health of the mother

a. Alive and well

b. Ill (give details)

c. c. Dead (give cause of death)

Signature of investigator

Date:

Section V: For those women who are pregnant at the time of the survey

1. ICMR No. Basti
2. Woman's name
3. Occupation
4. Were you engaged in heavy labour ? Yes/No
   a. Fetching water (uptill which month)
   b. Fetching firewood (" " ")________________
   c. Any other (" " ")________________
5. Last menstrual period ____________________
6. Is there fetal movement?
7. Any complaint during this pregnancy?

Signature of the Investigator

Date:

---

8. Examination (to be carried out by a doctor)
   a. Abdominal girth
   b. Fetal heart sounds
   c. Per abdomen
   d. Oedema
   e. Blood Pressure
   f. Other

Signature of the examining doctor

Date of examination

Annexure : III

Effects of toxic gases on the health of the women (clinic based data)

During the survey period (22-29 September 1985), a gynaecological clinic was run simultaneously by qualified gynaecologists in the survey team to examine women with gynaecological problems. Depending on the area where the survey team was carrying out the interviews, clinics were held at all the three areas viz., Kenchi Chola, JP Nagar and Kazi Camp selected for the study. The clinic was housed in rooms provided by the basti women and the necessary equipment was loaned to us by voluntary organisations and private dispensaries in Bhopal. SEWA, Bhopal, offered us the services of two nurses working with them. The clinic was open to all the women in the survey area whether they formed part of the sample or not. Women in the area had been informed earlier about the clinic through the pamphlet and the members of the survey team were encouraged to refer women with gynaecological or obstetrical problems. Detailed history was taken and physical examination including a pelvic examination was done by qualified gynaecologists. A total of 343 women were examined in the clinic. The characteristics of these 343 women were as follows.

Age	No. of women (n = 343)	%
10 - 14 yrs.	2	0.58
15 - 19 yrs.	23	6.7
20 - 29 yrs.	183	53.35
30 - 39 yrs.	95	27.7
40 +	34	9.9
Not recorded	6	1.75
Religion		
Muslim	152	44.3
Hindu	191	55.68

The findings on clinical examination were as follows:

Total No. of pregnant women examined	: 159
Clinically suspected malformed babies	: 6(3.77%)
Clinically suspectedd intra uterine growth retardation	: 10(6.3%)
Threatened/inevitable/missed/incomplete abortion	: 5(3.14%)

Total No. of non-pregnant women examined	: 184
Complete abortion since gas leak	: 51 (27.7%)
Pelvic Inflammatory Disease	: 21 (11.4%)
Menorrhagia/Polymenorrhoea	: 17 (9.24%)
Cervical erosion/Endocervicitis	: 26 (14.1%)
Vaginitis/Leucorrohoea	: 45 (24.46%)

Besides these, there was history of still births in 6 women, neonatal deaths in children born after gas leak in 11 cases. 4 women who had lost their children in the gas leak requested recanalisation as they had been sterilized.

Since these data are on a self selected sample of women attending the clinic, they need to be interpreted with caution. The clinic data suggest that probably the overall morbidity with regard to gynaecological problems in the exposed women has decreased in the 10 months following the gas leak as compared to the earlier clinical studies in Bhopal. However, it continues to remain high as compared to clinic based studies in unexposed population; with 24.45% having vaginitis/leucorrhoea, 14.1% with cervical erosion/endocervicitis, and 11.4% with pelvic inflamatory disease. In the case of women with leucorrhoea, the discharge from the vagina was typically profuse, thick, whitish yellow, without any foul smell or local irritation unlike any commonly found vaginal discharge of infective origin. For establishing aetiological diagnosis, women with the above mentioned gynaecological problems need to be investigated further and appropriate treatment needs to be suggested. There is a need for population based epidemiological study with facilities for examination at the field level and for laboratory, diagnostic investigations when needed.

Annexure : IV

Problems in Deliveries Post Gas Leak

From the surveyed population, extensive history was taken regarding deliveries that took place after the gas leak. A total of 253 women delivered in the AGL period. Of this only 18 women (7.1%) had conceived in December 1984 - the month of disaster, whereas the rest i.e., 235 women (92.9%) were already pregnant when the disaster occurred. At the time of gas leak, 89 women had entered the third trimester of pregnancy. A major symptom at the time of gas leak in these women was change in the fetal movements. 21 women (23.6%) reported an increase, 22 women (24.7%) reported a decrease and in 13 women (14.6%) the fetal movements had completely stopped. Changes in fetal movements were also noticed by women who entered the 20th week of gestation. The fetal movements were also considerably reduced in these pregnancies as compared to previous pregnancies. Only 1% of women reported painful contractions unlike fetal movements.

Post maturity appeared to be another problem. Of the 253 women who delivered in the AGL period, 32 women (12.65%) appeared to have given birth to post term babies as calculated from their last menstrual period. Almost all the women reported prolonged labour. Since culturally labour is not divided into first stage and second stage, it was difficult to ascertain which stage of labour had been prolonged. However, even women who had normal labour in their earlier pregnancies reported prolonged or difficult labour with labour lasting for more than 48 hours.

Women reported a decrease in breast milk production. This was in women who had successfully breast fed their earlier infants. Of the 223 women with a living child at the time of the survey, 45 women (20.18%) noticed a considerable decrease in breast milk production.

All these symptoms could indicate an adverse effect on the development of the child. Changes in fetal movement and post maturity could indicate intrauterine hypoxia, placental insufficiency and therefore probable intrauterine growth retardation, while suppression of breast milk could have had an adverse effect on the growth of the infant. Further studies are needed to explore these findings systematically.

Annexure : V

A critique of the ICMR study on pregnancy outcomes and reproductive health of women exposed to the toxic gases in Bhopal

Complete neglect of gynaecological problems.

The Indian Council of Medical Research (ICMR) and the Gandhi Medical College, Bhopal, have attempted to collect data on the reproductive outcomes in the gas affected population as part of their longterm epidemiological study. The proforma entitled "ICMR/GMC study on longterm effect of MIC gas"collects morbidity data under conditions affecting the following organs viz. lung, eye, GIT, skin, hearing and mental. **No information is collected regarding the gynaecological disorders** following the gas leak. Questions No. 49 to 54 to be administered to women between the ages of 15 to 49 years age group are related to **pregnancy outcomes only.** Question No. 49 enquires about the "present pregnancy status" and question No. 51 enquires into the "pregnancy status on 3.12.84". Since it is not clear at what point of time this proforma was administered i.e., in relation to the gas leak, and the date by which the collection of information was completed, it is not possible to tell from the proforma the gap in information between the gas leak and the time of administering the proforma. Since even as late as September 1985, when data were being collected for our study, the field workers of ICMR were still administering their proforma on longterm effects, we could say that the **gap in information** was for at least ten months. This gap would relate to those women who were not pregnant at the time of the ICMR survey, and who were not pregnant on 3.12.84 (their response to questions 49 & 51 being in the negative) but who had conceived between these two periods and had aborted before the proforma was administered to them. This is the first stage where **under reporting** occurs in the ICMR - GMC study. (See ICMR - GMC study proforma in Annexure VI).

The women who were pregnant at the time of the gas leak or were pregnant at the time of the administration of the proforma are then referred to a team from the Oby Gynaecological department of GMC involved in the ICMR sponsored research. Members of this team visit the women thus referred and administer a second proforma entitled "Epidemiological study of teratogenic effects of MIC affected population at Bhopal" (see Annexure VI). Questions 14 to 24 relate to pregnancy outcomes following the gas leak. Questions 15 & 17 relate to the LMP & EDD of the current pregnancy whereas for events occuring after the gas leak but prior to the administration of the proforma, only gestational age is enquired into. This is for abortion, still birth and live birth following the gas leak. As the study team of ICMR had not prepared an **indigenous events calendar**, rechecking these important dates and gestation periods, may be very difficult. It is possible that a second stage of misreporting takes place at this point. Since there were no written guidelines or report, we are not in a position to comment on methodology of the ICMR - GMC study.

Both these proforma contain information, albeit insufficient, relating to pregnancy outcome events only and do not attempt to collect information on either the gynaecological disorders in the nonpregnant women or on the health problems related to pregnancy. They thus reflect the dominant view of modern medicine which perceives **women as vehicles for the production of the progeny.** This view has led to the loss of valuable information regarding the specific toxic effects which women reported such as leucorrhoea, changes in the menstrual pattern, dysmenorrhoea, prolonged labour and suppression of lactation etc. While the failure to record such crucial information is serious enough from the medicolegal and scientific points of view, it also reflects the **inherent bias** in medical research to the health problems of women.

The inadequate and faultily designed proforma did, as expected, lead to an under estimation of adverse pregnancy outcomes in the ICMR study. During a meeting of ICMR in Delhi in June 1985, preliminary results of the pregnancy outcome study of the ICMR sponsored research in Bhopal were presented. Till date, according to the Chief Investigators, a total number of 3259 pregnancies had been recorded at the time of the gas leak. Of these, 15% had ended in abortions, the still birth rate was 2% and the rate of congenital malformation was 1.4%. Comparing these results with hospital based studies, in which spontaneous abortion rate was 25 30%, still birth rate 1.8 3.5%, congenital malformation 1.5 2%, it was concluded that although the spontaneous abortion rates had increased dramatically in the immediate post gas leak period, it had fortunately stabilized and the current rates were all within normal. In the meeting it was also stated that abortion rates "always" go up dramatically during periods of social and environmental stress such as war, floods, earthquakes because of psychological factors. The participants of the meeting also expressed a sense of relief that congenital malformation had not gone up but cautioned that the time to watch was "now" when the women who had been in the first trimester at the time of gas leak would deliver. While both these statements may sound unexceptional in themselves, they have to be placed in the context of Bhopal to understand their implications. Firstly, there was enough evidence to point to the extremely toxic nature of the gases as could be seen by the high mortality rate after the leak. Hence it was more likely that the spontaneous abortions and still briths in the immediate post disaster period were due to the direct toxic effect on the fetus in utero. But this was insufficient to explain the effect in pregnancies aborting several months after the gas leak. If the high adverse outcomes were due to "stress" alone, as stated by the ICMR team, neither was the statement substantiated by studies to support this view point, nor were we able to find any supportive evidence through library research. Secondly, it must also be remembered that these statements were being made at the time when controversy was raging about whether the gases had temporary local effects only or whether they affected organs other than lungs and eyes. Thirdly, ICMR's emphasis for assessing damage to the embryo and fetus seemed to rest on the assessment of congenital malformations alone, spontaneous abortion on the other hand was considered a regrettable and unfortunate fetal loss without grave implications.

By concentrating on congenital malformation alone, valuable information regarding pregnancies conceived after the gas leak and terminating in spontaneous abortions was lost in the ICMR study. This was regrettable on two counts. Firstly, it would have pointed to the systemic efect of the toxic gases, and their probable mutagenic potential (as the conceptions were in the period after the exposure) to be confirmed by cytogenetic studies. Secondly, by continuing the long term studies on spontaneous abortion rates, it would have been possible to monitor the continuing environmental risk the population in Bhopal was being exposed to.

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Annexure : VI

I.C.M.R. - G.M.C., STUDY ON LONG TERM EFFECT OF MIC GAS : DEPARTMENT OF PREVENTIVE & SOCIAL MEDICINE, GANDHI MEDICAL COLLEGE, BHOPAL.

NAME OF HEAD OF HOUSE HOLD : (IN CAPITALS) ____________________

NAME OF INDIVIDUAL : (IN CAPITALS) ____________________

ADDRESS : ____________________

____

____

1. JOB NO. (1–5) B 0 2 2 1
2. TYPE OF HOUSE HOLD (6)
   (Key- House hold old, interviewed 1.
   House hold old, not interviewed 2.
   New house hold, interviewed 3.
   New house hold, not interviewed 4.
3. LOCALITY (7–8)
4. SL. NO. OF FAMILY (9–12) (13)
5. SL. NO. OF MEMBER (14–15)
6. TYPE OF HOUSE (16)

Key- KUTCHA		PUCCA	
Canvas	0	Canvas	5.
atched	1	Thatched	6.
Tiles	2	Tiles	7.
Tin	3	Tin	8.
Concrete	4	Concrete	9.

7. TOTAL NO. OF FAMILY MEMBERS (AS ON 3-12-84) (17–18)
8. NO. OF GUESTS (IF ANY, ON (3-12-84) (19–20)
9. PER CAPITA MONTHLY INCOME (IN RUPEES) (21–24)
10. RELIGION (25)
    Key- Hindu 1
    Muslim 2
    Christian 3
    Sikhs 4
    Others 5
11. AGE (IN COMPLETED YEARS (AS ON 3-12-1984) (26–27)
12. SEX (28)
    (Key- Male 1.
    Female 2)
13. EDUCATION (29)
    (Key- Illiterate 1
    Literate 2
    Primary 3
    Middle 4
    Secondary 5
    College 6
    Technical 7)
14. OCCUPATION (Key in instruction manual) (30–31)
15. PRESENT/ABSENT IN THE HOUSE ON THE NIGHT ON GAS - LEAKAGE (32)
    Key- Present 1
    Absent 2)
16. IF ABSENT FROM HOUSE WHERE WERE YOU- (33)
    (Key-Not in Bhopal 1
    In Bhopal 2)
17. IF IN BHOPAL WHICH AREA (MENTION THE AREA BY NAME) NOT TO BE CODED)

____

____

____

18. LIVING STATUS ON THE DAY OF INTERVIEW 34 [ ]
(Key- Alive 1
Dead 2
Absent 3
Missing 4)

19. DATE OF DEATH 35 [| | | | |] 40
NAME OF INFORMANT

20. TYPE OF EXPOSURE [ ] 41
(Key-Sleeping Outside 1
Sleeping - inside 2

21. IF SLEEPING INSIDE WHERE WINDOWS OPEN OR CLOSED [ ] 42
(Key-Open 1
Closed 2)

22. WHAT DID YOU DO WHEN THE GAS LEAKAGE OCCURED [ ] 43
(Key-Ran away 1
Went outside 2
Protected by wet cloth to face 3
Stayed indoor 4
Covered with sheet/
(Please specify)

23. IF YOU RAN AWAY, WHAT MODE DID YOU TAKE [ ] 44
(Key-By foot 1
By vehicle 2
Both 3)

24. NATURE OF WORK DONE BY YOU BEFORE THE EPISODE (SPECIFY) [ ] 45

25. ARE YOU ABLE TO DO THE SAME WORK NOW [ ] 46
(Key- Yes 1
No 2)

26. IF NOT WHAT ARE YOUR PROBLEMS [ ] 46
(Key-Breathlessness 1
Chest Pain 2
Fatigue 3
Blackout 4
(1 + 2) 5
(1 + 3) 6
(1 + 4) 7
Any other combination 8
(Specify Combination)

27. HABITS
SMOKING - EVER [ ] 47
(Key-Yes 1
No 2

28. SMOKING CURRENT [ ] 48
(Key-Yes 1
No 2

29. ALCOHOL EVER [ ] 49
(Key-Yes 1
No 2

30. ALCOHOL-CURRENT [ ] 50
(Key-Yes 1
No 2

31. DID YOU CONSUME ALCOHOL ON THE NIGHT OF EPISODE [ ] 51
(Key-Yes 1
No 2

32. CHEW TOBACO-CURRENT [ ] 52
(Key-Yes 1
No 2

33. CHEW TOBACO-EVER [ ] 53
(Key-Yes 1
No 2

34. IMMEDIATE EFFECTS [ ] 54
DID THE GAS EXPOSURE HAVE ANY EFFECT IMMEDIATELY ON 3.12.84.
(Key-Yes 1
No 2)
IF YES, CONTINUE IF NO, PROCEED TO QUESTION 41.

IF YES

Condition	Effect Key-Yes 1 No 2	Were you hospitalised Key-Yes 1 No 2	Duration of hospitalisation in days	Duration of illness in days	Dates of hospitalisation (Not to be coded)	Name of hospital (Not to be coded)
1	2	3	4	5	6	7
35. Lung.	56	57	58 59	60 61		
36. Eye.	62	63	64 65	66 67		
37. GIT	68	69	70 71	72 73		
38. Skin	74	75	76 77	78 79		
39. Hearing	80	81	82 83	84 85		
40. Mental	86	87	88 89	90 91		

LATER EFFECTS (ON Set on 4.12.1984 or later)

41. DID YOU DEVELOP ANY COMPLICATIONS ON 4.12.1984 OR LATER. (Key-Yes 1 No 2) 92

IF YES, CONTINUE, IF NO, CLOSE INTERVIEW. PROCEED TO ITEM 49 ONLY FOR MARRIED WOMEN BETWEEN 15-49 YEARS.

Condition	Effect Key-Yes 1 No 2	After how-many weeks Key *	Were you hospitalised Key-Yes 1 No 2	Duration of hospitalisation Key *	Duration of illness in weeks Key *	Dates of hospitalisation (Not to be coded)	Name of hospital
1	2	3	4	5	6	7	8
42. LUNG	93	94	95	96	97		
43. EYE	98	99	100	101	102		
44. GIT	103	104	105	106	107		
45. Skin	108	109	110	111	112		
46. Hearing	16	17	18	19	20		
47. Mental	21	22	23	24	25		

Within 1 week - 1
1-2 Week - 2
2-3 Week - 3
3-4 Week - 4
4-8 Week - 5
8-12 Week - 6
More than 12 Week - 7
Still Continuing - 8

48. DID YOU DEVELOP ANY OTHER COMPLAINTS AFTER 4.12.84.

a) Tiredness ☐ 26
Key-Yes 1
No 2

b) Fatigue ☐ 27
Key-Yes 1
No 2

c) Giddiness(Chakkar) ☐ 28
Key-Yes 1
No 2

d) Anxiety(Ghabharat) ☐ 29
Key-Yes 1
No 2

e) Headache ☐ 30
Key-Yes 1
No 2

f) Bodyache ☐ 31
Key-Yes 1
No 2

g) Pain in the limbs ☐ 32
Key-Yes 1
No 2

PREGENANCY STATUS (ASK ONLY MARRIED WOMEN IN 15-49 YEARS AGE GROUP)

49. PRESENT PREGNANCY STATUS ☐ 33
Key-Yes 1
No 2

50. PERIOD OF GESTATION IN WEEKS 34 ☐☐ 35

51. PREGNANCY STATUS ON 3.12.1984 ☐ 36
Key-Yes 1
No 2

52. OUTCOME OF PREGNANCY ☐ 37
Key- Live Birth 1
Still Birth 2
Abortion 3
M.T.P. 4
Continuing 5

53. DURATION OF GESTATION AT THE TIME OF OUT COME OF PREGNANCY (IN WEEKS) 38 ☐☐ 39

54. DATE OF OUTCOME 40 ☐☐☐☐☐☐ 45

NAME OF INTERVIEWER

SIGNATURE OF INTERVIEWER

DATE________ ____ ___

NAME OF A.R.O.

NAME OF STATISTICIAN

DATE OF SCRUTINING

Key for occupation (No.14)

01. No. occupation 02. Professional technical and related worker. 03. Sales worker
04. Farmers, fisherman, hunters, Lumperman. related worker. 05. Worker in mines quarry 06. Worker in transport occupation. 07. Craftsmen labour not. elsewhere clarified. 08. Service workers.
09. Occupation unreported. 10. Members of armed forces. 11. Housewife.

EPIDEMIOLOGICAL STUDY ON TERATOGENIC EFFECTS OF MIC
IN EXPOSTED POPULATION AT BHOPAL

..GISTRATION

Name of head of House hold ____________________

Name of Woman ____________________ Husband ____________________

Address ____________________

1. ICMR PROJECT NO. 1 ☐☐☐☐☐
2. S.NO. OF HOUSEHOLD 6 ☐☐☐☐ 9
3. S.NO. OF WOMAN 10 ☐☐ 11
4. AREA CODE 12 ☐☐ 13
5. DATE OF VISIT 14 ☐☐☐☐☐☐
6. AGE OF WOMAN 20 ☐☐ 21
7. RELIGION 22 ☐

   1.Hindu 2.Muslim 3.Sikh
   4.Christian 5. Others
8. EDUCATION 23 ☐

   1. None 2. Primary 3. Secondary
   4. Graduate 5. Postgraduate/ Professional
9. CURRENT MARITAL STATUS 24 ☐

   1. Single 2. Married 3. Widow
   4. Separated 5. Divorced
10. PER CAPITA INCOME PER MONTH 25 ☐☐☐☐ 28
11. TYPE OF HOUSE 29 ☐

    1. Thatched hut 2. Masonary
    3. Block of huts 4. Banglow
    5. Tents 6. Others
12. HISTORY OF CONSANGUINITY

    1. Yes 2. No. 30 ☐
13. DURING THE PERIOD OF GAS LEAK WHERE HAVE YOU BEEN 31 ☐

    1. Inside house sleeping no symptoms 2. Inside house, came out no symptoms
    3. Inside house, symptoms +
    4. Outside house, symptoms +
    5. Outside area 6. Others
14. CURRENTLY PREGNANT 32 ☐

    1. Yes 2. No
15. IF YES, L.M.P. 33 ☐☐☐☐☐☐ 38
16. DURATION OF PREGNANCY (wks) 39 ☐☐ 40
17. E.D.D. 41 ☐☐☐☐☐☐ 46
18. DID SHE ABORT AFTER DEC.3, 1984 47 ☐

    1. No 2. Spontaneous abortion
    3. Induced Abortion
19. IF YES, GESTATIONAL AGE AT THE TIME OF ABORTION 48 ☐☐ 49
20. DID SHE DELIVER AFTER DEC.3, 1984 50 ☐

    1. No 2. Live birth 3.Still birth
21. IF DELIVERED AGE OF GESTATION 51 ☐☐ 52
22. IF LIVE BIRTH 53 ☐

    1. Is child alive 2. Died within one week 3. Died within 7-28 days
    4. Died later on
23. SEX OF CHILD 54 ☐

    1. Male 2. Female 3. Indeterminate
24. DATE OF BIRTH

    AGE: Months 55 ☐ Days 56 ☐☐ 57
25. AGE AT CONSUMMATION OF MARRIAGE (yrs) 58 ☐☐ 59
26. AGE AT FIRST CONCEPTION (yrs) 60 ☐☐ 61
27. ANY TREATMENT TAKEN FOR STERILITY 62 ☐

    1. Yes 2. No.
28. NO. OF PREGNANCIES 63 ☐☐ 64
29. NO. OF LIVE BIRTHS 65 ☐☐ 66
30. NO. OF STILL BIRTHS 67 ☐☐ 68
31. NO. OF SPON. ABORTIONS ☐ 69
32. NO. OF INDUCED ABORTIONS ☐ 70
33. NO. OF INFANT DEATHS (LESS THAN 12 MONTHS) ☐ 71
34. NO. OF LIVING CHILDREN

    MALE ☐ 72

    FEMALE ☐ 73
35. TIME ELAPSED SINCE LAST DELIVERY (mths) (EXCLUDE ABORTION) 74 ☐☐ 75
36. TOBACCO CONSUMPTION ☐ 76

    1. No 2. Chewing 3. Smoking 4. Both 5. Other
37. ALCOHOL CONSUMPTION ☐ 77

    1. No 2. Regular 3. Occassional
38. WORKING STATUS ☐ 78

    1. Housewife 2. Work in a office
    3. Work in a Industry
39. TYPE OF WORK ☐ 79

    1. Desk job 2. Labourer 3. Domestic

MEDICO FRIEND CIRCLE

The Medico Friend Circle (MFC) is a national organisation of health professionals and activists who share the common conviction that the present system of health services and medical education is lopsided in the interest of the privileged few. MFC believes that this system must be changed to serve the interests of the large majority, the poor. MFC fosters a `thought current' upholding human values; people and community orientation of health care and medical education; demystification of medical science and a commitment to medical interventions guided by peoples' needs and not by commercial interests.

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