

## Review

# Hepatitis B outbreak investigation report in Sabarkantha District, Gujarat State, February 2009

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**During the ongoing outbreak of Hepatitis-B in State of Gujarat as on April 11, 2009, total 593 confirmed cases had been registered with 94 deaths of unfortunate victims. It had been a major Public Health Challenge as the significant no. of deaths occurred over a short period in a focal area of the State and the Epidemiological Investigations carried out with the help of various departments and Institutions pointed the use and re-use of unsterilized syringes and needles as the root cause for this unfortunate event. This event has been unique in the way that public health interventions like Antiviral drug Lamivudin was instituted towards the treatment of acute Hepatitis-B cases being reported and was found useful and Mass-Vaccination of the affected population with Hepatitis-B injectable vaccine which conferred not only protective value but also built up confidence of the people. In addition during this outbreak all round actions were taken for Bio-Medical waste disposal, identifying culprits and resorting legal actions against them as well as creating awareness for safe injection practices amongst medical fraternity and people at large**

**Key words:** Hepatitis B, cirrhosis, HIV, Sabarkantha District, vaccine, liver infection.

## INTRODUCTION

Hepatitis B is a viral infection that attacks the liver and can cause both acute and chronic disease. The virus is transmitted through contact with the blood or other body fluids of an infected person - not through casual contact. About 2 billion people worldwide have been infected with the virus and about 350 million live with chronic infection. An estimated number of 600 000 persons die each year due to the acute or chronic consequences of hepatitis B. About 25% of adults who become chronically infected during childhood later die from liver cancer or cirrhosis (scarring of the liver) caused by the chronic infection.

The hepatitis B virus is 50 to 100 times more infectious than HIV. Hepatitis B virus is an important occupational hazard for health workers and the hepatitis B is preventable with a safe and effective vaccine. Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus. It is a major global health problem and the most serious type of viral hepatitis. It can cause chronic liver disease and puts people at high risk of death from cirrhosis of the liver and liver cancer. An estimated number of two billion people have been infected with the hepatitis B virus (HBV) worldwide and more than 350 million have chronic (long-term) liver infections. A vaccine against hepatitis B has been available since 1982.

Hepatitis B vaccine is 95% effective in preventing HBV infection and its chronic consequences, and is the first vaccine against a major human cancer.

## GEOGRAPHIC DISTRIBUTION OF HEPATITIS B

Hepatitis B is endemic in China and other parts of Asia. Most people in the region become infected with HBV during childhood. In these regions, 8 to 10% of the adult population is chronically infected. Liver cancer caused by HBV is among the first three causes of death from cancer in men, and a major cause of cancer in women. High rates of chronic infections are also found in the Amazon and the southern parts of eastern and central Europe. In the Middle East and Indian sub-continent, an estimated number of 2 to 5% of the general population is chronically infected. Less than 1% of the population in Western Europe and North American is chronically infected.

## THE INDIAN SCENARIO

India comes under the 'Intermediate' endemicity (2-7%)



Figure 1. Geographic map of Sabarkantha District.

zone as the mean national surface antigen carrier rate is around 4.7%. Assuming the population of India to be around 900 million, then there will be an estimation of 42.5 million carriers in the country. HBV infection in selected high risk group in India ranges between 12-74%.

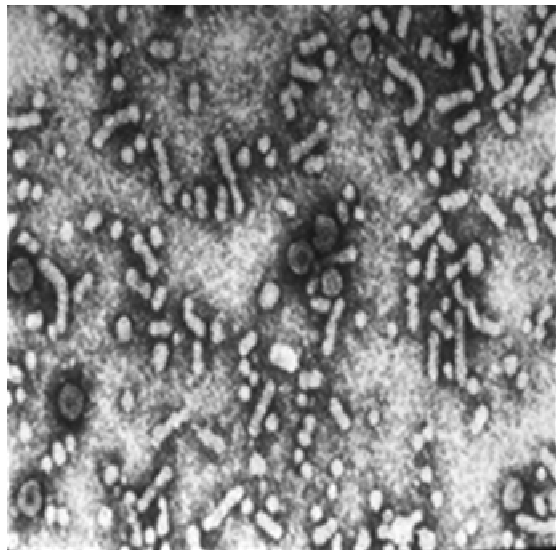
**GEOGRAPHIC PROFILE (AS PER CENSUS OF INDIA 2001)**

Sabarkantha District is situated in the northern part of the Gujarat state. The area covered by this district is 7390 km<sup>2</sup> and the rank of district is 12<sup>th</sup> in comparison of other district of the state. As per the population, it ranks 8<sup>th</sup> in comparison to other districts of Gujarat. The total population is 2082531 (males-1069554, females-1012977) and the population density per square kilometer is 282 persons. According to population density, Sabarkantha is ranked 13<sup>th</sup> dense district in the state and Sabarkantha district is having 7<sup>th</sup> rank as per the sex ratio (M: F=1000:947) in the state. Sabarkantha district has 8 towns, 13 talukas and 1389 villages. The economy of the district is basically dependent on agriculture as 62.8% workers are engaged in primary

sector. Important crops of the district are wheat, cotton, pulses and groundnut. The district comprises 93.5% Hindus, 5.7% Muslims, 0.5% Jains and 0.3% Christians populations. It is observed that July, August and September are the months when most of the rainfall of the season takes place in the district. An average annual rainfall in the district is 400 to 800 mm (Figure 1).

**MORPHOLOGY OF HEPATITIS B VIRUS**

Hepatitis B virus is a DNA genome. The infectious part of the virus is its nucleus, which is surrounded by a complex structure (nucleocapsid) containing several proteins. It is circular, partially double stranded. Hepatitis B virus has one dominant neutralizing epitope (antibodies against one strain of HBV will protect against all strains) but multiple serotype result from variations in two minor epitopes. Acute systemic infection transmitted by parenteral route via injections and transfusions, through sexual contact, mother to child (vertical), one infant to another and through unknown routes (in at least 20% of case). Incubation period is 6 week to 6 months and median incubation periods is less than 100 days.



**Figure 2.** Morphology of Hepatitis B virus.

In approximately 5-15% of cases, HBV infection fails to resolve and affected individuals become persistent carriers of the virus HBsAg the surface antigen: HBsAg is present in the blood stream during acute disease and in the carrier and chronic stage. Only 1% of chronic carriers clear their infection each year. Carriers are more likely to have had an asymptomatic rather than symptomatic form of hepatitis B (Figure 2).

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## THE INDIAN SCENARIO

India comes under the 'Intermediate' endemicity (2-7%) zone as the mean national surface antigen carrier rate is around 4.7%. Assuming the population of India to be around 900 million, there is an estimation of 42.5 million carriers in the country. HBV infection in selected high risk groups in India ranges between 12-74%.

## EVALUATION OF OUTBREAK

### Outbreak investigation

The first suspected case of hepatitis was admitted on the 26<sup>th</sup> January 2009 in Modasa hospital. However, it was perceived as an outbreak on 10<sup>th</sup> February 2009 on the basis of clustering of cases in Modasa town and active surveillance initiated promptly on 10<sup>th</sup> February 2009 by creating 12 teams, in Modasa towns and information were collected from private hospitals of Modasa. Case definition for identification of acute case was followed as per the national experts which include a case having HBsAg positivity (By ELISA) with SGPT level > 400 IU. During surveillance, persons having history of taken injection within the last six months, surgical procedure, dental procedure, tattooing and contact of found new cases are identified as high risk groups. And these high risk groups are specifically covered under mass vaccination drive for the control of Hepatitis-B. Subsequently from 11<sup>th</sup> February 2009, surveillance had been started in all blocks of Sabarkantha District.

The response to the outbreak situation was decided on the basis of investigations jointly done by state involving epidemiologist from Indian Institute of Public Health (IIPH), Gandhinagar and B. J. Medical College Ahmedabad; a team of public health experts from National Institute of Communicable Disease, Delhi; National Institute of Virology, Pune; All India Institute of Medical Science, New Delhi. A team of one Epidemiologist one Microbiologist is stationed at Modasa to help the local authorities in disease control measures and the details of the control measures are as follow:

1. Strengthened health care services delivery by deputing specialists, medical and paramedical personnel from different districts.
2. Multi pronged sustained IEC activities have been carried out by utilizing various methods like newspapers, cable TV, hoarding, pamphlets, and meeting of elected members, media and community on: Avoiding injections and insist on disposable/sterilized.
3. Self reporting of jaundice cases, showcasing of mass vaccination campaign.
4. Patient care is being provided through following:

- a. Patients have been admitted in the Sarvjanik hospital at Modasa for the treatment decided as per the standard protocol provided by the state.
- b. Four additional physicians were posted from adjoining districts to assist the hospital. Two doctors from Biliary Institution, New Delhi were deputed to provide help for patient management and laboratory aspects.
- c. The supplies of drugs, logistics and other related things required for patient management, dialysis and ventilatory support facilities were made available in adequate quantities.

d. Facility of ambulance vans have been made available for timely referral of the patients to higher medical centers, if required.

4. Laboratory testing of patients for anti HBc antibody and HBe antigen for HBs positive at BJMC and Modasa strengthening of local CHC and trust hospital separate ward at Sarvjanik Hospital, Modasa. Four ambulances placed for transfer of cases.

5. Vaccination started for care providers were later implemented for entire population

a. The immunization session was well set - up.

b. The staff engaged in this activity was well informed, trained and adequate in numbers.

c. A consent form in local language explaining the usage and limitations of the vaccine was in use. The vaccines were being given a vaccination card and also explained about the need of subsequent 2 doses.

d. The vaccine being used was a recombinant vaccine from Bharat Biotech International Limited. The dose being given was 0.5 ml up to 10 years of age and 1 ml above 10 years old.

e. The disposable syringes and needles supplied by the State Government were being used.

f. Proper bio-medical waste disposal practice being followed.

g. The staff giving the vaccines had also received the vaccination on the first day of the vaccination campaign itself.

The team members also visited some of the families of the admitted patients to elicit, the history of exposure to injections etc in the recent past. The team also elicited the knowledge of the community about this disease during these visits.

### **Preventive measure taken**

1. Field surveillance: Health staff surveyed 2,97,000 people of Modasa taluka in 1 week to detect 14,000 people with suspected exposure and are being followed on weekly basis for the symptoms and if need be for prompt referral. Those suspected are put on sero surveillance on protocol agreed upon by national experts. Blood collected by 26 teams from patients, suspected cases and contacts 4334. Community survey in a stratified sample: Assessment of presence of Hepatitis B antigen in the community as suggested by NICD experts is proposed to be done in short time in age and sex stratified sample of population from those areas which have not reported any case in current outbreaks.

2. Emphasized on the importance of IEC on safe injection practices covering following three major groups: Community members; healthcare providers, those involved in injection practices and blood collection for

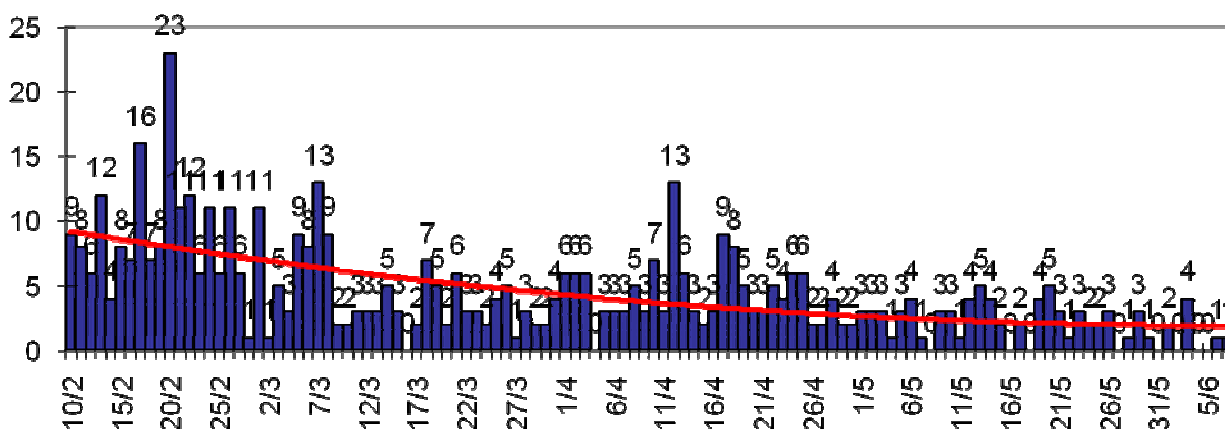
laboratory testing and traders involved in supply of syringes and needles.

3. Mass vaccination started from worst affected Modasa town on 23<sup>rd</sup> February 2009 after intensive IEC activity by establishing 62 booths with the facilities of cold chain maintenance, use of disposables, biomedical waste management. All beneficiaries have been registered, with signed consent. On 23<sup>rd</sup> and 24<sup>th</sup> February 2009, 74592 people were vaccinated by Hepatitis – B vaccine (first round), 61817 (second round, 22<sup>nd</sup>-23<sup>rd</sup> March), 40073 (third round, 3<sup>th</sup>-4<sup>th</sup> May)

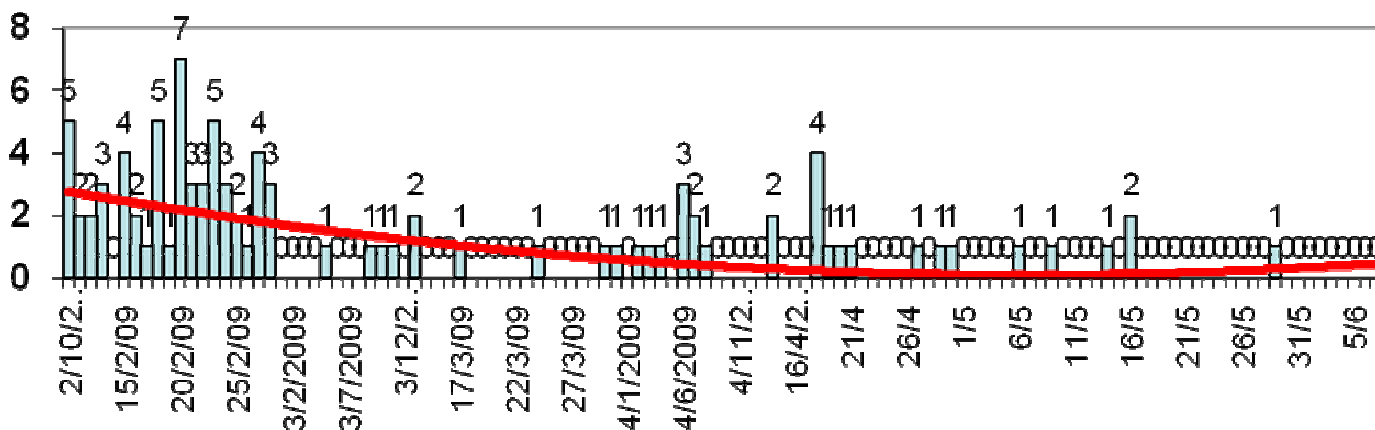
4. It was found that private clinics and hospitals are not following strict guidelines of BMW disposal as per the Act during investigation operation. Some clinics and hospitals were providing their BMW to local scrap handlers which were sent for recycle in illegal way. Legal actions have been carried out against such private Practitioners as well as scrap traders not only in Sabarkantha but in all districts of the State. All private medical practitioners are instructed to follow strict BMW disposal rules in written. A seminar of BMW disposal have been organized under the chairmanship of Hon'ble Health Minister, principal secretary (Health and FW) and commissioner of health at Gandhinagar and same programme was followed up to field level.

### **Treatment protocol**

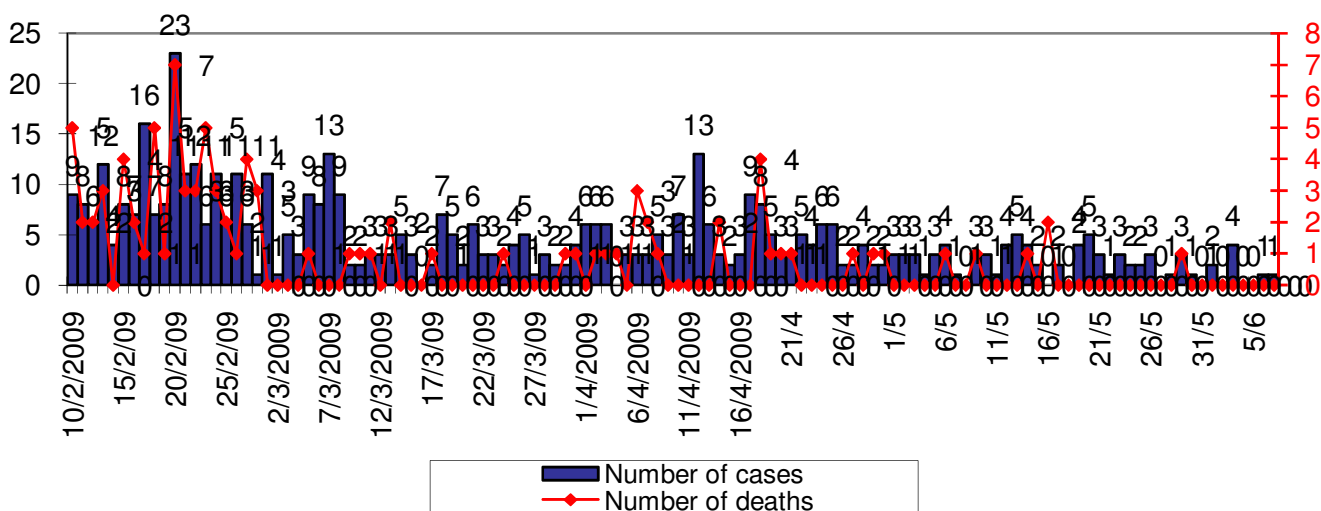
Professor B.D. Mankad, Head Department of Medicine B.J. Medical College, Ahmedabad presented the treatment protocol. He informed that the treatment protocol has been developed by experts from AIIMS, New Delhi; SGPGI, Lucknow and a physician from Central Team from Government of India. The treatment protocol highlights the patient management guidelines in various clinical situations along with the use of prophylactic antibiotics and anti-fungal for possible co-infections. Professor Mankad informed that though there is no documented role of anti-viral in the treatment of acute hepatitis B, the physicians were considering the use of Lamivudine for 2-3 months in the light of high mortality being observed. DGHS assured that technical inputs from experts on this issue would be made available. The first suspected case of hepatitis was admitted on the 26<sup>th</sup> January 2009 in Modasa hospital. However, it was perceived as an outbreak on 10<sup>th</sup> February 2009 on the basis of clustering of cases in Modasa town and since then a total of 137 cases and 43 deaths (case fertility rate = 31%) as on 27<sup>th</sup> March 2009 have been reported. The preponderance of cases (80%) has been reported from Modasa taluka of Sabarkantha District. The cases have also been reported from other talukas of the district (Meghraj, Himatnagar, Bayad, Bhiloda, Idar, and Vijaynagar) as depicted in the map. The distribution of cases and deaths in various talukas is depicted in Figures 3, 4, 5, 6, 7, 8 and 9.



**Figure 3.** Day-wise details of admissions and deaths from 10<sup>th</sup> February 2009 till 25<sup>th</sup> March 2009 is depicted in figure showing daily status of Hepatitis-B outbreak cases, Modasa, Gujarat. As on 25/3/09 it suggest high rate of incidence from 17<sup>th</sup> February to 7<sup>th</sup> March.



**Figure 4.** Showing daily status of Hepatitis-B outbreak deaths, Modasa, Gujarat, as on 7/6/09 which suggests high rate from 15/2/09 to 28/2/09.



**Figure 5.** Showing daily status of Hepatitis-B outbreak cases and deaths, Modasa, Gujarat, as on 7/6/09.

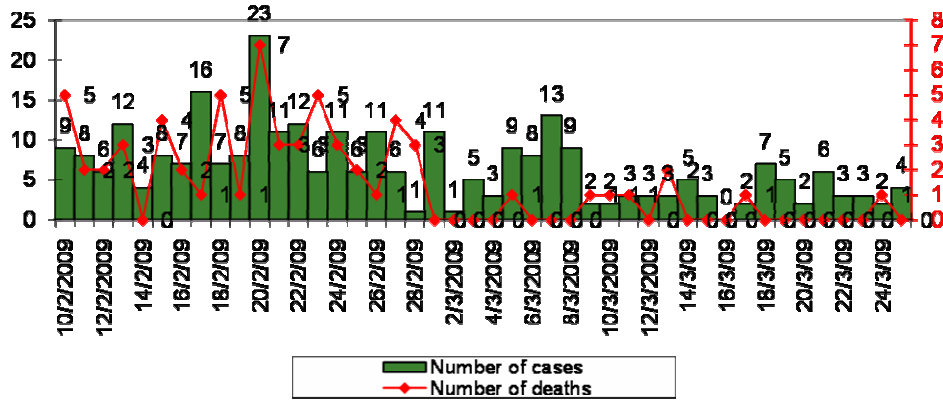


Figure 6. Showing daily status of Hepatitis-B outbreak cases and deaths, Modasa, Gujarat, as on 25/3/09.

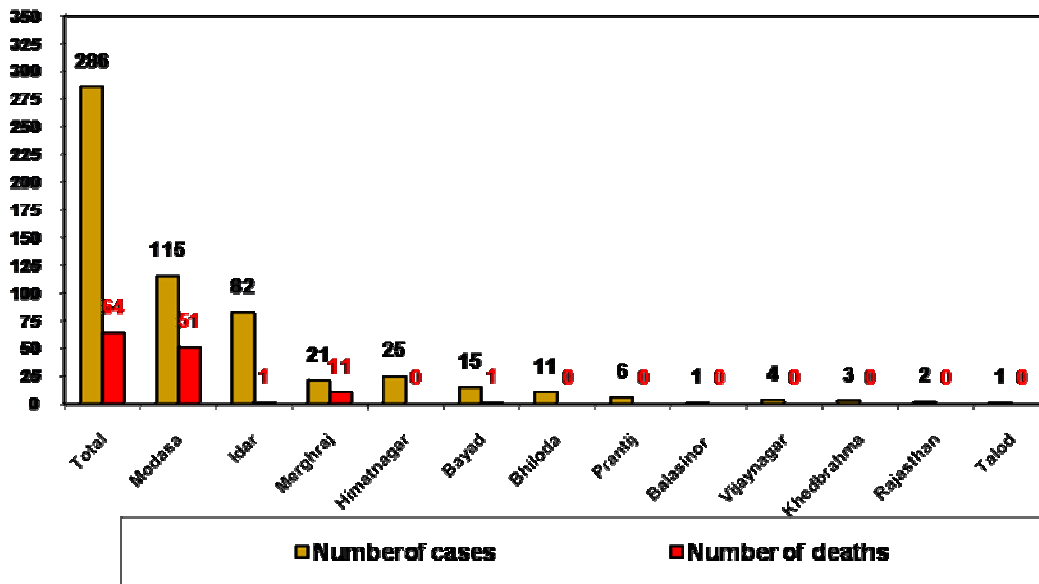


Figure 7. Showing block wise status of cases and deaths due to Hepatitis-B as on 25/3/09 which shows high incidence in Modasa and Idar blocks while case mortality in Modasa and Meghraj.

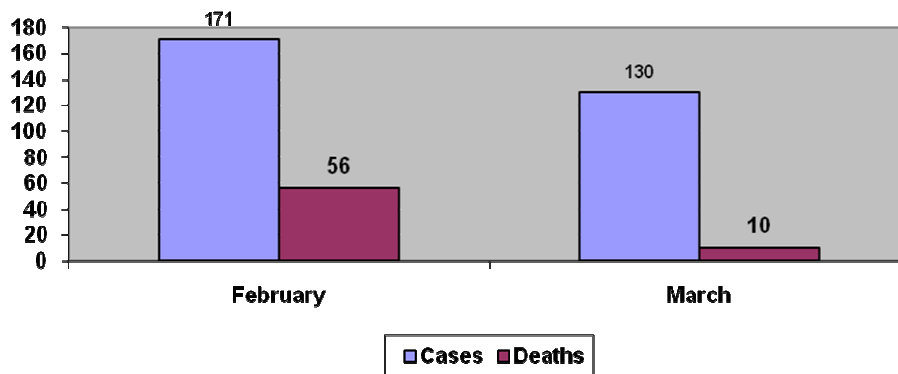
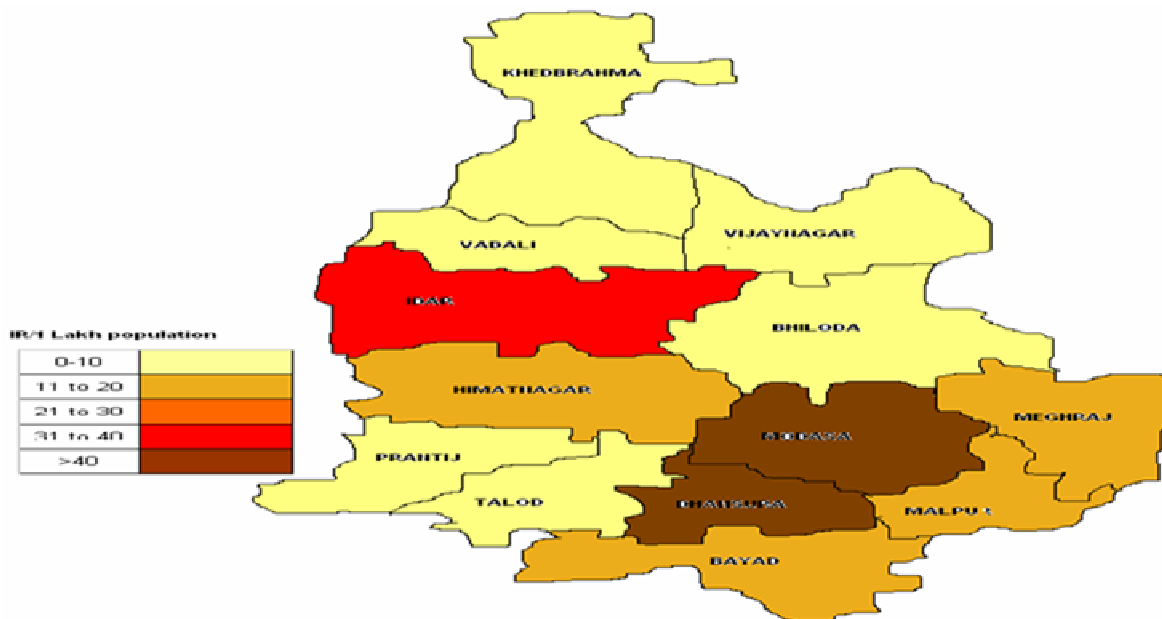


Figure 8. Month wise incidence of cases and deaths reported of Hepatitis-B in Sabarkantha district as shown suggests remarkable reduction in gravity of both due to public health measures taken.



**Figure 9.** Showing blockwise incidence rate/100000 population for Hepatitis- B outbreak in Sabarkantha Gujarat, February to March, 2009 as on 7/6/2009.

**Table 1.** Hepatitis-B analysis by age and sex Sabarkantha, Gujarat, as on 7/6/09 shows that male are affected more and population within 13 to 45 years of age group is prominently affected.

Variable		Number of case	Number of death
Age group (Year)	0-12	24	3
	13-45	394	65
	>45	94	25
Sex	Male	317	60
	Female	195	33
Total		512	93

**SITUATIONAL ANALYSIS**

Of the total cases, 24 have been discharged and 43 expired while the others continued to be admitted in various hospitals. 91 cases are males and 46 females (M: F -2:1). Most of the cases are in adolescents and adults and 1 case has been reported among < 5 year age children. The cases were presented with history of fever, nausea, vomiting, abdominal pain discomfort and developed jaundice followed by convulsions, altered sensorium leading to coma. Some patients developed renal failure. The laboratory investigations done on 10 samples of cases at NICD laboratories and on 14 samples at NIV, Pune laboratories revealed HBsAg positivity, IgM antibodies to hepatitis B core antigen, and high HBV viral load. The samples tested negative for hepatitis C, hepatitis E, HIV, leptospirosis and dengue.

In one case, the presence of hepatitis D (HDV) was demonstrated at NICD laboratories. Director NIV informed that in 3 cases, mutant HBV was observed explaining the reason of high mortality in the present episode. The epidemiological investigations revealed that of 56 cases, 27 had history of injection during incubation period of which 18 were given by a private practitioner of Modasa. The following results have been found in the event of Hepatitis-B outbreak in Sabarkantha District as shown in Tables 1 and 2. Out of 184 affected villages, clustering of cases (>4 cases reported) have been found amongst 6 villages (3.2%). Similarly, high deaths (>2 deaths/village) have been found in 6 villages (3.2%) out of the total 184 affected villages as shown in Table 3.

According to analysis duration of deaths, out of the total 66 deaths, the virulence of prevalent virus shows that > 68.2% of deaths had occurred within 1 to 6 days after

**Table 2.** Total Number of Villages along with their names wherein clustering of hepatitis cases occurred.

Number of case	Number of village	Name of high risk village with cluster of case
1	135	-
2	36	-
3	07	Bhachadiya, Medhasan, Davali, Mathasuliya, Umedpur, Gujarava, Goral.
4	03	Bodi, Varthu, Mathasur
5-9	01	Gambhirpura
>10	02	Modasa Town, Idar Town
<b>Total</b>	<b>184</b>	

**Table 3.** Names and number of villages wherein deaths occurred in patients of Hepatitis B during the outbreak

Number of death	Number of Village	Name of high risk village for death
0	139	-
1	39	-
2	03	Bherunda, Sayra, Jesingpura
3	02	Mathasuliya, Varthu
>4	01	Modasa Urban
<b>Total</b>	<b>184</b>	

**Table 4.** Indication of duration of indoor stay in a hospital in number of deaths due to Hepatitis B patients.

Number of day patient died after admission	Number of death (%)
1-2	13 (19.7)
3-4	24 (36.4)
5-6	08 (12.1)
>7	19 (28.8)

admission as shown in Table 4.

## CONCLUSION

Based on the available clinical, epidemiological and laboratory investigation reports the outbreak is due to acute hepatitis B viral infection leading to acute fulminant viral hepatitis in some patients. There has been evidence of anti-delta antibodies in just one patient and hence the possibility of involvement of hepatitis D virus which is usually associated with high mortality in HBV-infected individuals looks less- likely. There is at present no evidence of any other co-infection which could contribute to the increased mortality. There is need to find out the possibility of circulation of a naturally modified hepatitis B

virus mutant (HBV mutant) which could account for high mortality. Preliminary laboratory results indicate presence of both common and mutant viruses. There is also need to find out the role of host factors and other co-infections. There is strong evidence of unsafe injection practices in the affected areas.

## RECOMMENDATIONS FROM TEAMS VISITED

### DGHS team

1. Strengthen the awareness campaign to inform the community about modes of HBV transmission and the preventive measures required. This IEC campaign should also include those engaged in taking blood samples,



preparing blood smears and health workers in general.

2. The standard treatment protocol developed by a group of experts should be adhered to by all the treating health facilities. The protocol should be regularly reviewed and updated based on the clinical findings.

3. Ensure the availability of drugs, logistics and trained manpower for management of the patients.

4. Since the disease has a long incubation period the surveillance for timely detection of cases needs to be maintained for at least 6 - 9 months.

5. Use of paracetamol in jaundice patients both in the community and the hospitals should be discouraged.

6. Discourage the unnecessary use of injections, and promote the safe injection practices, and safe bio-waste disposal be continuously done at all the levels.

7. For ascertaining the reasons of high mortality, the following are recommended:

a. Look for HBV mutants.

b. Monitor the presence co-infection with other viruses / infectious agents.

c. Test for hepatitis delta virus in some more samples.

d. Carry out age stratified sero survey in the affected community to know the extent of the exposure.

8. The regulatory agencies should strictly enforce the mechanism to ensure that no used syringes etc. are recycled for use in the market.

9. Mass vaccination in worst affected areas.

10. Liver clinic as long term plan in Modasa city.

## **State rapid response team**

### ***Active surveillance***

### ***Public health interventions***

#### ***Deployment of rapid response teams***

1. As per the existing protocol along with the Chief District Health Officer Physician and Microbiologist of District Civil Hospital–Himmatnagar of District Sabarkantha made an immediate visit to the outbreak area of Modasa for primary assessment of patients and collection of serum samples for confirmation of the diagnosis. The local team visited patients who were admitted in a local NGO hospital and private nursing homes and collected serum samples, examined them and came out with a diagnosis of Hepatitis-B, based on which reports were to the state level.

2. Looking to the magnitude of the problem, rapid response team from B J Medical College and Civil Hospital Ahmadabad comprising physician, microbiology and epidemiologist was deputed from state level to Modasa to further investigate the outbreak on and based on their reports. Diagnosis was confirmed State RRT

evaluated patients again, re-examined serum samples at Medical College and also provided treatment and referral protocol for the patients and suggested preventive actions.

3. Deputy director (Epidemic) who has been identified as a Nodal Officer made a first visit to Modasa after evaluating the reports of the RRT and visited all patients who were admitted in different private nursing homes at Modasa, assessed biomedical disposals, visited the private pathologist laboratories, assessed the diagnostic kits being used and gathered the information of local patients referred outside Modasa and being treated at Ahmadabad- both at Medical College Hospital as well as in private and corporate Hospitals of Tertiary care.

4. A system of active surveillance was put on immediately in the whole of the district with predesigned uniform format to be used by peripheral field level staff.

5. Control rooms were set in immediately at Modasa block, district and state level with all facilities for transmission of information, feedback and consultations on the issues. It was also decided to collect information on new cases being admitted, those who are under treatment are being referred elsewhere and cases who got expired on a day to basis and merge this information with that of Modasa Sarvjanik Hospital (RSS Hospital-a local NGO hospital identified as first referral unit) to have an overall compiled data.

Besides immediate actions were taken to depute additional staff like physician, microbiologist, laboratory technicians, X-ray technician and staff nurses to the RSS Hospital to cope with an additional intake of patients.

6. RSS hospital Modasa was declared as a referral centre where all investigations and treatment was declared free to all patients of Hepatitis-B and the free laboratory services were offered even to the patients who were undergoing treatment in private nursing homes at Modasa. This was basically planned to have uniformity of diagnostic protocol being followed in Modasa and to have reliable results by Elisa confirmation

7. Elisa confirmation being more reliable; this testing facility was immediately made available at RSS Hospital-Modasa and after primary screening of samples by rapid card test. All positive samples and 10% of negative samples were initially re-tested by Elisa and within a couple of days a total testing was switched over to Elisa.

8. Primary discussion was held in confidence with the Chief District Health Officer Sabarkantha and Assistant Food and Drugs Commissioner District Sabarkantha to organize a surprise check up of certain chemist shops and clinics of private doctors since primary information collected so far gave indications that Hepatitis-B patients who were diagnosed had the history of receiving injections due to medical reasons from certain fixed clinics in the previous six months and to rule out the doubts of recycled or reused and repacked disposable syringes and needles. It was planned to collect samples also during the random visits jointly by the combined action group of medical officers and food and drugs

department officials

### **Surveillance activities**

1. Local rapid surveillance of Modasa hospitals along with the local areas was done on the very first day by deploying medical teams framed of medical officers and paramedical workers (MPHW) to have the immediate estimate of the problem which was brought to the notice of local block health officer by relatives of some of the patients who were under treatment and they also informed of few deaths in recent days due to Hepatitis-B in Modasa and at Ahmadabad.
2. CDHO-SK and EMO (district surveillance officer-SK) implemented house to house survey with a mandate given to the surveillance format itself to look for clinical symptoms like fever, nausea and vomiting, general weakness, pain and tenderness in hepatic region and appearance of jaundice—yellowish discoloration of sclera, nails and skin.
3. The survey also included questioner to elicit information of high risk behavior of the households in the sense of receiving any injections or intravenous fluids, undergone any surgical or laboratory procedures, dental extractions, blood transfusion, tattooing and also on history of exposure during the period of previous six months.
4. If during history taking; positive information was coming up then the information on name of the treating doctor and place of clinic were collected in the household concerned.
5. As fresh cases were also reported from adjoining block of Meghraj, survey was extended over also and within just couple of days (one week) a massive task of this house to house active surveillance at field level was finished by dedicated efforts.
6. This activity subsequently helped us to a greater extent in terms of making available to us an estimated number of high risk group of individuals for subsequent follow-up. Besides, it also trained staff and made them aware of Hepatitis-B clinical presentation and etiological aspects as well created community awareness of the magnitude which is essential for self-reporting in such situations.
7. High risk group of persons as listed by the survey are periodically visited by health workers —being evaluated and if found suspected of having any clinical symptoms — medical officer of concerned primary health centre is immediately informed who will in turn visit the suspected patient immediately —evaluate the case and will undertake immediate Lab investigation.
8. MOPHC has provided pre-designed formats to document every visit of such a suspected case and tracking is done once the case gets confirmed.
9. Two village level informers have been identified at least in every village to keep inform what has been the ongoing progress of such high risk group of persons in

their vicinity and some of these informers are contacted by daily telephone call from the block office by block IEC officer and these activity also gets monitored in the system of reporting

### **Media management**

1. Media —both print and electronic media are well managed by Frankly briefing and discussing with them the ongoing events on a day-to-day basis and allowing them to have proper coverage of high level meetings and discussion with national expert teams
2. Daily updated final reports are displayed at the end of the business day (that is, 18 P.M.) on public notice board outside the block office to pacify the anxiety prevailing.
4. All press cuttings are maintained in a file and are actively followed up for validation of useful information.
5. An effective Linkage is maintained with media to spread important health messages to the community with their continuous support.
6. A number of instances even printed version of reports are provided to media to sustain their confidence level in government efforts.

### **IEC activities**

1. Concurrent actions were taken up at commissioner of health services-Gandhinagar office to prepare-update and display area-specific, well designed IEC material with scientific messages in terms of hoardings, posters and news-paper advertisements —all containing coherent and focused do's and don'ts while receiving injectables under unavoidable circumstances and clear instructions on bio-medical safety both for public and medical and laboratory professionals.
2. Besides scrolling of IEC messages on local video channels, vernacular language was a continuous phenomenon
3. Special IEC efforts were done at the time of mass vaccination of hepatitis-B in Modasa town (population roughly 60000) to obtain proper mobilization, for their reassurance and not to remain in a state of complacency since this vaccine was not a substitute for stringent bio-medical waste management protocols.
5. Surveillance activities were continued and community was continuously encouraged to do a voluntary self reporting on acquiring of any of the aforementioned listed complaints

### **Referral transport assistance**

Right from day-one, free ambulance services were made available at RSS hospital-Modasa for free of cost referral of Hepatitis-B patients within and outside the Sabarkantha

District and even for transportation of dead bodies of the unfortunate victims of the disease for referral of critical patients to Ahmadabad- Three 108 well equipped ambulances were deployed round the clock.

### **Case definition**

1. Looking to the endemic situation of Modasa block, simultaneous reporting of Hepatitis-B cases from number of villages in blocks of District: Sabarkantha, it was inferred that the problem was quite widespread.

2. In such a situation, it was necessary to apply special criteria for confirmation of a true clinical case in settings of District: Sabarkantha otherwise, so many carriers of Hepatitis-B would be registered as clinical entities and will inflate the data and distort the true epidemiological picture.

3. It was felt by the experts that in such a situation, normal SGPT levels will usually be raised at community level and a cut-off value of 10 times of normal range (15-40 i.u.) should be applied to exclude false positive clinical cases. Hence, the case definition for confirmed cases of Hepatitis-B was fixed with the following criteria only for District: Sabarkantha- HBsAg+ve; IgM Anti-HBc+ve; HBeAg+ve and SGPT levels of 400 i.u. and above.

4. As this case definition was meticulously applied in subsequent registering of confirmed cases and reporting to the authorities of cases and deaths of Hepatitis-B on a daily basis, discrepancies did prevail amongst figures reported in print and electronic media as well as official figures; still the scientific views were adhered to and explained. The criteria for confirmation were not applicable to the sporadic cases of Hepatitis-B being reported from other districts of the state and they were not included in the daily reports of outbreak of Hepatitis-B (as they belonged to areas outside epidemic region) but a separate mention was done to maintain transparency in public records.

5. As such sporadic cases of Hepatitis-B being reported by other districts of Gujarat amounted to cases and deaths up to-

6. Cases of Hepatitis-B who belong to other places outside Sabarkantha district but were treated in Modasa were included in the reports, if they provided the history of local stay for 6 months and above

### **Anti-viral treatment**

1. Expert group probably for the first time considered treating of diagnosed and evaluated cases of Hepatitis-B in public health settings with an anti-viral drug tablet Lemivudine after proper evaluation of each and every case separately.

2. The following protocol was devised and implemented for starting anti-viral drugs

3. Patients were selected mainly on the basis of their Investigations: Symptomatic patients, with clinical jaundice, SGPT>400, HBsAg +ve, Anti HB core-Ag, IgM +ve, e Ag +ve).

4. Gradually, it was realized that lot of time is lapsed to start antiviral treatment even in a critical patient in the absence of reports of investigations- hence as per the advice of the expert team which visited Modasa on 12-13<sup>th</sup> April-2009 that antiviral should start immediately in a confirmed case on Day-1 and may be reviewed in light of reports later on.

5. Because of this intervention itself antiviral coverage got improved.

### **Mass vaccination**

1. After careful deliberations with local teams and overall review of the development and occurrence of good number of cases of Hepatitis-B from Modasa Town itself and noting of the fact that Modasa Town had attained an Endemic status of the problem-lot of exposure of the local population to the prevailing virus and since there was no reliable information available what no of people of Modasa might have received Injections contaminated with Hepatitis-B virus from the accused Local Doctor over a period of time before the problem was noticed as an epidemic as well as ongoing possible transmission of the virus in the Town- the expert <sup>Team</sup> suggested for Mass Hepatitis-B vaccination immediately

2. Mass vaccination was considered as a tool to check the secondary transmission of the virus at community level

3. Vaccination schedule was compressed in three (3) doses at 00, 01 and 02 months intervals in the outbreak situation

4. Calculated risk was taken in this process since mass vaccination was assorted via the same Injectable route in the given situation-and any negligence would aggravate existing problem statement.

4. It was a challenge to procure required number of adult and pediatric doses of the vaccine along with auto disable-disposable syringe needles etc. just within few days and mobilize to Modasa.

5. Peripheral health staff required in large number had to be identified and shifted to Modasa with a previous day stay arrangements.

6. A detailed training on safe injection practices and biomedical disposal aspects as per prescribed norms was impacted by subject experts on the previous day with audio-visual presentations and demo given.

7. Needful equipments like color coded plastic bags, containers, hypochlorite solution; surgical and thick rubber hand gloves etc were supplied along with necessary literature right on the previous day and mobilized to identify locations of vaccination booths.

8. Estimated population of Modasa was 60000 and extra

provision of vaccine was made to the tune of 25%

9. Entire city was divided in 60 vaccination booths on the basis of intensified polio vaccination PROGRAMME and the same population was allotted

10. Advance IEC was done with greater intensity.

11. Banners were displayed to guide the people to the site of vaccination.

12. Required number of formats and registers were printed in advance to maintain proper records-booth wise.

13. Cold chain was constantly maintained and mobile teams were provided to supply vaccine-ice, syringe needles and other items for biomedical waste.

14. Special arrangements were done for periodic collection of biomedical waste from vaccination booths and the final lifting and disposal at the end of the business day by the identified agency

15. Out of panicky situation, it was anticipated that people from nearby surrounding villages would turn up on the city booths for Hepatitis-B vaccination and it exactly happened so.

16. Still they were given the vaccine

17. People who received the injectable vaccine were informed of the fact that this vaccine may not have an expected effect on the mutant virus identified and they may develop the disease in spite of vaccination-possible signs/symptoms of the disease and when they should report for due treatment and investigations- as well as the next due date of vaccination.

18. To achieve a desired coverage, it was decided to extend the vaccination programme at 3 sites for another 2 days.

19. Co-operation of police Department –Home guards and volunteers was taken to maintain law and order situation on every booth.

20. Full support was assured from local administrators and leaders by involving them in the process of mobilization of the community

21. Media was properly briefed and proved very supportive

### ***Important statistics (As on 12<sup>th</sup> April -2009)***

1. Out of 360 confirmed cases of Hepatitis-B in District: Sabarkantha history of receiving injections in previous six months was available, 142 patients from 61 different private medical practitioners and nursing homes.

2. While history of receipt of injection in the previous six months could be elicited in 56 unfortunate patients who died.

3. History of receipt of injection from a private practitioner- allopathic doctor with M.B.B.S. qualification- was given in case of 68 confirmed patients of Hepatitis-B and also in 45 patients who died subsequently.

4. Out of persons who have been registered as suspect patients of Hepatitis-B by ongoing day-to-day village-wise surveillance activities, 95 patients could be registered on

the basis of clinical and microbiological criteria and a special area-specific case definition strictly adhered and applied to District Sabarkantha and Modasa-as suggested very initially by national expert teams which has been religiously followed throughout till date.

5. So far, 13 deaths have also been recorded among the patients who were diagnosed out of suspects found during survey. As on 12<sup>th</sup> April 360, total cases have been registered as confirmed cases of Hepatitis-B with deaths and cases in the pediatric age group of 0-12 years.

6. Out of 360 total cases the history of developing Hepatitis-B amongst close contacts had been available in 4 patients.

7. Out of 360 total cases about 145 patients developed from the high risk group of persons who are under continuous vigilance by the local health administration.

8. It is worthwhile to note that 2 patients registered in Modasa provided history of receipt of 1-2 dose of Hepatitis-B vaccination during the Modasa town mass administration campaigns.

9. History of discharge and re-admission to the health facility for Hepatitis-B treatment was available in 2 patients.

### **Prevention**

All infants should receive the hepatitis B vaccine: This is the mainstay of hepatitis B prevention. The vaccine can be given as either three or four separate doses, as part of existing routine immunization schedules. In areas where mother-to-infant spread of HBV is common, the first dose of vaccine should be given as soon as possible after birth (that is. within 24 h). The complete vaccine series induces protective antibody levels in more than 95% of infants, children and young adults. After age 40, protection following the primary vaccination series drops below 90%. At 60 years old, protective antibody levels are achieved in only 65 to 75% of those vaccinated. Protection lasts at least 20 years and should be long life. All children and adolescents younger than 18 years old and not previously vaccinated should receive the vaccine. People in high risk groups should also be vaccinated, including: Persons with high-risk sexual behavior; partners and household contacts of HBV infected persons; injecting drug users; persons who frequently require blood or blood products; recipients of solid organ transplantation; those at occupational risk of HBV infection, including health care workers; and international travelers to countries with high rates of HBV.

The vaccine has an outstanding record of safety and effectiveness. Since 1982, over one billion doses of hepatitis B vaccine have been used worldwide. In many countries where 8 to 15% of children used to become chronically infected with HBV, vaccination has reduced the rate of chronic infection to less than 1% among immunized children. As of December 2006, 164 countries

vaccinate infants against hepatitis B during national immunization programmes a major increase compared with 31 countries in 1992, the year that the World Health Assembly passed a resolution to recommend global vaccination against hepatitis B.

## Treatment

There is no specific treatment for acute hepatitis B. Care is aimed at maintaining comfort and adequate nutritional balance, including replacement of fluids that are lost from vomiting and diarrhea. Chronic hepatitis B can be treated with drugs, including interferon and anti-viral agents, which can help some patients. Treatment can cost thousands of dollars per year and is not available to most patients in developing countries. Liver cancer is almost always fatal, and often develops in people at an age when they are most productive and have family responsibilities. In developing countries, most people with liver cancer die within months of diagnosis. In higher income countries, surgery and chemotherapy can prolong life for up to a few years in some patients. Patients with cirrhosis are sometimes given liver transplants, with varying success

## DISCUSSION

On exploring the history of the patients who suffered with Acute Hepatitis-B in this outbreak it was found that out of 574 confirmed cases of Hepatitis-B 210 patients had given history of receipt of injection in preceding six months due to some or other reason.

It is worthwhile to note that out of above 210 recipients of Injections 93 patients had received injection from a single local General Medical Practitioners in Modasa and out of above 93 patients 51 patients had died due to Acute Hepatitis-B.

Ultimately legal actions were initiated against that Doctor and a Police complaint was lodged by incorporating appropriate rules.

We have noticed similar findings in a similar publication pertaining to Khata-Amba, Parsa and Charadu of Mehsana district of Gujarat in January 1997 (World Health Organization 1996, 76(1), 93-98) published by Singh et al. (1996). Wherein use of unsterilized injection practices had been the root cause.

Normally Acute Hepatitis-B does not have such a high mortality but a concomitant Hepatitis-D infection (HDV) results into significant higher death rates in HBV patients. This association of HBV and HDV was observed also in the HBV Modasa outbreak as reported by National Center of Disease Control, New Delhi report by Dr Arvind Rai dated 2<sup>nd</sup> March 2009 which indicates presence of Genotype D in 5 samples tested (NCDC, 2009.)

Ongoing outbreak of Hepatitis-B Modasa was studied in greater detail by National Institute of Virology, Pune-India.

As per the published article in Journal of Viral Hepatitis online on 26<sup>th</sup> November 2010 (Willey Online Library) (Arankalle et al., 2010) mentions that on sequence analysis of the serum samples of patients of Acute Viral Hepatitis from Modasa at National Institute of Virology, Pune-India, showed the presence of Pre Core and Basal Core Mutants and 4 amino acid substitutions exclusively among Fulminant Hepatic Failure (FHF) cases None of the self-limiting patients exhibited these dual mutations. Genotype D was predominant, D1 being present in all FHF cases while D2 was most prevalent in Acute Viral Hepatitis cases.

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## REFERENCES

- Singh J, Bhatia R, Gandhi JC, Kaswekar AP, Khare S, Patel SB, Oza VB, Jain DC, Sokhey J (1996). Outbreak of viral hepatitis B in a rural community in India linked to inadequately sterilized needles and syringes. *Bull. World Health Organ.*, 76(1): 93-98.
- Arankalle VA, Gandhi S, Lole KS, Chadha MS, Gupte GM, Lokhande MU (2010). An outbreak of hepatitis B with high mortality in India: association with precore, basal core promoter mutants and improperly sterilized syringes. *J. Viral Hepatit.*, 10(1111): 1365-2893.
- National Center of Disease Control (NCDC) (2009). The Department of Biochemistry and Biotechnology, New Delhi Report dated 02-03-2009.