Clinical Profile Of Influenza A/H1N1 (Swine Flu) In A Tertiary care Centre (At A Large Teaching Hospital)

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ABSTRACT

Introduction:

A new pandemic, caused by Influenza A/H1N1 virus which emerged in Mexico since March 2009, has already affected India including Vidarbha, causing more than 50 deaths in Nagpur region. Hence it is very imperative to study clinical profile and outcomes of this new infectious disease

.Aims:

1)To study the clinical profile of cases of Influenza A/H1N1 and 2) to assess the factors associated with mortality in these cases

Methods:

Study Design: Ongoing observational analytical prospective study. All suspected cases of Influenza A/H1N1 (n=1062)attending swine flu OPD /emergency from 13th August 2009 to 11th October 2010 were clinically evaluated. They were categorised into C, B and A (mild, moderate and severe respectively) & treated as per guide lines with Oseltamivir (462 cases). Nasal and throat swabs were collected in 159 cases and were sent to NIV Pune for PCR analysis. All these 159 cases were evaluated clinically & followed up for treatment compliance and outcome

Results:

Of the 159 cases tested for Influenza A/H1N1 RT-PCR analysis 52 (32.70%)were positive for Influenza A/H1N1.(Confirmed cases).M: F ratio was1.2:1.Amongst the confirmed group maximum cases25(48.07%) were in the age group of of 21 to 39 years. 11 (21.5%) of the confirmed cases reported within 48 hours. Fever in 40 (76.9%), sore throat 35(67.3 %), cough 34(65.3%), running of nose 32(61.3%), breathlessness 23 (44.2%) were the common symptoms. Congested throat 35 (67.3%), tachycardia 28(28.3%), crepitations 17 (32.9%), cyanosis 5(9.6%) were signs in confirmed cases. Mortality was present in 08 cases (overall 0.75%,tested 5.03%,confirmed 15.38%). None of the expired patients presented in first 48 hours of onset of symptoms, 06 out of 08 expired patients (75 %) had co-morbid illnesses like Diabetes mellitus 3 (37.5%), Hypertension 2 (25%), Ischaemic heart disease 1 (12.5%), PNC state 1(12.5%), and Malaria in 1(12.5%).All suspected & confirmed cases received Oseltamivir in therapeutic doses as per guidelines.

Conclusions :

High index of suspicion and early institution of Oseltamivir therapy, and special care to those with comorbid condition may be beneficial in improving prognosis of Influenza A/H1N1 infection. However, exact predictors of mortality and factors leading to respiratory failure in cases of Influenza A/H1N1 needs to be studied further.

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Introduction:

The Pandemic, Swine Flu is a type of viral fever caused by a new mutated strain Influenza A Virus subtype H1N1 which infects humans. This novel type of virus is a combination of four Influenza viruses(North American Swine, North American Avian, Human Influenza and Eurasian Swine)and represents quadruple genetic assortment(Gene swapping)and is better named as Influenza A/H1N1 to avoid confusion over danger posed by pigs. The disease is highly infectious, much more infectious than seasonal Flu, Humans lack natural immunity against this disease and the people are not vaccinated .Influenza pandemics have also been reported in past, In 1918,Spanish Flu, caused by Influenza A H1N1 caused 50 million deaths. Asian Flu(Influenza AH2N2)in 1957was responsible for 1-4 million deaths and Hong Kong Flu(H3N2), in 1968caused 1-4 million deaths. The current Pandemic has emerged from Mexico since March 2009 and has already affected more than 208 countries, including India. The first case of H1N1 Influenza has been registered 16 thMay 2009 in Hyderabad, and first death from Pune on 3rd August 2009. Pune has emerged as epicenter of this epidemic. Till date, 924 deaths have been reported from Maharashtra, of which More than 50 have been reported from Nagpur district. Therefore, it is very imperative to document clinical profile and factors associated with mortality because of this new infectious disease.[1,2]

Influenza virus, has two surface antigens, Haemagglutinin, (HA1 to 17)and Neuraminidase (N1 to9) which exist in different combinations. The genome of Influenza virus contains RNA which has an imperfect replication mechanism which causes it to mutate at a higher rate. In addition, genome of Influenza virus occurs in eight segments which can easily break apart from one another and attach to genomes of other Influenza virus. The Influenza virus is also known to have phenomena of antigenic shift (gradual change over a period resulting from point mutations) responsible for frequent Influenza epidemics and Antigenic drift when genetic combination of human with animal /Avian virus take place resulting in sudden, complete and major change leading to novel subtypes of viruses different from parent virus, and if such novel virus has sufficient genes from H1 virus which makes it readily transmissible from person to person, it may cause pandemics. There is enough evidence to suggest that Human Influenza virus responsible for last 3 pandemics and current H1N1 pandemic contained gene segments closely related to Avian Inluenza Virus.[1,2]

Materials And Methods:

Present Hospital based, prospective observational analytical ongoing study is being undertaken to document the clinical profile of cases of Influenza A/H1N1 infection and to assess the factors associated with mortality in a tertiary care centre at Indira Gandhi Government Medical College Nagpur from 13 August 2009 to 11 October 2010. All suspected cases(n=1062) of Influenza A/H1N1 attending Swine flu OPD/Emergency were included in the study. All cases were clinically evaluated for signs and symptoms of Influenza A/H1N1 infection. Cases were categorized into C(cases having mild fever ,sore throat, running of nose,600)category- B(high grade fever and severe sore throat in addition to category C symptoms,397)and category-A (category B symptoms and difficulty in breathing, presence of other diseases like Heart, Kidney or Lung diseas,65,) according to guidelines issued by, Government of Maharashtra.[3,4] Category C (Mild)patients were treated symptomatically and followed up and were not prescribed Oseltamivir. Category B patients were treated with Oseltamivir 75 mg twice a day for 5 days (adult dose) in addition to symptomatic treatment and were followed up. Category A patients were advised admission in identified Isolation Ward,, treated with Oseltamivir and other supportive therapy. Of 1062 cases(462 cases were treated with oseltamivir,) and in 159 cases throat swabs and nasal swabs were collected and sent for PCR analysis for detection of Influenza A/ H1N1 virus[3,4]. which came positive only in 52 cases. Detailed clinical profile for Influenza A/H1N1 was studied in 159 cases who were tested for H1N1 (107 negative,52 positive).Confirmed cases were treated with Oseltamivir. All Cases(107 +52) were followed up for compliance with treatment, complications and outcome of the disease. Guidelines issued by Ministry Of Health and Family Welfare, Government of India and Government of Maharashtra, from time to time regarding testing of

patients for influenza A/H1N1 by sending nasal and throat swabs for PCR analysis and management of suspected and confirmed cases of influenza A/H1N1were followed [5,6,]

Results:

There were 107 suspected A/H1N1 negative cases & 52 confirmed cases of A/H1N1. From 13th August 2009 to 31st March 2010, 94 samples of nasal and throat swabs were sent for H1N1 testing of which 19 reported positive (20.2%). However, rom 1st April 2010 to 31st July 2010 , only 6 samples had to be sent of which only 01 was positive for H1N1&from 1st August 2010 to 11 th October 2010 nasal and throat swabs of 59 patients were sent for PCR analysis of H1N1 infection, 32 were positive in the present study indicating that there was increase in number of cases of Influenza A/H1N1 from August 2010 onwards.

Out of 159 cases tested for H1N1 infection,89(55.9%) were males and 70 were females (44.1%), (M:F ratio 1.2:1)10 out of 107 suspected but H1N1 negative cases 08(7.40%) cases were less than 12 years of age 13(12.14%) cases in the age group of 13 to 19 years. Maximum cases 86 (80.37%) were in the age group of 20 to 60 years.

Out of 52 confirmed cases of Influenza A/H1N1,02(3.84%) cases were less than 12 years of age. 07(13.46%) were in the age group of 13 to 19years.,Maximum cases 42(80.76%) were in 20 to 59 age group,& only 01(1.9%) case was above 60 years of age.

Region wise distribution of H1N1 negative cases revealed that 82 out of 107 cases (76.63%), were from Nagpur district region,14(13.08%) from rest of Vidarbha ,05 (4.67%)from Maharashtra outside Vidarbha, and 06(5.60%) from Madhya Pradesh. Among 52 confirmed cases from our centre,45(86.5%) were from Nagpur district region,03(5.7%)from rest of Vidarbha,01(1.9%)from Maharashtra (outside Vidarbha) and 03(5.7%) from Madhya Pradesh

56 out of 107 cases (52.33%) tested negative for H1N1 infection, reported within 48 hours of onset of symptoms while 11 out of 52 confirmed cases (21.5%) reported within 48 hours of onset of symptoms. Fever, cough running of nose were the commonest symptoms in suspected but H1N1 negative cases as well as the confirmed cases.(SeeTable no1) Breathlessness a symptom indicating severe category was also present in significant no of cases. Amongst. clinical signs Congested throat, tachycardia, tachypnoea were commonly seen in both confirmed ,suspected H1N1negative cases of swine flu & those who died. (See Table no.2)

Mortality was present in 03(2.80%) suspected H1N1 negative cases and 08(15.38%) confirmed cases (04male&04females) at our centre .All other patients improved (98.9%). Mean age of confirmed cases of Influenza A/H1N1 who expired was 39.5 years of which 2 were in the age group of 20 to 39 years (25%) and 06 in age group of 40 to 59 years(75%) All the cases who expired are less than 60 years of age.06 deaths (75%) are from Nagpur district region and 02 (25%) from Madhya Pradesh. Mean hospital stay of these cases is 1.3 days(2hours to 3 days).01 female patient was in post natal state (6 days).Mean duration of illness in these cases was 8.6 days ,all of them presented beyond the 48 hours of onset of symptoms(100%)and revealed bilateral extensive opacities on X-Ray chest(100%). All the confirmed cases of Influenza A/H1N1 in whom mortality was present was admitted in critical condition, had significant hypoxia at the time of admission(Mean pO_2 41mmHg, mean oxygen saturation 68.2%) all of these cases were in respiratory failure (Type I) Thrombocytopenia was documented in 03 cases (37.5%)leucopenia in 02(25%)Acidosis in 02(25%),raised SGOT and SGPT in 01(12.5%),increased levels of Alkaline phosphatase in 02,(25%) 01 case was in hypotension at the time of admission. All these cases were administered Oxygen inhalation, were put on mechanical ventilator, & were treated with oseltamivir, and other supportive management in the form of antibiotics, Intravenous fluids, vasopressors, Insulin (where ever recommended) . Associated comorbid illnesses in these cases of H1N1 influenza who expired, have already been mentioned in table no.2.

There were no serious side effects of oseltamivir therapy in our study and Oseltamivir was well tolerated by most of the patients. .Nausea ,vomiting, giddiness and drowsiness were the reported side effects only occasionally.

Table 2: Comorbidities in cases of H1N1 Influenza in various categories

Comorbid condition	Suspected Cases H1N1 negative(n=107) (%)	Confirmed cases (n=52) (%)	Expired cases of H1N1 influenza (n= 08) (%)
Bronchial asthma	06(5.6)	3(5.7)	0 (0.0)
COPD	01(1.86)	0(0.0)	0(0.0)
Pulmonary Koch's (treated)	03(2.80)	0(0.0)	0(0.0)
Diabetes mellitus	08(7.47)	3(5.7)	03(37.5)
IHD	03(7.47)	2(3.8)	01(12.5)
Anaemia	10(9.34)	4(7.6)	02(25)
Obesity	13 (12.14)	2(3.8)	0(0.0)
Pregnancy	06(5.66)	2(3.8)	0(0.0)
Malaria	01(1.80)	1(1.9)	1(12.5)
Hypertension	14(13.08)	2(3.8)	002(25)
hepatitis	02(1.86)	0(0.0)	0(0.0)
HIV (immunocompromised state)	01(0.6)	0(0.0)	0(0.0)
PNC	01(0.93)	01(1.9)	01(12.5)
Epigastric tendeness	02(1.86)	Zero	Zero
Systolic murmur	02(1.86)	Zero	Zero

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Discussion:

As this new pandemic caused by Novel Influenza A /H1N1 virus was declared, swine flu OPD was started at our centre and patients were evaluated and treated as per guidelines issued by Government of Maharashtra, Ministry Of Health and Family Welfare, Government of India, in collaboration with WHO [8]. Initial guidelines mentioned that all suspected cases should undergo PCR analysis for detection of Influenza A/H1N1 virus, nasal and throat swabs were collected and sent at NIV Pune and treated with Oseltamivir if the report is positive for H1N1. Accordingly, in initial period number of patients

tested for presence of H1N1 Influenza was more and numbers of patients treated with Oseltamivir were comparatively less. However, once it was confirmed that the H1N1 epidemic had established, and as the number of positive H1N1 cases increased, guidelines changed and focused more on presumptive treatment without testing for PCR and recommended that testing (PCR) should be restricted to only severely ill patients of H1N1 which require hospitalization and mild to moderate cases were presumed to be cases of H1N1 and treated accordingly without testing for H1N1, since the PCR test to confirm the diagnosis was expensive and available only at NIV, Pune, which could not bear the increasing load of samples to be tested. All clinically suspected cases of Influenza A/H1N1 should be categorized into mild, moderate and severe (C, B and A respectively and indicated that all mild cases should be treated symptomatically, moderate cases to be treated with Oseltamivir in addition to symptomatic therapy and severe cases should be hospitalized, throat swabs and nasal swabs of these patients to be collected and sent for detection of H1N1 influenza A virus. All severe category patients should be treated with Oseltamivir in addition to other supportive therapy. With this change in guidelines, the number of patients treated with Oseltamivir increased and number of samples collected for H1N1 detection became less.As all suspected cases were not subjected for testing,the number of confirmed cases may not reflect true positive cases in the community which may be actually much more than number detected by the collected samples.[9,10]

In the present study, commonest symptoms observed were Fever, sore throat,cough,& headache in confirmed as well as suspected H1N1negative cases. similar type of observations are also reported by previous author, Eccles R.[11]

Cholewinska et al [12]has studied clinical manifestations in 109 cases of swine flu and reported that the disease is uncomplicated in 67% ,fever cough,and myalgia to be the common symptoms. Complications observed in indoor cases were Bacterial superinfections associated with swine flu, ARDS and shock syndrome, secondary bacterial pneumonia and neurological complications. Severe hypoxemia, multilobar pneumonia, and dramatic signs and symptoms progression, were reported in 8 individuals. All patients required admission to intensive care unit and the mechanical ventilation. One patient died due to ARDS and encephalits

Over all mortality observed in the present study was 0.75%.(in tested,cases,5.03%)but in confirmed cases it was15.3%(08 cases).Though the mortality in the confirmed cases appears high,this may not reflect actual case fatality rate,because large number of cases belonging to category C and B were not subjected for H1N1 testings and the maximum number of tested samples were from category A(severe cases) . In fact , actual mortality because of H1N1 Influenza may be much lower than documented because large number of cases might have not reached or referred to the designated medical centres if they have a milder illness.Some of the patients might not have even reported with the symptoms to the doctors.Data from other centres also needs to be analysed for the same.The ANZIC Influenza Investigators in 2009 studied 722 patients of Influenza A/H1N1 admitted in Intensive Care Unit and reported mortality as 14.3%[13] All the confirmed cases if Influenza A/H1N1 who expired were admitted in the critical state,and had already developed established respiratory failure.All of them had Hypoxia and had bilateral extensive radio-opacities on X-ray chest.Mean duration of illness in these cases was 8.6 days and none of them presented in first 48 Hours of onset of symptoms. out of these 8 cases in whom mortality was reported because of H1N1 Influenza,comorbid illnesses were observed in 6 cases (75%) ,

Baustia et al[14] has studied clinical aspects of pandemic 2009 InfluenzaA/H1N1 and reported mortality to be 0.5% in his study ,However could actually range from 0.0004% to 1.47%

All the deaths observed at our centre were less than 60 years of age. Among the 52 positive cases reported, only 1 was above 60 years of age.However,data regarding age distribution of cases of Influenza A/H1N1 needs to be compared with other designated medical centes, and it should also be thought whether this population above 60 years of age has immunity against the disease because of prior epidemics or pandemics.and needs further detailed studies.

Baehr et al[15] in April 2010 reported that the new pandemic influenza A H1N1 2009 virus has shown a different clinical behavior in different age groups,

with higher rate of hospitalization and higher comorbidity in cases more than 50 years of age. The median age of the 124 hospitalized patients was 33 years (range: 15-82 years) and 36% had comorbidities with fever, cough, myalgia and sore throat being the main symptoms; 16 cases had pneumonia. Of the 124 patients, 77% were of age <5o years and 23% had age >50 years with comorbidity of 21% and 86%, respectively.

Majority of suspected and confirmed cases of Influenza A/H1N1 at our region are from Nagpur district region because the designated medical centres for swine flu were established at every district and patients might have reported to the nearby designated centre. However, we had 3 positive cases from Madhya Pradesh of which 2 expired.67(62.61%) out of 107suspected but H1N1 negative cases and only 11 (21.5%) out of 52 confirmed cases reported within first 48 hours of onset of illness and received Oseltamivir. It has been recommended that Oseltamivir used in first 48 hours of onset of H1N1 Influenza may be more beneficial for improving the clinical outcome than when used beyond 48 hours[16]

Except for the mortality which was present in 03 suspected but H1N1 negative and0 8 confirmed all other cases improved (98.9%).All other isolated and admitted patients were discharged after 7days of hospitalization None of the case who initially presented in mild or moderate category progressed to severe stage in the present study, however needs to be compared with other centres. Oseltamivir was practically unutilized drug before the pandemic, and was well tolerated by most of the patients. Minor side effects reported occasionally (like nausea, vomiting ,giddiness or drowsiness), none of the case had reported any serious side effects at our centre .[16]

Vaccination for prevention of Influenza A/H1N1 was started at our centre from 10th August 2010 It is available only for hospital employees and upto 30th October2010 , after 292 subjects (62 doctors)have been vaccinated(after obtaining willingness) with PANENZA (Sanofi Pesteur) 0.5 ml IM 2 doses, 21 days apart. Most of the doctors including Internists and those working in clinical subjects have refused vaccination .reasons for these could be that it became available very late, its exact period of efficacy is not well known or short lasting and by this time most of us might have developed immunity against Influenza A/H1N1 as a result of either asymptomatic or mild infection. No serious side effects were reported after vaccination except fever, drowsiness and nasal congestion in occasional cases.[17,18]

Though the over all mortality because of Influenza A/H1N1 appears to be low, we cannot exactly predict in the initial stages of disease that which patient is going to develop respiratory failure and what are the exact predictors of mortality. All the deaths in the present study are in relatively younger age, and in 25% without any comorbidities. Results from other centres need to be analysed. It is important to evaluate the interventions undertaken during the current pandemic, reviewing and sharing the experiences and lessons learnt would help to build better capacities in dealing with future pandemics.

Limitations: As this is a Hospital based study ,it has a selection bias. Only the patients who attended the swine flu OPD or emergency at our centre were included .In order to get true reflection of clinical profile and outcome it is essential to have community based studies and also data from other hospitals which treat Swine Flu patients needs to be analysed.Study is also limited by small sample size and mild cases of Influenza A /H1N1 who did not report to Swine Flu OPD could not be included.

Conclusions

High index of suspicion and early institution of Oseltamivir therapy may be beneficial in improving prognosis of Influenza A/H1N1infection.exact predictors of mortality and factors leading to respiratory failure in these cases needs to be studied further.

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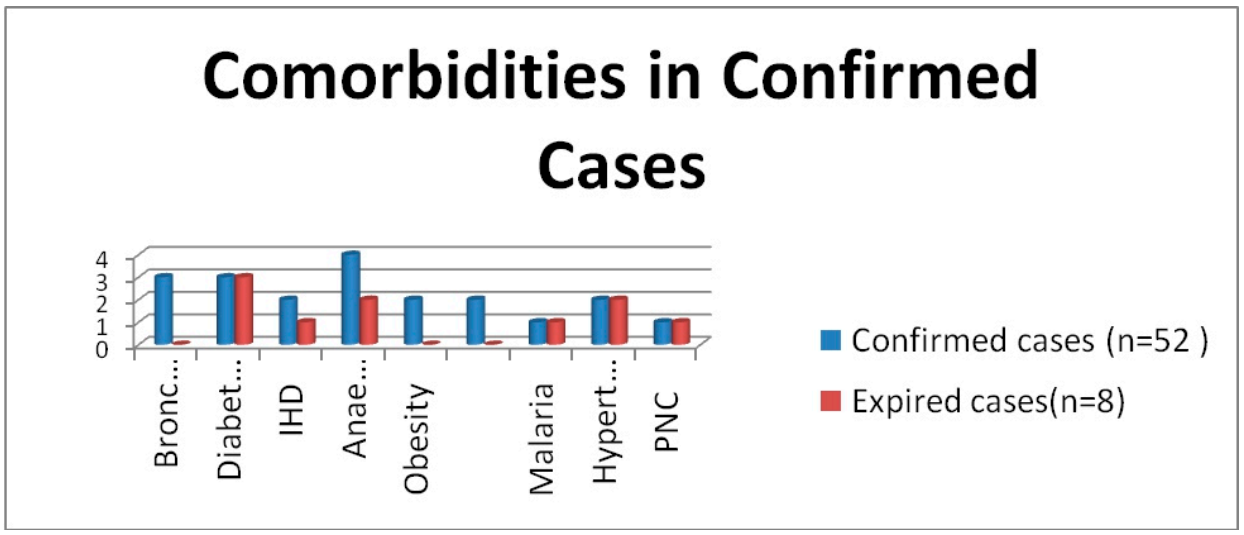
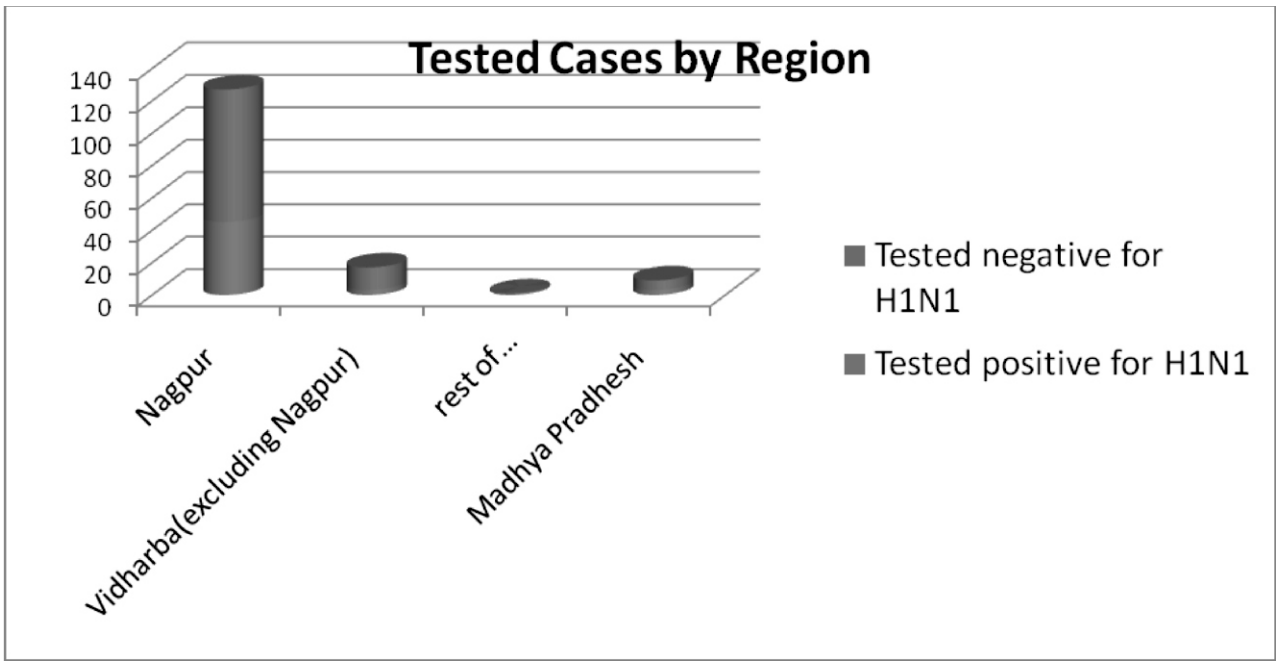
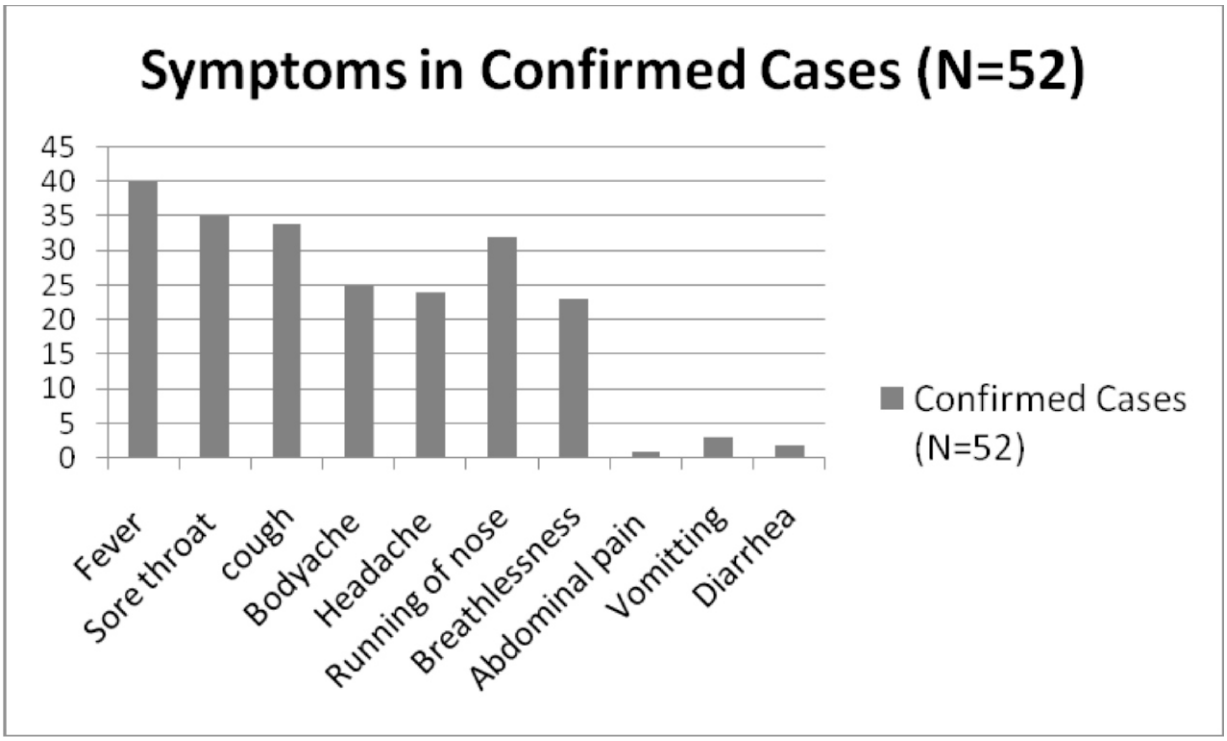
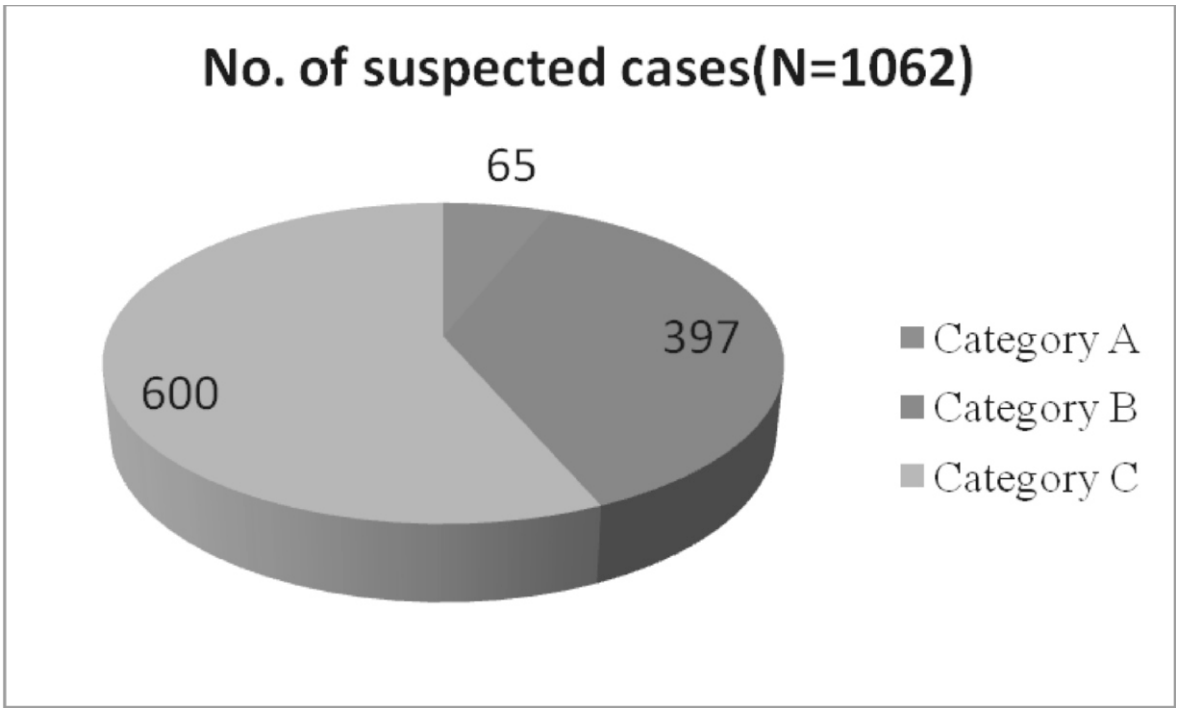
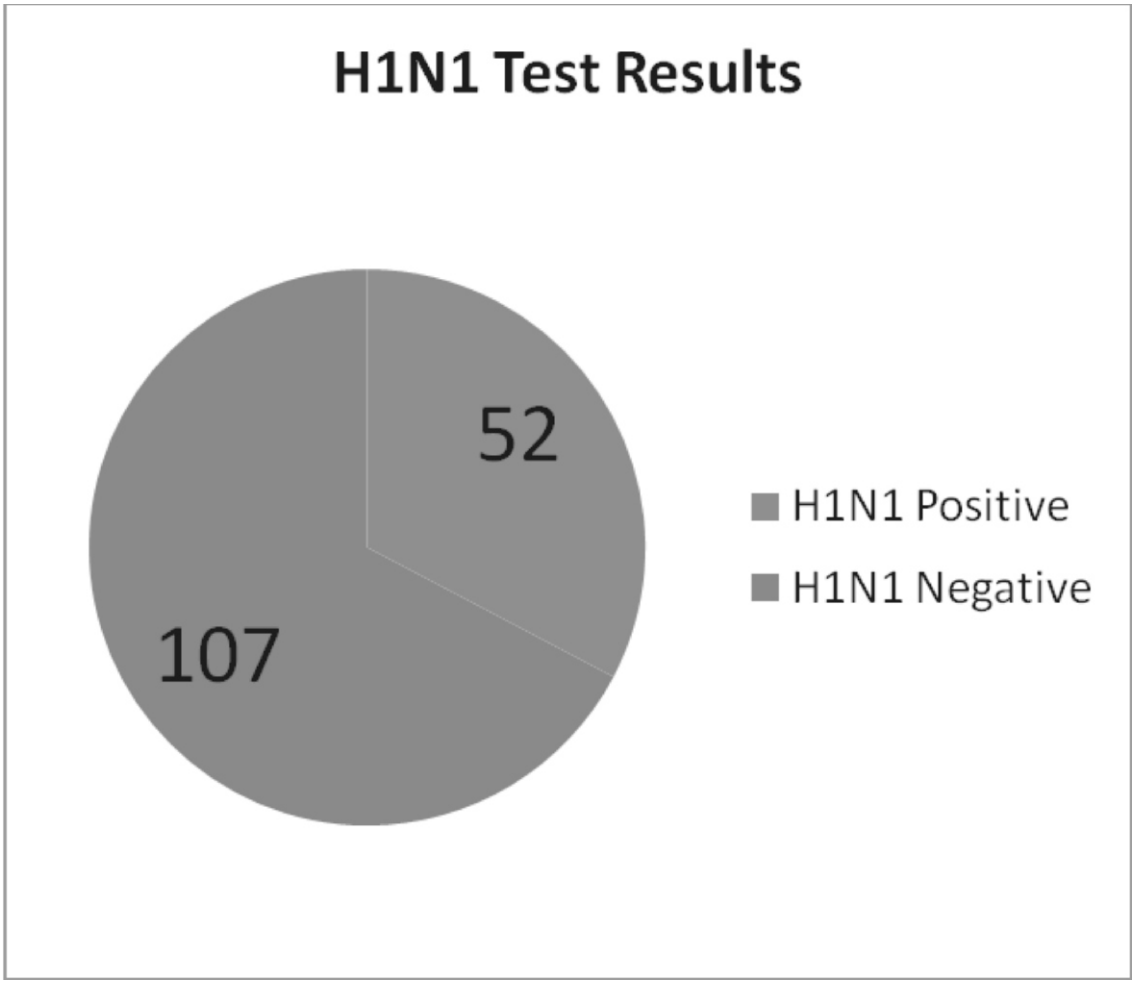



Tested Cases by Region
140
120
100
80
60
40
20
0
Nagpur
Vidharba(excluding Nagpur)
rest of...
Madhya Pradhesh
Tested negative for H1N1
Tested positive for H1N1


Symptoms in Confirmed Cases (N=52)
45
40
35
30
25
20
15
10
5
0
Fever
Sore throat
cough
Bodyache
Headache
Running of nose
Breathlessness
Abdominal pain
Vomitting
Diarrhea
Confirmed Cases (N=52)


No. of suspected cases(N=1062)
65
397
600
Category A
Category B
Category C


H1N1 Test Results
52
107
H1N1 Positive
H1N1 Negative