A REPORT ON

Guiding Principals for Pharmacists to fight against Swine Flu (H1N1)

Compiled by:

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Acknowledgement

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Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)
# Contents

**Abbreviations**

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbreviations</td>
<td>6</td>
</tr>
</tbody>
</table>

**1. Introduction and Background of the Disease**

- *Influenza (Flu) the Disease*  
- *Pandemic Influenza*  
- *Influenza A*  
- *Novel Influenza A (H1N1) [Swine Flu]*  

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction and Background of the Disease</td>
<td>7</td>
</tr>
</tbody>
</table>

**2. Role of Pharmacist in current Pandemic Influenza**

- *Role of Community Pharmacist*  
- *Role of Hospital Pharmacist*  
- *Role of Pharmacists in Pharmacovigilance*  
- *Annexure 2.1.: ADR Reporting Form*  
- *Annexure 2.2: List of Pharmacovigilance Centres*  

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Role of Pharmacist in current Pandemic Influenza</td>
<td>22</td>
</tr>
</tbody>
</table>

**3. Detection and Diagnosis of Novel Influenza A (H1N1) Virus in Humans**

- *Identification of cases*  
- *Diagnosis Tests*  
- *Role of Pharmacist in Diagnosis*  
- *Annexure 3.1: List of Identified Bio Safety Laboratories (BSL-3) for Processing Clinical Samples by GOI*  

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Detection and Diagnosis of Novel Influenza A (H1N1) Virus in Humans</td>
<td>31</td>
</tr>
</tbody>
</table>

**4. Clinical Management, Treatment & Pharmacist’s Participation:**

- *Groups at high risk for complications*  
- *Clinical management of the new influenza A (H1N1) virus infection*  

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Clinical Management, Treatment &amp; Pharmacist’s Participation:</td>
<td>42</td>
</tr>
</tbody>
</table>
5. Novel influenza A (H1N1) in Special Conditions

- Pregnant women and breast feeding mothers
- Children Under 1 Year of Age
- People with heart disease, stroke, and cardiovascular disease
- HIV-infected Adults and Adolescents

6. Resistance to Anti-viral Medicines and Role of Pharmacists

- Annexure 6.1 Instructions to All Port Offices of CDSCO and to All State Drug Controller by Drugs Controller General (I)

7. Prevention

- General Preventative Measures and Role of Pharmacist
- Hand Hygiene
- Respiratory and Cough Etiquette
- Cleaning Measures at Home
- Role of Pharmacist in training person taking care of case of swine flu at home
- Role of Pharmacist in Educating Consumers Proper Use of Mask
- Annexure 7.1: How to Wash Your Hands Properly?
- Annexure 7.2: Cover Your Cough
- Annexure 7.3: Do’s and Don’ts for Community
- Annexure 7.4: Influenza A(H1N1)- How to Protect Yourself and Others
- Annexure 7.5: How to use Mask Properly?
8. Vaccination

9. Infection control measures at health facility
   - Role of Hospital Pharmacist
   - Decontaminating contaminated surfaces, fomites and equipment
   - Guidelines for waste disposal
   - Annexure 9.1: Notice to All Patients in Hospital

10. Health facility managing the human cases of Novel Influenza A (H1N1)
    - During Pre Hospital Care
    - During Hospital Care
    - Use of PPE
    - Annexure 10.1: Standard Operating Procedures on Use of PPE

11. Guidance to Travellers and Role of Pharmacists
    - Annexure 11.1: Travel Advice! Swine Flu

12. Role of Government and Contact Information for Pharmacists and other Healthcare Professionals
    - List of State Nodal Officers and contact details of Control Room in India
    - List of airports along with identified Isolation/Critical care Facilities in India

13. Novel Influenza A (H1N1) [Swine Flu] FAQ

14. Pandemic (H1N1) 2009 – update

Bibliography
Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
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<td>CDSCO</td>
<td>Central Drugs Standard Control Organization</td>
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<td>GOI</td>
<td>Government of India</td>
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<tr>
<td>CrCl</td>
<td>Creatinine Clearance</td>
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<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
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<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<td>Ministry of Health and Family Welfare</td>
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<td>Personal Protective Equipment</td>
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<td>BLS</td>
<td>Bio Safety Laboratory</td>
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<td>PIL</td>
<td>Patient Information Leaflet</td>
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<td>GBS</td>
<td>Guillain-Barré Syndrome</td>
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1. Introduction and Background of the Disease

Influenza (Flu) the Disease

Background

Annual influenza epidemics in humans affect 5–15% of the population, causing an estimated half million deaths worldwide per year.¹,²

Influenza (the flu) is a contagious respiratory illness caused by influenza viruses. It is caused by a virus that affects mainly upper respiratory tract—the nose, throat, bronchi and, occasionally, lungs.

The infection is spread through airborne transmission or direct contact with infected secretions. The virus is transmitted easily from person to person via droplets and small particles produced when infected people cough or sneeze. It is indicated that patients can transmit the infection 3 to 5 days from clinical onset in adults, and up to 7 days in children. Infection usually lasts for about a week, and is characterized by sudden onset of high fever, aching muscles, headache and severe malaise, non-productive cough, sore throat and rhinitis.

Due to this non-specific presentation, influenza is often indistinguishable from other viral respiratory diseases such as the common cold or viral pneumonia. It can cause mild to severe illness. If no complications occur, recovery usually takes place within 2 to 7 days from the onset of clinical manifestations. Most people recover without requiring any medical treatment. In the very young, the elderly and people suffering from medical conditions such as lung diseases, diabetes, cancer, kidney or heart problems, and influenza poses a serious risk. In these people, the infection may lead to severe complications of underlying diseases, pneumonia and death.

¹ Stohr K. Influenza—WHO cares.
² Lancet Infectious Diseases 2002;2(9):517
Influenza Virus

There are three types of influenza viruses: A, B and C.

Influenza A viruses are divided into subtypes based on two proteins on the surface of the virus: the hemagglutinin (H) and the neuraminidase (N). The current Novel Influenza A (H1n1) [Swine Flu] is a subtypes of influenza A virus.

Influenza B viruses are not divided into subtypes. Influenza B viruses also can be further broken down into different strains. Influenza B viruses infect primarily only humans and cause epidemics every few years.

Influenza type C infections cause a mild respiratory illness and are not thought to cause epidemics. Influenza C viruses infect only humans and pigs and usually cause sporadic cases of localized outbreaks.

Key Facts -Influenza (Seasonal)

- Influenza is an acute viral infection that spreads easily from person to person.
- Influenza circulates worldwide and can affect anybody in any age group.
- Influenza causes annual epidemics that peak during winter in temperate regions.
- Influenza is a serious public health problem that causes severe illnesses and deaths for higher risk populations.
- An epidemic can take an economic toll through lost workforce productivity, and strain health services.
- Vaccination is the most effective way to prevent infection.
Pandemic Influenza

What is Pandemic?

A pandemic is a global disease outbreak. An influenza pandemic occurs when a new influenza A virus emerges for which there is little or no immunity in the human population, begins to cause serious illness and then spreads easily person-to-person worldwide.\(^3\)

The World Health Organization has proposed two mechanisms for the emergence of the pandemic influenza:

• Genetic reassortment
  ▪ This occurs when two different viruses infect the same host to exchange genetic material. The new virus can then infect humans to cause serious disease for which humans have no immunity.

• Adaptive mutation or stepwise changes
  ▪ This occurs during infection of humans to slowly become more transmissible in humans during sequential transfer.

\(^3\) [http://www.pandemicflu.gov/general/whatis.html](http://www.pandemicflu.gov/general/whatis.html)
WHO Pandemic Influenza Phases:

**History of Pandemic episodes of Influenza A**

- The 1918–1920- A H1N1 “Spanish Flu”, which killed more than 20 million people worldwide, is informative as a “worst case scenario” for a flu pandemic.
- The 1957–1958 H2N2 “Asian Flu” with 4 million fatalities worldwide
- The 1968–1969 H3N2 “Hong Kong Flu” with 4 million fatalities worldwide.

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4 WHO Pandemic Phase Descriptions and main actions by phase. Global Influenza Programme
Historical overview

History suggests that influenza pandemics have probably occurred during at least the past four centuries, with a heavy toll on human life. The highly pathogenic avian influenza, which was first recognized in Italy in 1878, is extremely contagious in birds and is rapidly fatal, with a mortality rate approaching 100%. During the 20th century, three influenza pandemics have occurred among humans.

1918: Spanish flu [A (H1N1)]

The Spanish influenza pandemic is the catastrophe against which all modern pandemics are measured. It is estimated that approximately 20% to 40% of the population worldwide became ill, and that over 20 million people died. Many people died very quickly. Those who did not succumb to the disease within the first few days often died of complications from the flu, such as pneumonia or other opportunistic infections. One of the most unusual aspects of the Spanish flu was its ability to kill young adults. The reasons for this remain uncertain. With the Spanish flu, mortality rates were high among healthy adults as well as the usual high-risk groups. The attack rate and mortality rate were highest among adults 20 to 50 years old. The severity of this pandemic flu virus has not been seen again.

1957: Asian flu [A (H2N2)]

In February 1957, the Asian influenza pandemic was first identified in the Far East. Immunity to this strain was rare in people under 65 years of age, and a pandemic was predicted. In preparation, vaccine production began in late May 1957, and health officials increased surveillance for flu outbreaks.

The pandemic resulted in an estimated 4 million deaths. Unlike the virus that caused the 1918 pandemic, the 1957 pandemic virus was quickly identified due to advances in scientific technology. Vaccine was available in limited supply by August 1957. Most influenza- and pneumonia-related deaths occurred between September 1957 and March 1958. The highest rates of death were among the elderly.

By December 1957, the worst seemed to be over. However, during January and February 1958 there was another wave of illness among the elderly. This is an example of the potential “second wave” of infections that can develop during a pandemic. The disease infects one group of people...
first; after infections appear to decrease, they may increase again in a different part of the population. Although the Asian flu pandemic was not as devastating as the Spanish flu, about 69 800 people died in the United States alone.

1968: Hong Kong flu [A (H3N2)]
In early 1968, the Hong Kong influenza pandemic was first detected in Hong Kong. It is estimated to have claimed another 4 million lives. This virus was first detected in Hong Kong in early 1968 and spread to the United States later that year. Influenza A (H3N2) viruses still circulate today. Illness did not become widespread in the United States until December, but deaths from the virus peaked between December 1968 and January 1969.

Pandemic scares
Several pandemic scares have occurred since 1976. A novel virus identified at Fort Dix, United States, labelled as “killer flu” was thought to be related to the Spanish flu virus of 1918. The virus later came to be known as the “swine flu”. In May 1977, influenza A/H1N1 viruses isolated in northern China spread rapidly, and caused epidemic disease in children and young adults (< 23 years) worldwide. The virus was referred to as “Russian flu”. The most recent pandemic scares occurred in 1997 and 1999. In 1997, at least several hundred people became infected with the avian A/H5N1 flu. In 1999, another novel avian flu virus, A/H9N2, was found which caused illness in two children in Hong Kong. In the current millennium, influenza A (H5N1) emerged with genes from human influenza virus and those from highly pathogenic avian influenza viruses in 2003 and brought the world close to an influenza pandemic.5

5 World Health Organization. Regional office for South-East Asia- Communicable Disease Newsletter May 2009 Volume 6 Issue 1
Influenza A

Background:

Influenza A is unique among the major pandemic threats in that it could potentially infect 30% of the world’s population within a matter of months. Even at a conservative overall mortality rate of 2%, it would result in around 135 million deaths worldwide within the first year of a new pandemic outbreak. This is about 4 times the total mortality attributed to HIV-1 in the last 30 years. Aquatic birds are the natural reservoir of all influenza virus subtypes. Once a novel strain of influenza has crossed the species barrier from birds into a mammalian host, it may persist in that new host species for many decades. Molecular evidence exists for the presence of influenza A in at least 18 mammalian species. Refer below mentioned Table 1.1:

Table 1.1: Species distribution of haemagglutinin serotypes from the NCBI Influenza Resource

<table>
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</table>

6 The 2009 H1N1 influenza outbreak in its historical context: Derek Gatherer- Journal of Clinical Virology 45 (2009)
Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)

Note that serotypes 1–5, 7, 9, 10 and 13 have all been found at least once in mammals.

Influenza A virus

The influenza virus is an RNA virus which belongs to the family Orthomyxoviridae. The virus has an envelope made of lipid-plus-matrix and transmembrane proteins and contains segmented RNA genome associated with nucleoprotein and three viral polymerase proteins (Pb1, Pb2 and PA). The virus particle has spike-like projections consisting of the hemagglutinin (H) and the neuraminidase (N) glycoproteins.

Influenza A viruses are further classified into subtypes according to the properties and their H and N glycoproteins. There are in total 16 serotypes of haemagglutinin, and 9 serotypes of neuraminidase. Of the 16 known serotypes of influenza A haemagglutinin, 6 have been isolated from humans at the molecular level (H1, H2, H3, H5, H7, and H9). Haemagglutinin functions in the binding of the virus to its putative target cell, whereas neuraminidase plays a role in exit of the virus from the cell in preparation for another round of infection.

Incubation Period of Influenza A virus

Knowledge of the incubation period is essential in the investigation and control of infectious disease, but statements of incubation period are often poorly referenced, inconsistent, or based on limited data. The incubation period of an infectious disease is the time between infection and symptom onset.8 This period is widely reported because it is useful in infectious disease

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surveillance and control, in which the time of symptom onset may be the only indication of the time of infection.

Table 1.2: Summary of incubation period of Influenza estimates in published literature

<table>
<thead>
<tr>
<th>Disease</th>
<th>Literature Estimates* (days)</th>
<th>Number of estimates (%)</th>
<th>Participants in experimental† studies (n)</th>
</tr>
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<tr>
<td></td>
<td>Range</td>
<td>Central Tendency</td>
<td>Unsourced estimates</td>
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<tr>
<td>Influenza</td>
<td>1-4</td>
<td>2</td>
<td>54 (50%)</td>
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</table>

*Literature estimates show the range of incubation periods consistent with most published estimates and the most frequently stated central tendency (e.g., median, mean) for the incubation period; estimates that did not specify a type (e.g., “the incubation period is 5 days”) were assumed to be statements of central tendency.
†Observational studies did not always report a defined number of participants, so a subject count is only reported for experimental studies.

The Lancet Infectious Diseases, (Vol. 9 No. 5 page no 296) estimates median incubation period of influenza A to be 1-4 days (95% CI 1.3–1.5), and the dispersion to be 1.51 (95% CI 1.43–1.60). 5% of influenza A cases will develop symptoms by 0.7 days (95% CI 0.6–0.8), and 95% by 2.8 days (95% CI 2.5–3.2) after infection. Incubation period estimates for influenza A were sensitive to a single study with substantially different findings from other studies.9

Excluding this study resulted in a median incubation period of influenza A of 1.9 days (95% CI 1.8–2.0), with dispersion of 1.22 (95% CI 1.17–1.29).

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Parametric and non-parametric estimates of the incubation period

Cumulative percentage of cases developing symptoms by a given day under the estimates for the log-normal distribution (continuous line) are shown compared with the non-parametric estimates calculated by the method of Turnbull\(^\text{10}\) (rectangles). Rectangular regions represent estimates with equivalent support (i.e., not statistically distinguishable).

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Novel Influenza A (H1N1) [Swine Flu]

Background

The one predictable aspect of influenza is its unpredictability. While attention was focused on the threat of an avian influenza H5N1 pandemic emerging from Asia, a novel influenza virus of swine origin emerged in North America, and is now spreading worldwide. During April 2009, a novel H1N1 virus was detected in epidemiologically unrelated cases of influenza-like illness in California and was subsequently recognized to be the cause of a major outbreak of respiratory disease in Mexico that had been ongoing for some weeks previously.

Every year the influenza A virus undergoes minor genetic changes known as “antigenic drift” which results in the evolution of a strain that is slightly different than the previous year. Major antigenic changes that occur because of mutations or genetic reassortment between influenza viruses of animals, birds and humans are called “antigenic shifts” and result in evolution of a novel strain. In the past all pandemics of influenza were preceded by the appearance of a novel strain.

Human and avian viruses can infect pigs\textsuperscript{11} and the respiratory tract of pigs is believed to express both sialic acid (SA)_2,3Gal (bind avian influenza) and SA_2,6Gal (bind human influenza) receptors that will permit infection with both avian and human influenza viruses.\textsuperscript{12} There is also ample evidence that avian and human viruses establish long term lineages in pigs and that these viruses reassort in pigs. Reassortment between avian and human viruses implies infection of both viruses in the same host and same cell. Humans are poorly permissive to avian viruses\textsuperscript{13,14} and avian species are poorly permissive to human viruses. Since swine are known to be permissive to both avian and human influenza viruses, they have been proposed as a “mixing vessel” for the generation of pandemic viruses through reassortment.\textsuperscript{14} It should be noted however, that there is no direct evidence that pigs played a role in the genesis of any of the three pandemics of the 20\textsuperscript{th} century.

Genetic characterization of novel influenza virus A (H1N1):

The genetic composition of influenza A (H1N1) virus has been elucidated completely. The genetic structure of this virus is the result of reassortment of genes from the following four influenza viruses:\(^{15}\):

- *North American swine influenza*
- *Asian/European swine influenza*
- *Human influenza*
- *Avian influenza (non H5)*

Thus Scientists call this a "quadruple reassortant" virus\(^ {16}\).

Novel Influenza virus A (H1N1)\(^ {17}\)

Phylogenetic analyses of the current novel influenza A(H1N1) revealed that the HA, NP and NS genes arise from the classical swine H1N1 lineage, the NA and M genes from the avian-like Eurasian swine H1N1 lineage while the PB2, PB1 and PA are from the North America H3N2 triple reassortant lineage. While it is true that the Novel H1N1 virus has virus gene segments of swine, human and

\(^{15}\) World Health Organization. Regional office for South-East Asia- Communicable Disease Newsletter May 2009 Volume 6 Issue 1

\(^{16}\) Centers for Disease Control and Prevention (CDC). Novel H1N1 flu (Swine Flu) and You. [http://www.cdc.gov/h1n1flu/qa.htma](http://www.cdc.gov/h1n1flu/qa.htma) accessed on 18\(^ {16}\) July 2009.

\(^{17}\) World Health Organization. Regional office for South-East Asia- Communicable Disease Newsletter May 2009 Volume 6 Issue 1
avian origin, these genes were already established in the triple reassortant swine in North America and in the Eurasian swine H3N2 or H1N1 viruses for many years. Thus the immediate reassortment event that led to the generation of novel influenza A (H1N1) very probably reassortment between two or more swine viruses, viz. the triple reassortant H1N2 (or H1N1) and the Eurasian H3N2 or H1N1 swine viruses. The currently available genetic sequence information does not allow identification of the immediate precursor of the novel influenza A (H1N1) virus or where such a reassortment may have taken place.

Transmission

The virus is spread from person-to-person. It is transmitted as easily as the normal seasonal flu and can be passed to other people by exposure to infected droplets expelled by coughing or sneezing that can be inhaled, or that can contaminate hands or surfaces. People may be infected by touching something with flu viruses on it and then touching their mouth or nose.

Clinical Features and Epidemiology

The spectrum of disease caused by new influenza A (H1N1) virus infection ranges from non-febrile, mild upper-respiratory tract illness to severe or fatal pneumonia. Most cases appear to have uncomplicated, typical influenza-like illness and recover spontaneously.

The symptoms of novel H1N1 flu virus in people are similar to the symptoms of seasonal flu and include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills, muscle and joint pain and fatigue. A significant number of people who have been infected with this virus also have reported diarrhoea and vomiting. The incubation period varies from 2-7 days and the patient is infectious one day prior to onset of disease and up to seven days after the onset of clinical features.

**Pandemic Influenza A (H1N1) 2009**

On 11 June 2009, WHO raised the level of pandemic alert from phase 5 to phase 6, indicating that an influenza pandemic is under way, the first in 41 years. Phase 6 is characterized by sustained human-to-human transmission caused by community-level outbreaks in at least 1 country in ≥2 WHO regions. Designation of this phase indicates that containment of the virus to a particular geographical area is no longer possible. During previous pandemics, influenza viruses took >6 months to spread as widely as the new influenza A (H1N1) pandemic virus has taken to spread in <6 weeks since the first cases were detected in California (USA) in 2009.

At this time, WHO considers the overall severity of the influenza pandemic to be moderate. This assessment is based on scientific evidence available to WHO, as well as input from its Member States on the pandemic's impact on their health systems, and their social and economic functioning.

The moderate assessment reflects that:

1. Most people recover from infection without the need for hospitalization or medical care.

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22 World Health Organization. Regional office for South-East Asia-Communicable Disease Newsletter May 2009 Volume 6 Issue 1

*Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)*
2. Overall, national levels of severe illness from influenza A (H1N1) appear similar to levels seen during local seasonal influenza periods, although high levels of disease have occurred in some local areas and institutions.

3. Overall, hospitals and health care systems in most countries have been able to cope with the numbers of people seeking care, although some facilities and systems have been stressed in some localities.
2. Role of Pharmacist in current Pandemic Influenza

Pharmacists are uniquely positioned and most easily accessible healthcare professionals in the community. Even in developing countries like India, most of the people communicate and take treatment advice on minor ailments from pharmacist only! Among all Healthcare Professionals, pharmacist is the one who have wide compass and can communicate with people most effectively. Pharmacists are often the first point of contact for patients experiencing flu-like symptoms. As the most accessible health care professional, pharmacists have an important role to play in current situation of Pandemic Novel Influenza A (H1N1) i.e. swine flu.

*Role of community as well as hospital pharmacist during Pandemic Novel Influenza A (H1N1) has been described in detail in subsequent chapters.*

**Role of Community Pharmacist**

Community pharmacist is only healthcare professional who will interact with several individuals each day and this is major platform to communicate with common individuals. In India large number of patient pool goes directly to pharmacies and depends on pharmacist to tell them what medicines to take.

Major role of community pharmacist is to educate consumers on preventive measures as described in Chapter- 7 “Prevention” (Page No.-72) and disseminate concise and up-to-date information to the public. This can be done as follows:

*a) Verbal Communication with Consumers:*

While dispensing medicines, pharmacist should effectively initiate dialogue on swine flu, general preventive measures to be followed with consumers especially those who have travelled from affected areas, without creating unnecessary panic situation. It is very important that pharmacist should convey people stocks of recommended anti-viral medicines is not available at retail pharmacist because of inappropriate use of these medicines could increase risk of developing
resistance. Also while dispensing mask it is very important that retail pharmacist should educate consumers proper use of mask.

b) *Use of Retail Pharmacy:*

This is the place which is easily accessible to common people. Individuals with common ailments and with prescription from GP, visit Pharmacy shop. Community Pharmacist should display posters describing the current general information of swine flu, its symptoms, how and what are preventive measures etc. Posters for those who have travelled from affected areas should be displayed. Such informative posters should be displayed inside and outside of retail pharmacy in such a way that these posters should draw consumer’s attention immediately and make desired impact. Use of advanced technology for this purpose is advisable. Since most of patients with little or no information will visit pharmacy shops content of such displays should be simple and in a local language with pictorial presentation. Additionally such displays should also highlight that trained pharmacist is available in pharmacy to answer query related to swine flu. This will certainly encourage consumers to ask more about swine flu.

c) *Distribution of Leaflet:*

Patient Information Leaflet serves as major source of information. Leaflets play an important part in supplementing and reinforcing information provided by healthcare professionals. PILs with simple and local language should disseminate general information on disease, drugs, hand hygiene, proper use of mask respiratory hygiene/cough etiquettes etc.

In case of suspected/probable or confirmed patient in community, retail pharmacist should pro-actively play role in monitoring patient’s situation and educating preventive measure to patient as well caretaker and household members.

Pharmacist must keep himself updated regarding current situation of novel influenza in his community and should ask consumers to follow local Government guidelines or decisions such as closure of schools, colleges, cinemas etc.
Role of Hospital Pharmacist

The Government of India has banned the retail sale of oseltamivir phosphate in the Indian market. Retail pharmacist shall not be able to sell the drug across the counter. The Government of India is maintaining adequate stocks of the drug which would be distributed among the people free of cost through the public health network as and when the need arises. So major role of hospital pharmacists is dispensing of anti-viral medicine in hospital as per prescription from doctor. While despising hospital pharmacist should guide patients on below mentioned points (for detail Role of Hospital Pharmacist on dispensing antiviral medicines refer Chapter no 4: “Clinical management and Treatment and Pharmacist’s Participation” Page No.-42)

a) When to take medicine (before or food)
b) How to store medicines
c) What are common side effects?
d) Certain important patient instructions

Currently other recommended anti-viral medicine Zanamivir is not included in the line of treatment of Novel Influenza by GOI, MOHFW but as per Government policy as when it would be available, hospital pharmacist has to play vital role in training patient how to use inhaler correctly.

Hospital pharmacist should play role in infection control in healthcare facility by displaying visual alerts indicating steps follows by person with flu-like symptoms, hand hygiene, respiratory etiquette and should monitor same. If patient is required to wear mask, hospital pharmacist should guide patient proper use of mask.

While dispensing medicines and at time of discharge of confirm patients of swine flu, hospital pharmacist should guide patients, caretakers and close contact to follow general preventive measures.
**Role of Pharmacists in Pharmacovigilance:**

Adverse Drug Reactions are fourth to sixth leading cause of death among hospitalised patients and it occurs in 0.3 per cent to 7 per cent of all hospital admissions, the incidence of serious ADRs is 6.7 per cent\(^{25}\). There is a rapid increase in the number of new drugs entering the market from last few decades, India being the second most populated country has over one billion potential drug consumers, and no amount of pre-clinical and clinical data is sufficient to conclude the complete safety of a drug, under this scenario it becomes necessary to report any untoward reaction of any pharmaceutical product to assess its safety and efficacy to ensure maximal patient health. The National Pharmacovigilance Programme (NPP) encourages reporting of all suspected drug related adverse events. The reporting of seemingly insignificant or common adverse reactions would be important since it may highlight a widespread prescribing problem. Hospital pharmacist should play crucial role of reporting ADR of anti-viral medicines to National Pharmacovigilance Centres. Hospital pharmacist should instruct patient to inform pharmacist/doctor/nurse if he/she experiences any adverse or side effects due to anti-viral or other medicine. In case of confirm patient of swine flu who has got discharge from hospitals but doctor has asked him to continue anti-viral medicines or doctor has prescribed prophylactic doses of ant-viral medicines to close contacts of patient, community pharmacist should encourage patient to report him any adverse effect that he/she is experiencing because of medicine and should actively participate in pharmacovigilance notification.

Pharmacist should download ADR form link: [http://cdsco.nic.in/html/ADR_form_PDF_file.pdf](http://cdsco.nic.in/html/ADR_form_PDF_file.pdf) (see Annexure 2.1 for ADR reporting form Page No.-26) and mail to nearest pharmacovigilance centre (see Annexure 2.2 Page No.-28 for list of national pharmacovigilance centres) or report online directly to the centre using JIPMER online link: [http://www.jipmer.edu/charu/login.php](http://www.jipmer.edu/charu/login.php)

\(^{25}\) [http://www.pharmacovigilance.co.in/whyadrreporting.html](http://www.pharmacovigilance.co.in/whyadrreporting.html)
Annexure 2.1: ADR Reporting Form

Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)

ADVICE ABOUT REPORTING

Report adverse experiences with medications

Report serious adverse reactions. A reaction is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- You're not certain the product caused adverse reaction
- You don't have all the details although point nos. 1, 5, 7, 8, 11, 15, 18 & 19 (see reverse) are essentially required.

Who can report:

- Any health care professional (Doctors including Dentists, Nurses and Pharmacists)

Where to report:

- After completing, please return this form to the same Pharmacovigilance centre from where you received.
- A list of countrywide Pharmacovigilance Centres is available at www.cdscxn.nic.in

What happens to the submitted information:

- Information provided in this form is handled in strict confidence. Peripheral Pharmacovigilance Centres will forward this form to the Regional Pharmacovigilance Centres, where the causality analysis is carried out and the information is forwarded to the Zonal Pharmacovigilance Centres. Finally, the data is statistically analysed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.
- Data is periodically reviewed by the National Pharmacovigilance Advisory Committee constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with responsibility to review the data and suggest any interventions that may be required.

ATTENTION

HEALTH CARE PROFESSIONALS

Your 5 Minutes Can Help Us Ensure Safer Medications

Please return this form to:

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)
Annexure 2.2: List of Pharmacovigilance Centres

**NATIONAL PHARMACOVIGILANCE PROGRAMME** is divided into 2 zonal centres, 5 regional centres and 24 peripheral centres

### Two Zonal Centres

<table>
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27 [http://www.pharmacovigilance.co.in/nppcentreslist.html](http://www.pharmacovigilance.co.in/nppcentreslist.html)
## 24 PERIPHERAL CENTRES

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**Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)**

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Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)

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<td>JSS College of Pharmacy, Rocklands, Ootacamund-643 001, Tamil Nadu</td>
</tr>
<tr>
<td>Head, Dept. of Pharmacy</td>
<td>0423-2443393, Mobile: 9443433199</td>
</tr>
<tr>
<td>Practice</td>
<td></td>
</tr>
</tbody>
</table>
3. Detection and Diagnosis of Novel Influenza A (H1N1) Virus in Humans

**Identification of cases**

**Clinical findings:** Patients with confirmed novel influenza A (H1N1) virus infection present with acute febrile respiratory illness (fever >38°C) with the spectrum of disease from influenza-like illness to pneumonia. Virus may be shed from a day before onset of clinical symptoms to up to 7 days after onset.

**Mild disease:** Patients with uncomplicated disease due to confirmed novel influenza A (H1N1) virus infection have experienced fever, chills, headache, upper respiratory tract symptoms (cough, sore throat, rhinorrhea, shortness of breath), myalgias, arthralgias, fatigue, vomiting, or diarrhoea. In New York City, 95% of patients with novel influenza A (H1N1) met the case definition for influenza-like illness (subjective fever plus cough and/or sore throat). A mild case of Influenza A H1N1 is defined as a person with sudden onset of fever of >38 °C and cough or sore throat in the absence of other diagnoses (ILI).

**Severe disease:** There is insufficient information to date about clinical complications of this novel influenza A (H1N1) virus infection. Among persons infected with previous variants of swine influenza viruses, clinical syndromes have ranged from mild respiratory illness, to lower respiratory tract illness, dehydration, or pneumonia. Severe outcomes, including respiratory failure and death similar to that seen in previous variants of swine influenza viruses have occasionally occurred. Although data on the spectrum of illness are not yet available for this novel influenza A (H1N1), clinicians should expect complications to be similar to seasonal influenza: exacerbation of underlying chronic medical conditions, upper respiratory tract disease (sinusitis, otitis media, croup) lower respiratory tract disease (pneumonia, bronchiolitis, status asthmaticus), cardiac (myocarditis, pericarditis), musculoskeletal (myositis, rhabdomyolysis), neurologic (acute and post-infectious encephalopathy, encephalitis, febrile seizures, status epilepticus), toxic shock syndrome, and secondary bacterial pneumonia with or without sepsis. Severity criteria include: Fever >38°C; Dyspnoea; Tachypnoea; Hypotension; Hypoxia; Chest X-ray abnormality.
Patients who required hospitalization, including both those who were previously healthy and those with chronic underlying medical conditions, have frequently experienced rapidly progressive, serious lower respiratory tract disease. Other well-recognized influenza complications in those seriously ill with the new influenza A (H1N1) infection have included secondary bacterial infections, rhabdomyolysis with renal failure, myocarditis, and worsening of underlying conditions (for example, asthma and cardiovascular disease).

**Diagnosis Tests**

Diagnosing influenza clinically is often difficult because of the variability of symptoms and the numerous other causes of 'influenza-like illness'. An accurate result from an influenza test performed at the bedside, or within hours of presentation, may assist in diagnosis and patient management. In patients presenting with cough and fever, testing for influenza is indicated when the clinical diagnosis is unclear, if antiviral therapy is a consideration, and in cases of suspected pandemic influenza.

**Specimen Collection**

The type and quality of the specimen as well as the timing of its collection are all factors which may significantly affect the sensitivity of a test.

Upper respiratory tract specimens as recommended for seasonal influenza investigation are the most appropriate. Samples should be taken from the deep nostrils (nasal swab), nasopharynx (nasopharyngeal swab), Nasopharyngeal aspirate, throat or bronchial aspirate. It is not yet known which clinical specimen gives the best diagnostic yield but preferably Nasopharyngeal aspirates in young children and paired nasal and throat swabs (Fig. 3.1) in adults using specialised viral swabs are the most practical specimens to collect.
A good quality respiratory tract specimen is particularly important for rapid antigen detection tests, which rely on the presence of adequate numbers of infected respiratory epithelial cells. Viral shedding peaks in the first 48–72 hours of illness, thus the sensitivity is greatest for specimens collected within this time period.
**Storing Specimens**

- Store specimens at 4 °C before and during transportation within 48 hours
- Store specimens at -70 °C beyond 48 hours
- Do not store in standard freezer – keep on ice or in refrigerator
- Avoid freeze-thaw cycles
- Better to keep on ice for a week than to have repeat freeze and thaw

Appropriate precautions should be taken in collecting specimens since this may expose the collector to respiratory secretions from patients.

There is, as yet, no information on the diagnostic value of non-respiratory specimens, e.g., stool samples.

Acute and convalescent serum specimens should be used for the detection of rising antibody titres.

Word Heath Organization recommends that suspected clinical cases of swine-like H1N1 influenza A infection are confirmed by:

1. Specific RT-PCR assays that differentiate new influenza A (H1N1) from seasonal influenza viruses,
2. The isolation and identification of swine-like H1N1 influenza, or
3. The detection of a fourfold rise of neutralization or HAI antibodies to new influenza A (H1N1)

**Molecular diagnostics**

Molecular diagnostics are currently the method of choice for influenza A (H1N1) swine lineage (swl) virus (A/California/4/2009-like viruses). The use of different target gene assays is more appropriate for correct identification of this virus.

The following gene targets are important: type A influenza matrix gene; haemagglutinin gene specific for influenza A (H1N1)swl virus and haemagglutinin gene specific for seasonal influenza A H1/H3 and other subtypes.

The following protocols are currently available:
— influenza A type-specific conventional and realtime PCR

— CDC realtime RT-PCR (rRT-PCR) protocol for the detection and characterization of influenza A (H1N1) (version 2009).

Sequence analyses of the type A influenza matrix gene PCR product using the primers in the WHO protocols will differentiate between M genes of swine-lineage and seasonal H1N1 viruses; however, additional analysis should be performed to confirm the origin of the virus.

Conventional RT-PCR assays are currently being evaluated. An update will be published by WHO when available.

**Virus isolation and typing by haemagglutination inhibition or immunofluorescence:**

Current protocols for virus isolation of seasonal influenza viruses using MDCK cells and egg inoculation can be used, although their sensitivity remains to be determined. Turkey, chicken, guinea pig and human red blood cells will agglutinate with the influenza A (H1N1)swl virus.

Polyclonal antibodies specific for subtype H1 seasonal influenza viruses from the WHO influenza reagent kit will not react in the haemagglutination inhibition (HAI) test with the current influenza A (H1N1) virus. Results obtained using the H1 monoclonal antibodies in the WHO kit should not be taken as conclusive and further verification is recommended.

**Rapid tests or immunofluorescence:**

The sensitivity and specificity of rapid-point-of-care or immunofluorescence tests designed for direct detection of influenza A viruses are currently unknown. An update will be published by WHO when available. It should be emphasized that these tests will not differentiate seasonal influenza from influenza A (H1N1)swl virus.

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28 Refer Annexes 1 and 2 of WHO Information for Laboratory Diagnosis of New Influenza A (H1N1) Virus in Humans at http://www.who.int/csr/resources/publications/swineflu/WHO_Diagnostic_RecommendationsH1N1_20090521.pdf


30 Refer Annexes 1 of WHO Information for Laboratory Diagnosis of New Influenza A (H1N1) Virus in Humans at http://www.who.int/csr/resources/publications/swineflu/WHO_Diagnostic_RecommendationsH1N1_20090521.pdf
Serology:

HAI and microneutralization tests using influenza A (H1N1) swi virus are expected to be able to detect antibody responses following infection.

Interpretation of laboratory results:

- PCR — A sample is considered positive if results from tests using two different PCR targets (e.g. primers specific for universal M gene and swine H1 haemagglutinin gene) are positive but the PCR for human H1 + H3 is negative. If RT-PCR for multiple haemagglutinin (HA) targets (i.e. H1, H3, and H1-swine-lineage) give positive results in the same specimen, the possibility of PCR contamination should first be excluded by repeating PCR procedure using new RNA extract from the original specimen or RNA extract from another specimen. If repeated positive results for multiple HA targets are obtained, this raises the possibility of co-infection, which should be confirmed by sequencing or virus culture.31
- CDC realtime PCR assays — Results should be interpreted as described in the CDC H1N1 real time assay manual.32
- A negative PCR result does not rule out that a person may be infected with influenza A (H1N1) virus. Results should be interpreted in conjunction with the available clinical and epidemiological information. Specimens from patients whose PCR results are negative but for whom there is a high suspicion of A (H1N1) infection should be further investigated and tested by other methods such as virus culture or serology, to rule out influenza A (H1N1)swi infection33
- Serology — A four-fold or greater rise in specific influenza A (H1N1)swi virus antibody titres indicates recent infection with the virus.
- Sequencing — At this stage, sequencing of at least one target product is essential for confirmation of conventional PCR.

31 Refer Annexes 3 of WHO Information for Laboratory Diagnosis of New Influenza A (H1N1) Virus in Humans Annex 3 shows a flowchart for use in interpreting PCR results. at http://www.who.int/csr/resources/publications/swineflu/WHO_Diagnostic_RecommendationsH1N1_20090521.pdf


33 Refer flowchart in Annex 3 of WHO Information for Laboratory Diagnosis of New Influenza A (H1N1) Virus in Humans at http://www.who.int/csr/resources/publications/swineflu/WHO_Diagnostic_RecommendationsH1N1_20090521.pdf
• Virus isolation — Identification and typing of a cultured influenza virus can be carried out by PCR, indirect fluorescent antibody (IFA) testing using specific NP monoclonal antibodies, or HA and antigenic analysis (subtyping) by HAI using selected reference antisera.

**Biosafety:**

Diagnostic laboratory work on clinical specimens from patients who are suspected cases of influenza A (H1N1)swl virus infection should be conducted in BSL-2 containment conditions with the use of appropriate personal protective equipment (PPE). All clinical specimen manipulations should be done inside a certified biosafety cabinet (BSC). Please refer to the WHO Laboratory biosafety manual, 3rd edition.34

Virus isolation currently requires higher biosafety containment measures. Please refer to the document WHO Laboratory biorisk management for laboratories handling human specimens suspected or confirmed to contain influenza A (H1N1) causing the current international epidemics for recommended guidance.35

**Testing algorithms:**

The overall approach to influenza virus detection by RT-PCR should be considered in the context of the national situation, e.g., how many specimens can be handled (throughput), what gene sequence to target for RT-PCR, and whether to use concurrent or sequential testing for RT-PCR of M, NP and HA genes.

**Good laboratory practices:**

Standard protocols for all procedures should be in place and reviewed regularly. Making sure that the recommended reagents are used and handled properly is critical, as reactions are complex and problems with a single reagent can have large effects on the results obtained.

Validation:
All protocols should always be validated in each laboratory to ensure adequate specificity and sensitivity using the same controls that are employed in each run.

Quality assurance:
Standard quality assurance protocols and good laboratory practices should be in place. Participation in the National Influenza Centres (NIC) evaluation exercises (external quality assessment programme) is highly recommended to confirm that laboratories are achieving an adequate level of sensitivity and specificity in their tests.

Training of personnel:
Familiarity with protocols and experience in correct interpretation of results are cornerstones for successful execution of the diagnostic tests.

Facilities and handling areas:
Specimen and reagent handling facilities (including cold chains) with appropriate separation for different steps of RT-PCR must be in place to prevent cross-contamination. Facilities and equipment should meet the appropriate biosafety level. RT-PCR should be performed in a space separate from that used for virus isolation techniques.

Equipment:
Equipment should be used and maintained according to the manufacturer's recommendations.

Role of Pharmacist in Diagnosis
Role of Pharmacist in diagnosis is very minimal however, the basic awareness about swine flu can be optimally created among all vulnerable and/or suspected persons by the pharmacist (without creating unnecessary panic) and pharmacist should guide suspected cases (especially those who are returned from affected area and experiencing flu-like symptoms) immediately contact ‘Outbreak Monitoring Cell, National Institute of Communicable Diseases’ or call 011-23921401.
In India National Institute of Virology, Pune is an existing WHO reference laboratory for avian influenza H5. This laboratory along with National Institute of Communicable Diseases has been allocated by Government of India for testing influenza A H1N1 or any other novel influenza virus. If the sample load requires additional laboratories Government of India may allocate other two BSL-3 laboratories namely National Institute of Cholera And Enteric Diseases, Kolkata and Regional Medical Research Centre, Dibrugarh.
Annexure 3.1: List of Identified Bio Safety Laboratories (BSL-3) for Processing Clinical Samples by Government of India

1. National Institute of Virology

National Reference Centre and WHO (H5) Reference Laboratory

Director: Dr. A. Mishra Mobile - +91-09970178555

24X7 contact number for informing about sample collection: 020-26006210/290

Head Office:

20/ A, Dr. Ambedkar Road.
Post Box No. 11, India
Pune 411001
Tel.No. : +91-20-26124386/+91-20-26127301/+91-20-26006290
Fax No. : +91-020-26122669/+91-020-26126399
E-mail address: nivicl@pn3.vsnl.net.in

Pashan Office

MCC 130/1 Sus Road.
Pashan, India
Pune 411021
Tel.No. : +91-020-26006390
Fax No. : +91-020-25871895
E-mail address: nivicl@pn3.vsnl.net.in

36 Annexure XVI DRAFT Action Plan Pandemic Preparedness and Response for Managing Novel Influenza A H1N1 (earlier called Swine flu) (or that arising from any other novel strain of Influenza), Directorate General of Health Services Ministry of Health and Family Welfare, New Delhi http://www.mohfw.nic.in/SWINEFLU.htm accessed 18th July 2009
2. National Institute of Communicable Diseases

Special DG & Director: Dr Shiv Lal
Contact No. (office): +91-11-23913148

HOD, Microbiology: Dr Shashi Khare
Mobile: +91 -9899900731

24X7 contact number for informing about sample collection: +91-11-23921401

Directorate General of Health Services
Ministry of Health and Family Welfare (GOI)
22, Sham Nath Marg
New Delhi-110 054 India.
Phone: +91-11-23946893 (PS to Director)
+91-11-23971 272/060/344/524/449/326 (Board Numbers)
Fax: +91-11-23922677
E-mail: dirnicd@bol.net.in, dirnicd@del3.vsnl.net.in

3. Regional Reference Laboratories (Standby labs)

a. National Institute of Cholera And Enteric Diseases
   P-33 CIT Road, Scheme XM,
   Beliaghata, Kolkata - 700010
   INDIA.
   Phone: +91-33-23500448/23501176/ 23537519
   Fax : : +91-33-2350-5066/2353-2524;
   Email: niced@cal2.vsnl.net.in / bsujit@vsnl.net

b. Regional Medical Research Centre
   N.E. region (Indian Council of Medical Research)
   Post Box# 105, Dibrugarh 786001, Assam, India.
   Phone: +91-373-2381494

4. Additional BSL laboratories being Commissioned :
   a. Central Research Institute, Kasauli
   b. Haffkine Institute, Mumbai.
4. Clinical Management and Treatment: Pharmacist’s Participation

Appropriate case management is a crucial component of outbreak response and can help to reduce morbidity and mortality and reduce disease transmission.

Case definitions:

A Suspected Case
A suspected case of the new A H1N1 virus infection is defined as a person with acute febrile respiratory illness (reported or documented fever, and one of the following: cough, sore throat, shortness of breath, difficulty in breathing or chest pains) with onset:

- within 7 days of close contact with a person who is a probable or confirmed case of the new influenza A (H1N1) virus infection, or
- within 7 days of travel to a community internationally where there has been one or more confirmed novel influenza A (H1N1) cases, or
- resides in a community where there are one or more confirmed new influenza cases

A Probable case of new influenza A (H1N1) virus infection is defined as an individual with an influenza test that is positive for influenza A, but is unsubtypable by reagents used to detect seasonal influenza virus infection

OR

An individual with a clinically compatible illness or who died of an unexplained acute respiratory illness who is considered to be epidemiologically linked to a probable or confirmed case.

A Confirmed case of new influenza A(H1N1) virus infection is defined as an individual with laboratory confirmed new influenza A(H1N1) virus infection by one or more of the following *:

- real-time RT-PCR,
• viral culture

• four-fold rise in new influenza A (H1N1) virus-specific neutralizing antibodies.

* Note: The test(s) should be performed according to the most currently available guidance on testing (http://www.who.int/csr/disease/swineflu/en/index.html).

**Groups at high risk for complications**

Currently, insufficient data are available to determine who is at higher risk for complications of novel influenza A (H1N1) virus infection. Thus, at this time, the same age and risk groups who are at higher risk for seasonal influenza complications should also be considered at higher risk for novel influenza A (H1N1) complications. Data seems to show that the populations affected most by A(H1N1) are different from those affected by seasonal flu.

**These risk groups include:**

- Children younger than 5 years old. The risk for severe complications from seasonal influenza is highest among children younger than 2 years old.
- Adults 65 years of age and older.
- Persons with the following conditions:
  - Chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological (including sickle cell disease), neurologic, neuromuscular, or metabolic disorders (including diabetes mellitus);
  - Immunosuppression, including that caused by medications or by HIV;
  - Pregnant women;
  - Persons younger than 19 years of age who are receiving long-term aspirin therapy;
  - Residents of nursing homes and other chronic-care facilities.
**Clinical management of the new influenza A (H1N1) virus infection**

Most human cases of new influenza A (H1N1) virus infection have had uncomplicated illness of limited duration. Hospitalization or antiviral therapy is therefore not likely to be required for most patients.

The specific risk factors that predict increased risk of progressive disease are incompletely understood. Clinicians and caregivers should watch for signs of possible clinical deterioration (for example, difficulty in breathing, chest pain, coughing up coloured sputum, altered level of consciousness and confusion) and refer such patients immediately to hospital. Clinicians should also take into account any underlying co-morbidities (such as immune-compromising conditions, pre-existing chronic lung or cardiovascular disease, diabetes).

<table>
<thead>
<tr>
<th><strong>Modalities</strong></th>
<th><strong>Strategies</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NSAIDS, antipyretics</strong></td>
<td>Paracetamol or ibuprofen is prescribed for fever, myalgia and headache. Avoid administration of salicylates (aspirin and aspirin containing products) in children and young adults (&lt; 18 years old) due to risk of Reye’s syndrome.</td>
</tr>
<tr>
<td><strong>Antiviral therapy</strong></td>
<td>If treatment needed, oseltamivir or zanamivir (Currently not included in the line of treatment of novel influenza as per GOI, MOHFW) The new influenza A (H1N1) virus is currently resistant to amantadine and rimantadine.</td>
</tr>
<tr>
<td><strong>Antibiotics</strong></td>
<td>Antibiotic chemoprophylaxis should not be used. In case of pneumonia, antibacterial agents should be administered, if required, as per locally accepted clinical practice guidelines. Patient on mechanical ventilation should be administered antibiotics prophylactically to prevent hospital associated infections.</td>
</tr>
<tr>
<td><strong>Corticosteroids</strong></td>
<td>Moderate to high dose steroids are NOT recommended. They are of unproven benefit and potentially harmful.</td>
</tr>
</tbody>
</table>
Low dose corticosteroids (Hydrocortisone 200-400 mg/ day) may be useful in persisting septic shock (SBP < 90).

Oxygen therapy

Patients with signs of tachypnea, dyspnea, respiratory distress and oxygen saturation less than 90 per cent should be supplemented with oxygen therapy. Types of oxygen devices depend on the severity of hypoxic conditions which can be started from oxygen cannula, simple mask, partial re-breathing mask (mask with reservoir bag) and non re-breathing mask. In children, oxygen hood or head boxes can be used. If medical oxygen is not available, industrial oxygen can be used. Oxygen treatment of newborn infants should follow guidelines. Oxygen saturation and maintain SaO2 over 90% (95% for pregnant women).

Advance respiratory support

Treatment of ARDS associated with the new influenza A (H1N1) virus infection should be based upon published evidence-based guidelines for sepsis-associated ARDS. Lung protective mechanical ventilation strategies should be used. Patients with severe pneumonia and acute respiratory failure (SpO2 < 90% and PaO2 <60 mmHg with oxygen therapy) must be supported with mechanical ventilation.

IV Fluids and Parenteral nutrition may be required

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Antiviral Medicines

Zanamivir (Relenza) is not included in the line of treatment or prophylaxis of Novel Influenza A (H1N1) [Swine Flu] as per "DRAFT Action Plan Pandemic Preparedness and Response for Managing Novel Influenza A H1N1 (earlier called Swine flu) (or that arising from any other novel strain of Influenza)" as well in "Swine Flu-Clinical management Protocol and Infection Control Guidelines," issued by Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. (Available online at [http://www.mohfw.nic.in/SWINEFLU.htm](http://www.mohfw.nic.in/SWINEFLU.htm) accessed on 18th July 2009). But as per WHO the new influenza A (H1N1) viruses are currently susceptible to Zanamivir as well, we have included detailed information of Zanamivir on lines of Oseltamivir [dose, patient instructions, monograph, steps of using Relenza (Zanamivir-Inhalation Powder) etc.] in view that this information will be useful to pharmacists whenever drug would be available in India as per Government policy.

During an influenza outbreak, medications can prevent influenza illness, lessen symptoms, and prevent complications. Antiviral drugs are prescription medicines with activity against influenza viruses, including swine influenza viruses. Antiviral drugs can be used to treat swine flu or to prevent infection with swine flu viruses. Antiviral drugs can make illness milder and make patient feel better faster. They may also prevent serious influenza complications. These medications must be prescribed by a health care professional. Influenza antiviral drugs only work against influenza viruses they will not help treat or prevent symptoms caused by infection from other viruses that can cause symptoms similar to the flu.

Clinical judgment is an important factor in treatment decisions. Persons with suspected novel H1N1 influenza who present with an uncomplicated febrile illness typically do not require treatment unless they are at higher risk for influenza complications.
Treatment with anti-viral medicines is recommended for:

1. All hospitalized patients with confirmed, probable or suspected novel influenza (H1N1).
2. Patients who are at higher risk for seasonal influenza complications (Page No.-43)

Two adamantanes (amantadine and rimantadine) and 2 neuraminidase inhibitors (oseltamivir and zanamivir) are available for treatment of Influenza. The new influenza A (H1N1) viruses are currently susceptible to the neuraminidase inhibitors (NAIs) oseltamivir and zanamivir but resistant to amantadine or rimantadine (adamantane or M2 inhibitor drugs).40

Because of high levels of resistance to amantadine during the 2005 to 2006 season (resistance increased from 1.9% in 2002 to 91% in 2006)41, adamantanes are not currently recommended. Since the H1N1 virus is new, clinical efficacy data on antiviral treatment are not yet available. Based on its in vitro susceptibility patterns and clinical experiences derived from seasonal and avian H5N1 influenza infection, early administration of NAIs might reduce severity and duration of illness caused by the new H1N1 virus infection, and might also contribute to prevent progression to severe disease and death. Antiviral therapy may be beneficial especially for the following groups:

- pregnant patients, in whom administration of antiviral medicines should be carefully evaluated taking possible benefits and risks into consideration;
- patients with progressing lower respiratory disease or pneumonia;
- patients with underlying medical conditions.

If used, antiviral treatment should ideally be started early, but it may also be used at any stage of active disease when ongoing viral replication is anticipated or documented. Influenza antiviral drugs work best when started soon after illness onset (within two [2] days), but treatment with antiviral drugs should still be considered after 48 hours of symptom onset, particularly for hospitalized patients or people at high risk for influenza-related complications. It is possible that the virus may replicate for a prolonged period of

40 http://www.cdc.gov/mmwr/PDF/wk/mm5817.pdf
time in some patients as a result of the lack of pre-existing protective immunity. There are important pharmacological differences to consider when choosing NAIs for treatment. Oseltamivir is administered orally and gives higher systemic level. Zanamivir is delivered by oral inhalation with low systemic absorption however currently Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India has not recommended Zanamivir as drug of choice for treatment or Chemo Prophylaxis of Novel influenza A (H1N1). Oseltamivir is the recommended treatment for lower respiratory tract complications.

**Recommended antiviral treatment regimens**

### Oseltamivir

For adolescents (13 to 17 years of age) and adults the recommended oral dose is 75 mg oseltamivir twice daily for 5 days. For infants older than 1 year of age and for children 2 to 12 years of age recommended doses are as follows:

<table>
<thead>
<tr>
<th>Weight Range</th>
<th>Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>15kg or less</td>
<td>30 mg orally twice a day for 5 days</td>
</tr>
<tr>
<td>15-23kg</td>
<td>45 mg orally twice a day for 5 days</td>
</tr>
<tr>
<td>24-40kg</td>
<td>60 mg orally twice a day for 5 days</td>
</tr>
<tr>
<td>&gt;40kg</td>
<td>75 mg orally twice a day for 5 days</td>
</tr>
</tbody>
</table>

### Zanamivir (currently not included in the line of treatment as per GOI, MOHFW)

Zanamivir is indicated for treatment of influenza in adults and children (>5 years). The recommended dose for treatment of adults and children from the age of 5 years is two inhalations (2 x 5mg) twice daily for 5 days.
Role of Pharmacists while dispensing recommended antiviral medicines for novel influenza:

Patient Instructions for counselling by Pharmacists: Oseltamivir

While dispensing Oseltamivir capsules or liquid (suspension) hospital pharmacist should instruct patient as follows; (At present in India community pharmacies do not have access to Oseltamivir)

- To inform pharmacist or doctor immediately if allergic reaction develops.
- To inform pharmacist, nurse or doctor if patient experiences any side effect because of medicine.
- To take medicine as per doctor’s instructions i.e. how much of this medicine to use and how often. Ask patient not to use more medicine or use it more often than instructed by doctor.
- To preferably take Oseltamivir after food (Oseltamivir may be taken with or without food. Tolerability may be increased when taken with food in some patients.)
- To keep all medicine away from children and never share medicine with anyone.
- To keep using this medicine for the full treatment time, even if patient feel better after the first few doses. Warn patient that if he stops using medicine too soon, his infection may not clear up.
- That if patient misses or forgets to use his medicine, use it as soon as he/she can. If it is almost time for his next dose, wait until then to use the medicine and skip the missed dose. Instruct patient not use extra medicine to make up for a missed dose.
- To store the capsules at room temperature, away from heat, moisture, and direct light.
- To shake the oral liquid medicine before each use. Measure the oral liquid medicine with a marked measuring spoon, oral syringe, or medicine cup.
- To store dry powder at room temperature and the reconstituted oral liquid in the refrigerator (2 to 8 degrees Celsius Do not freeze.), away from heat and direct light. Use the medicine within 10 days after you fill the prescription. (After reconstitution)
- This medicine may cause abnormal behaviour that may lead to injury. Ask patient (adult or child) to report any unusual thoughts or behaviours that trouble, especially if they are new
or are getting worse quickly. Instruct patient (adult or child) to inform doctor if experiences trouble sleeping, get upset easily, have a big increase in energy, or start to act reckless. Also ask to inform doctor if patient (adult or child) have sudden or strong feelings, such as feeling nervous, angry, restless, violent, or scared.

**Important Information for Pharmacists about Anti-viral Drugs:**

- **Monograph: Oseltamivir**

**Class**

This drug is a member of the following class(es):
- Antiviral
- Neuraminidase Inhibitor, Influenza A&B Virus

**Extemporaneous Formulation to be prepared by pharmacists - Oral route:**

**Compounding Oral Suspension from Oral Capsules**

a) The following directions are for emergency preparation of oseltamivir oral suspension (15 mg/ml) compounded from oseltamivir capsules only in the event that the commercially manufactured oseltamivir powder for suspension (12 mg/ml) is not readily available. Preparation of oseltamivir suspension 15 mg/ml as follows will provide 1 patient with enough medication for a 5-day course of treatment or a 10-day course of prophylaxis.

b) **Oseltamivir suspension 15 mg/ml may be compounded using oseltamivir 75 mg capsules with either Cherry Syrup or Ora-Sweet SF (sugar-free). Other vehicles have not been studied**

c) First, calculate the total volume of an oral suspension needed to be compounded and dispensed for each patient. The total volume required is determined by the weight of each patient provided in the following table:

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42. MICROMEDEX(R) [DRUGDEX® System] Healthcare Series Vol. 141

43. BNF 57 edition

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d) Second, determine the number of capsules and the amount of vehicle (Cherry Syrup or Ora-Sweet SF) needed to prepare the total volume, previously calculated (30, 40, 50 or 60 ml), of compounded oral suspension (15 mg/ml) using the following table:

<table>
<thead>
<tr>
<th>Body Weight (kg)</th>
<th>Body Weight (lbs)</th>
<th>Total Volume to Compound Per Patient (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 kg or less</td>
<td>33 lbs or less</td>
<td>30 ml</td>
</tr>
<tr>
<td>16 to 23 kg</td>
<td>34 to 51 lbs</td>
<td>40 ml</td>
</tr>
<tr>
<td>24 to 40 kg</td>
<td>52 to 88 lbs</td>
<td>50 ml</td>
</tr>
<tr>
<td>41 kg or greater</td>
<td>89 lbs or greater</td>
<td>60 ml</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Volume Needed</th>
<th>30 ml</th>
<th>40 ml</th>
<th>50 ml</th>
<th>60 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of 75 mg Capsules Required</td>
<td>6 caps (450 mg)</td>
<td>8 caps (600 mg)</td>
<td>10 caps (750 mg)</td>
<td>12 caps (900 mg)</td>
</tr>
<tr>
<td>Required Volume of Vehicle (Cherry Syrup or Ora-Sweet SF)</td>
<td>29 ml</td>
<td>38.5 ml</td>
<td>48 ml</td>
<td>57 ml</td>
</tr>
</tbody>
</table>
e) Third, follow the procedure below for compounding the oral suspension (15 mg/ml) from oseltamivir 75 mg capsules:

1) Carefully separate the capsule body and cap, and transfer the contents of the required number of oseltamivir 75 capsules into a clean mortar.
2) Triturate the granules to a fine powder.
3) Add one-third (1/3) of the specified amount of vehicle and triturate the powder until a uniform suspension is achieved.
4) Transfer the suspension to an amber glass or amber polyethyleneterephthalate (PET) bottle. A funnel may be used to eliminate any spillage.
5) Add another one-third (1/3) of the vehicle to the mortar, rinse the pestle and mortar by a triturating motion and transfer the vehicle into the bottle.
6) Repeat the rinsing with the remainder of the vehicle.
7) Close the bottle using a child-resistant cap.
8) Shake well to completely dissolve the active drug and to ensure homogeneous distribution of the dissolved drug in the resulting suspension. Oseltamivir phosphate readily dissolves in the specified vehicles. The suspension is caused by some of the inert ingredients of the oseltamivir capsules, which are insoluble in these vehicles.
9) Put an ancillary label on the bottle indicating "Shake Gently Before Use". The compounded suspension should be gently shaken prior to administration to minimize the tendency for air entrapment, particularly with the Ora-Sweet SF vehicle.
10) Advise the parent or guardian that any remaining medication after completion of treatment or prophylaxis must be discarded.
11) Add the appropriate expiration date and storage conditions to the label:
   a) Refrigeration: Stable for 5 weeks (35 days) when stored under refrigeration at 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit).
   b) Room Temperature: Stable for 5 days when stored at room temperature, 25 degrees Celsius (77 degrees Fahrenheit).
f) Label the bottle with the appropriate dosing instructions based on body weight provided in the following table:

<table>
<thead>
<tr>
<th>Body Weight (kg)</th>
<th>Body Weight (lbs)</th>
<th>Dose</th>
<th>Volume per Dose</th>
<th>Treatment Dose</th>
<th>Prophylaxis Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 kg or less</td>
<td>33 lbs or less</td>
<td>30 mg</td>
<td>2 ml</td>
<td>2 ml twice daily for 5 days</td>
<td>2 ml once daily for 10 days</td>
</tr>
<tr>
<td>16 to 23 kg</td>
<td>34 to 51 lbs</td>
<td>45 mg</td>
<td>3 ml</td>
<td>3 ml twice daily for 5 days</td>
<td>3ml once daily for 10 days</td>
</tr>
<tr>
<td>24 to 40 kg</td>
<td>52-88 lbs</td>
<td>60 mg</td>
<td>4 ml</td>
<td>4 ml twice daily for 5 days</td>
<td>4 ml once daily for 10 days</td>
</tr>
<tr>
<td>41 kg or more</td>
<td>89 lbs or more</td>
<td>75 mg</td>
<td>5 ml</td>
<td>5 ml twice daily for 5 days</td>
<td>5 ml twice daily for 5 days</td>
</tr>
</tbody>
</table>

*Dose Adjustments:*
- renal impairment: influenza treatment; CrCl 10-30 ml/min, 75 mg once a day for 5 days
- renal impairment: influenza prophylaxis; CrCl 10-30 ml/min, 75 mg every other day or 30 mg once a day
- avoid if CrCl less than 10 ml/min.
- hepatic impairment: no dose adjustment for patients with mild or moderate hepatic impairment; no data in severe hepatic impairment
**Contraindications**

hypersensitivity to oseltamivir phosphate or any other component of the product

**Monitoring**

- fever
- symptomatic improvement

**Precautions**

1) abnormal behaviour and delirium leading to injury, sometimes fatal, have been reported, primarily in paediatric patients.
2) anaphylaxis has been reported.
3) concomitant use with intranasal live attenuated influenza vaccine (LAIV) not recommended within 2 weeks before or 48 hours following oseltamivir phosphate administration unless medically necessary; may interfere with vaccine efficacy.
4) hereditary fructose intolerance; oseltamivir oral suspension contains 2 g of sorbitol per 75 mg dose; exceeding maximum daily sorbitol limit may cause dyspepsia and diarrhoea.
5) renal impairment (creatinine clearance less than 30 ml/min); dose adjustment recommended
6) skin reactions, serious (e.g., toxic epidermal necrolysis, Stevens-Johnson Syndrome, and erythema multiforme) have been reported.

**Mechanism of Action:**

1) Neuraminidase inhibitors prevent neuraminidase from cleaving host-cell receptors and releasing new virus by imitating the natural substrate of the influenza neuraminidase which allows them to bind to the sialic acid receptor.
2) Oseltamivir (GS 4104) is the ethyl ester prodrug of GS 4071, a selective inhibitor of influenza A and B neuraminidase.
3) The neuraminidase (sialidase) enzyme (expressed on the viral surface) hydrolyzes terminal sialic acid residues from glycoproteins, oligosaccharides, and glycolipids, and is required for
infectivity of influenza virus; neuraminidase may be essential for elution of newly synthesized virions from infected cells.

**Adverse effects**

Oseltamivir is generally well tolerated; gastrointestinal side effects (transient nausea, vomiting, abdominal pain) may increase with increasing doses, particularly above 300 mg/day. Occasionally it may cause bronchitis, insomnia and vertigo. Less commonly angina, pseudo membranous colitis and peritonsillar abscess have also been reported. There have been rare reports of anaphylaxis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, skin rashes. Also reported Cardiac dysrhythmia, Facial swelling, Gastrointestinal hemorrhage, Hemorrhagic colitis, Hepatitis, Seizure, visual disturbances In children, most frequently reported side effect is vomiting. Infrequently, abdominal pain, epistaxis, bronchitis, otitis media, dermatitis and conjunctivitis have also been observed. Rare neuropsychiatric symptoms such as confusion or abnormal behaviour have occurred after beginning treatment for seasonal influenza with oseltamivir, particularly in children and adolescents, but the contribution of oseltamivir to these events is unknown.

**Patient Instructions for counselling by Pharmacists: Zanamivir** (Currently not included in the line of treatment as per GOI, MOHFW)

- At present GlaxoSmithKline’s Relenza containing Zanamivir is available in market (not in India) as per authenticated published literature.
- Relenza(R) is a powder that is used with its own special inhaler device called a Diskhaler(R). Individually measured doses of the powder are held in a foil blister pack

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45 MICROMEDEX(R) [DRUGDEX® System] Healthcare Series Vol. 141

46 BNF 57 edition

47 http://www.fda.gov/medwatch/safety/2008/safety08.htm#Tamiflu

called a Rotadisk(R). Each Rotadisk contains 4 blisters. Each blister contains 5 mg of active drug and 20 mg of lactose powder (which contains milk proteins). Each Rotadisk(R) is placed into the Diskhaler(R). The Diskhaler(R) pierces each blister one at a time to load the correct dose into the chamber when ready to use the medicine. Whenever this medicine would be available in India it will be pharmacist’s responsibility to educate patient the proper use of device. Hospital pharmacist should ask patient to read entire leaflet before using RELENZA. Even if patient has had a previous prescription for Relenza, read the leaflet to see if any information has changed.

- To inform pharmacist or doctor immediately if allergic reaction develops.
- To inform pharmacist, nurse or doctor if patient experiences any side effect because of medicine.
- To take medicine as per doctor’s instructions i.e. how much of this medicine to use and how often. Ask patient not to use more medicine or use it more often than instructed by doctor.
- That if patient misses or forgets to use his medicine, use it as soon as he/she can. If it is almost time for his next dose, wait until then to use the medicine and skip the missed dose. Instruct patient not use extra medicine to make up for a missed dose.
- If patient is also using an asthma inhaler use it before use of zanamivir.
- To always check inside the mouthpiece to make sure it is clear before each use. If foreign objects are in the mouthpiece, they could be inhaled and cause serious harm.
- To always replace the cover after each use.
- To keep using this medicine for the full treatment time, even if patient feel better after the first few doses. Warn patient that if he stops using medicine too soon, his infection may not clear up.
- To keep the medicine in the foil pouch until ready to use it. Store at room temperature, away from heat and direct light. Do not freeze. Do not break the foil on the Rotadisk(R).
- To keep all medicine away from children and never share medicine with anyone.
Monograph: Zanamivir\textsuperscript{49,50} (Currently not included in the line of treatment as per GOI, MOHFW)

Class
Antiviral
Neuraminidase Inhibitor, Influenza A&B Virus

Monitoring

\begin{itemize}
\item fever
\item symptomatic improvement
\item respiratory function; in patients with underlying airways disease
\end{itemize}

Contraindications
hypersensitivity to zanamivir or any component of the product including lactose (milk proteins)

Precautions

\begin{itemize}
\item abnormal behaviour and delirium leading to injury have been reported, primarily in paediatric patients
\item airway disease, such as asthma or COPD; not recommended due to serious cases of bronchospasm, some fatal
\item Inhalation: if administered concurrently, use inhaled bronchodilator first
\item uncontrolled chronic illness
\item allergic reactions, including oropharyngeal edema, serious skin rashes, and anaphylaxis have been reported
\item concomitant use of intranasal live attenuated influenza vaccine (LAIV); do not administer LAIV within 2 weeks before or 48 hours following zanamivir administration unless medically necessary; may interfere with vaccine efficacy
\end{itemize}

Renal Failure: no dosage adjustment required

\textsuperscript{49} MICROMEDEX(R) [DRUGDEX® System] Healthcare Series Vol. 141
\textsuperscript{50} BNF 57 edition
**Mechanism of Action**

Selective inhibitor of influenza A and B virus neuraminidase

a) Inhibits viral cleavage of sialic acid from cell surface glycoconjugates which inhibits the release of newly formed virus from the surface of infected cells.

b) Prevents viral spread across the mucous lining of the respiratory tract

**Adverse effects**

Inhaled zanamivir has been temporally associated with bronchospasm and patients with pre-existing airway disease appear to be at increased risk for this severe adverse reaction.

- **Common**
  - Musculoskeletal: Arthralgia (influenza treatment, less than 1.5%), Rheumatic arthritis, acute
  - Neurologic: Dizziness (influenza treatment, 1% to 2%)
  - Respiratory: Cough (influenza prophylaxis in paediatric patients, 16%), Nasal symptom (influenza prophylaxis in paediatric patients, 20%), Pain in throat (influenza prophylaxis in paediatric patients, 11%), Sinusitis (influenza treatment, 2% to 3%)
  - Other: Fever with chills (influenza prophylaxis, 5%)

- **Serious**
  - Cardiovascular: Cardiac dysrhythmia
  - Dermatologic: Facial edema, Rash, Urticaria (influenza treatment, less than 1.5%)
  - Immunologic: Anaphylaxis, Immune hypersensitivity reaction
  - Neurologic: Seizure
  - Psychiatric: Abnormal behaviour, Delirium
  - Respiratory: Edema of pharynx, Respiratory depression, Respiratory distress
**Chemo Prophylaxis**

Chemoprophylaxis should be given to

- All close contacts of suspected, probable and confirmed cases. Close contacts include household/social contacts, family members, workplace or school contacts, fellow travellers etc.
- All health care personnel coming in contact with suspected, probable or confirmed cases
- Government should monitor situation and should take appropriate decision on mass chemoprophylaxis.

**Oseltamivir**

<table>
<thead>
<tr>
<th>Group</th>
<th>Chemoprophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>75-mg capsule once per day for 10 days after last known exposure to an ill confirmed case</td>
</tr>
<tr>
<td>Children ≥ 12 months</td>
<td></td>
</tr>
<tr>
<td>15 kg or less (1 to 2 years of age)</td>
<td>30 mg orally once per day for 10 days after last known exposure to an ill confirmed case</td>
</tr>
<tr>
<td>16-23 kg (3 to 5 years of age)</td>
<td>45 mg orally once per day for 10 days after last known exposure to an ill confirmed case</td>
</tr>
<tr>
<td>24-40 kg (6 to 9 years of age)</td>
<td>60 mg orally once per day for 10 days after last known exposure to an ill confirmed case</td>
</tr>
<tr>
<td>&gt;40 kg (10 years and older)</td>
<td>75 mg orally once per day for 10 days after last known exposure to an ill confirmed case</td>
</tr>
</tbody>
</table>
**Zanamivir** (Currently not included in the line of treatment as per GOI, MOHFW)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Treatment Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adults</strong></td>
<td>Two 5-mg inhalations (10 mg total) once per day for 10 days after last known exposure to confirmed case</td>
</tr>
<tr>
<td><strong>Children (age 5 years and older)</strong></td>
<td>Two 5-mg inhalations (10 mg total) once per day (age, 5 years or older) once a day for 10 days after last known exposure to confirmed case</td>
</tr>
</tbody>
</table>
Annexure 4.1: Steps of Using Zanamivir-Inhalation Powder

Currently Zanamivir (Relenza) is not included in line of treatment as per GOI MOHFW however as when it would be made available by GOI in India Pharmacist should educate patients to use Relenza as follows:

Step A: Load the medicine into the DISKHALER

Step B: Puncture the blister

Keep DISKHALER Level for Steps B and C

51 http://www.relenza.com/inhaler-step-by-step.html (This site is intended for US residents only.)
Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)

Step C: Inhale

Step D: Move the medicine disk to the next blister for the next inhalation
Annexure 4.2: Parts of the Diskhaler\textsuperscript{52}

\begin{itemize}
  \item **COVER**: keeps the DISKHALER clean and free of foreign matter; replace cover when not in use.
  \item **WHITE MOUTHPIECE**: where the medicine is inhaled by mouth.
  \item **DARK BROWN WHEEL**: rotates to the next blister of medicine.
  \item **WHITE TRAY**: pulls in and out of DISKHALER body.
  \item **RAISED RIDGES**: help you pull out the tray for loading.
  \item **NEEDLE**: punctures the blister to release medicine.
  \item **DISKHALER BODY**:
  \item **HALF-CIRCLE FLAP**: lifts up and down to operate plastic needle.
  \item **SILVER MEDICINE DISK**: contains 4 blisters of medicine; the disk fits into the dark brown wheel inside the DISKHALER.
\end{itemize}

\textsuperscript{52} \url{http://www.relenza.com/parts-of-your-inhaler.html} (This site is intended for US residents only.)
5. Novel influenza A (H1N1) in Special Conditions

*Pregnant women and breast feeding mothers:*

Evidence from the previous pandemics of 1918-1919 and 1957-1958 and from seasonal influenza suggests that pregnant women are likely to be at increased risk of morbidity and mortality related to infection with this novel flu virus.\(^5\) Several hospitalizations including fatal outcomes have been reported in pregnant women infected with the new H1N1 virus.

Pharmacist should instruct pregnant women as following:

- To take everyday steps as described in Chapter 7 “Prevention” (Page No.-72) to help prevent the spread of germs and protect health.

- If pregnant woman is experiencing flu-like symptoms, ask her to stay at home, limit contact with others, and call doctor. Doctor will decide if testing or treatment is needed.

- Instruct pregnant woman to seek emergency medical care right away if she experiences below mentioned warning signs as follows:

  - Difficulty breathing or shortness of breath
  - Pain or pressure in the chest or abdomen
  - Sudden dizziness
  - Confusion
  - Severe or persistent vomiting
  - Decreased or no movement of your baby
  - A high fever

Anti-viral medicines in Pregnancy:\(^{54}\):

*Oseltamivir and zanamivir are "Pregnancy Category" medications, indicating that no clinical studies have been conducted to assess the safety of these medications for pregnant women. Although a few adverse effects have been reported in pregnant women who took these medications, no relation between the use of these medications and those adverse events has been established. Pregnancy should not be considered a contraindication to oseltamivir or zanamivir use. Because of its systemic activity, oseltamivir is preferred for treatment of pregnant women. The drug of choice for chemoprophylaxis is less clear. Zanamivir may be preferable because of its limited systemic absorption; however, respiratory complications that may be associated with zanamivir because of its inhaled route of administration need to be considered, especially in women at risk for respiratory problems.*

Brest feeding mothers also should take everyday precautions described in Chapter-7 “Prevention” (Page No.-72). In addition, pharmacist should instruct feeding mothers to not to cough or sneeze in the baby's face while feeding baby, or any other time mother and baby are close. If possible, only family members who are not sick should care for infants.

Pharmacist should guide feeding mothers that if they are sick and there is no one else to care for their baby, wear a facemask, if available and tolerable, and instruct to cover mouth and nose with a tissue when coughing or sneezing. Mothers who are breastfeeding and taking medicine to treat flu because they are sick should express their breast milk for bottle feedings, which can be given to baby by someone who is not sick. Mothers who are breastfeeding and are taking medicines to prevent the flu because they have been exposed to the virus should continue to feed their baby at the breast as long as they do not have symptoms of the flu such as fever, cough, or sore throat.

*Oseltamivir and Zanamivir during Breastfeeding\(^{55}\):*

Infant risk cannot be ruled out. Weigh the potential benefits of drug treatment against potential risks before prescribing this drug during breastfeeding.

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\(^{54}\) Centers for Disease Control and Prevention (CDC). Interim Guidance on Antiviral Recommendations for Patients with Novel Influenza A (H1N1) Virus Infection and Their Close Contacts May 6, 2009 11:00 PM ET [http://www.cdc.gov/h1n1flu/recommendations.htm](http://www.cdc.gov/h1n1flu/recommendations.htm) accessed on 10\(^{th}\) July 2009.

\(^{55}\) MICROMEDEX(R) [DRUGDEX System] Healthcare Series Vol. 141
**Children Under 1 Year of Age**

Children under one year of age are at high risk for complications from seasonal human influenza virus infection. The characteristics of human infection novel (H1N1) influenza virus are still being studied, and it is not known whether infants are at higher risk for complications associated with novel (H1N1) influenza virus infection compared to older children and adults, very little is known about prevention of novel H1N1 flu infection in infants.

Oseltamivir is not licensed for use in children less than 1 year of age. However, limited safety data on oseltamivir treatment for seasonal influenza in children less than one year of age suggest that severe adverse events are rare.

Because infants experience high rates of morbidity and mortality from influenza, infants with novel (H1N1) influenza virus infections may benefit from treatment using oseltamivir.

**Dosing recommendations for antiviral treatment of children younger than 1 year using oseltamivir.**

<table>
<thead>
<tr>
<th>Age</th>
<th>Recommended treatment dose for 5 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;3 months</td>
<td>12 mg twice daily</td>
</tr>
<tr>
<td>3-5 months</td>
<td>20 mg twice daily</td>
</tr>
<tr>
<td>6-11 months</td>
<td>25 mg twice daily</td>
</tr>
</tbody>
</table>

**Dosing recommendations for antiviral chemoprophylaxis of children younger than 1 year using oseltamivir.**

<table>
<thead>
<tr>
<th>Age</th>
<th>Recommended prophylaxis dose for 10 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;3 months</td>
<td>Not recommended unless situation judged critical due to limited data on use in this age group</td>
</tr>
<tr>
<td>3-5 months</td>
<td>20 mg once daily</td>
</tr>
<tr>
<td>6-11 months</td>
<td>25 mg once daily</td>
</tr>
</tbody>
</table>
Doctors should be aware of the lack of data on safety and dosing when considering oseltamivir use in a seriously ill young infant with confirmed novel (H1N1) influenza virus infection or who has been exposed to a confirmed novel (H1N1) influenza case, and carefully monitor infants for adverse events when oseltamivir is used.

**People with heart disease, stroke, and cardiovascular disease:**

Patients with chronic cardiovascular disease and cerebrovascular disease (CVD) are at increased risk of experiencing an acute exacerbation of disease during influenza epidemics. Health care providers should be aware that influenza might produce increased number of cardiovascular events, leading to increased hospitalizations and they should know use of resources to treat acute coronary events, heart failure, and stroke.

Pharmacist should instruct such patient as following:

- It is especially important to wash the hands often with soap and water and follow other basic hygiene to avoid infection.
- Maintain a two week supply of medications.
- Do not stop taking medications without first consulting to doctor, especially in the event of influenza or a respiratory infection.
- Patients with heart failure should be alert to changes in their breathing and should promptly report changes to their physicians.

The information above is important for people with heart disease, stroke, and cardiovascular disease. Pharmacist should guide such patients based on above mentioned information while dispensing cardiovascular medications for such patients. **However while counselling pharmacist should communicate without creating unnecessary panic situation.** Also pharmacist should keep adequate stocks of commonly used cardiovascular medicines in their pharmacy during current pandemic of novel influenza A (H1N1).
**HIV-infected Adults and Adolescents:**

Adults and adolescents with HIV infection, especially persons with low CD4 cell counts, are known to be at higher risk for viral and bacterial lower respiratory tract infections and for recurrent pneumonias. Evidence that influenza can be more severe for HIV-infected adults and adolescents comes from studies among HIV-infected persons who had seasonal influenza; these data are limited. However, several studies have reported higher hospitalization rates, prolonged illness and increased mortality, especially among persons with AIDS. It is possible that HIV-infected adults and adolescents are also at higher risk for novel influenza A (H1N1) virus infection complications. Pharmacists in this situation should concentrate more on such patients and guide them thoroughly on preventive measures discussed in Chapter -7 “Prevention” (Page No.-72).
6. Resistance to Anti-viral Medicines and Role of Pharmacists

Resistance can develop to antiviral drugs used for influenza. However at this time, there is no evidence to indicate the development of widespread antiviral resistance among pandemic H1N1 viruses.

WHO has been informed by health authorities in Denmark, Japan and the Special Administrative Region of Hong Kong, China of the appearance of H1N1 viruses which are resistant to the antiviral drug oseltamivir (known as Tamiflu) based on laboratory testing. These viruses were found in three patients who did not have severe disease and all have recovered. Investigations have not found the resistant virus in the close contacts of these three people. The viruses, while resistant to oseltamivir, remain sensitive to zanamivir.

WHO and its partners are monitoring antiviral drug resistance. Close to 1000 pandemic H1N1 viruses have been evaluated by the laboratories in the Global Influenza Surveillance Network for antiviral drug resistance.

The widespread, inappropriate use of currently recommended anti-viral medicines could increase the risk of the virus developing resistance to them. Government of India has banned retail sale of Oseltamivir. Refer Annexure 6.1 (Page No.-70) for letters issued by Drugs Controller General (I) to All Port Offices of CDSCO and to All State Drug Controller in this regard. Pharmacist during current situation should not stock recommended anti-viral medicines for swine flu. Also should guide consumers not to buy anti-viral medicines from internet pharmacies to prevent swine flu. Additionally illegal internet pharmacies take orders and payments with no assurance of the medicines being delivered, and those customers who do receive medicines have no guarantee of the safety, quality or effectiveness of the medicines, thereby seriously putting their health at risk.

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56 World Health Organization. Warning on purchase of antivirals without a prescription, including via the Internet 14 May 2009 Information Exchange System Alert No. 122
Annexure 6.1: Instructions to All Port Offices of CDSCO and to All State Drug Controller by Drugs Controller General (I)57

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002

F.No.DCI/Misc/2009/2413

Date:

OFFICE MEMORANDUM

SUB: Import of “Oseltamivir phosphate” products (Tamiflu) - Reg.

It is understood from media reports that “Oseltamivir phosphate” (Tamiflu) capsules are being sold at pharmaceutical retail outlets at very high price by taking advantage of Swine flu. This product is meant for Govt. supply only and it is not permitted to be sold through retail Chemist and Druggist in India.

There is a possibility that some of the importer may be procuring this product through internet / courier / speed post etc. from outside India. Therefore, it is directed you to keep a proper vigil on import of the subject product so as to ensure that no such products, ordered through internet, are imported by courier / speed post and delivered to consumers / for personal use.

The action taken by you in this regard may be communicated to this office.

(DR. SURINDER SINGH)
DRUGS CONTROLLER GENERAL (I)

To
All Port Offices of CDSCO

Copy forwarded for information to:
1. PPS DG, DGHS, Nirman Bhawan, New Delhi
2. JS(DP), DGHS, Nirman Bhawan, New Delhi
3. JSC(VC), DGHS, Nirman Bhawan, New Delhi

57 http://cdsco.nic.in/Oseltamivir.pdf

Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)
To,

All State Drugs Controller.

Sub :- Retail / Whole Sale of 'Oseltamivir phosphate' (Tamiflu) – reg

Sir,

There are media report that Oseltamivir phosphate (Tamiflu) capsules are being sold at various Pharmaceutical retail outlet at very high price by taking advantage of Swine flu. This product is meant for Govt. supply only and it is not permitted to be sold through retail chemist & Druggist in India. Indiscriminate use of the drug by public could result in the virus developing resistance to this.

Further, it is also pertinent to mention that as per Gazette notification (S.O.526E dated 12th April 2006) of Ministry of Consumer Affairs:-

a) No manufacture, distributor, stockist, dealer or any other person licensed to sell drugs shall sell any preparation containing the drug 'Oseltamivir phosphate' except to the Central Government or a State Government or Union Territory Administration (UTA) or such other agency or agencies as the Government may by order in writing, designate. (This Clause not apply for export, out of India).

b) The Central Government, State Govt. or UTA shall make arrangement for the distribution "Oseltamivir Phosphate" and formulation based there on through Public Health Systems, as it considers appropriate.

In view of the above you are requested to keep a vigil on the movement/ manufacture/ sale of this product in your jurisdiction and direct your staff to visit retail/ whole sale chemist/ Pharmacies especially those who are suspected to be involved in selling of subject Drug to ensure that the drug is not sold through retail outlet.

The action taken by you in this regard may be communicated to this office.

(Dr Surinder Singh)
Drugs Controller General (I)

C.C

1. All Zonal/Sub-Zonal offices of CDSCO, with a request to co-ordinate with state authorities/ send CDSCO inspectors to ensure proper action in this regard.

2. PPS to DG, DGHS Nirman Bhawan, New Delhi

3. Joint Secretary (V.C), Nirman Bhawan, New Delhi

4. Joint Secretary (D P), Nirman Bhawan, New Delhi

Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)
7. Prevention

*General Preventative Measures and Role of Pharmacist:*

There is no vaccine available right now to protect against novel H1N1 virus. But there are everyday actions that can help prevent the spread of germs that cause respiratory illnesses like influenza. Since Government of India has banned retail sell of recommended anti-viral medicine (Oseltamivir) for treatment and for chemo prophylaxis current novel influenza A (H1N1), community pharmacist have vital role to play in prevention. Community Pharmacist should take leading position to prevent spread of disease and to educate common individuals

Community pharmacist should effectively communicate with consumers and should-

- Ask consumers to perform hand hygiene frequently, by washing with soap and water or using an alcohol based hand rub, especially if touching the mouth and nose and surfaces that are potentially contaminated. Educate consumers the proper technique of washing hands.
- Instruct consumers to refrain from touching mouth and nose, eyes. Germs spread this way.
- Ask healthy persons to maintain distance of at least 1 meter (more than an arm's length) from any individual with influenza-like symptoms.
- Instruct healthy persons to avoid or reduce as much as possible the time spent in close contact with people who might be ill.
- Advice people to reduce as much as possible the time spent in crowded settings.
- Guide consumers to keep their living and working place clean and improve airflow in their living space by opening windows as much as possible.
- Ask consumers to practice good health habits including, eating nutritious food, minimizing stress keeping physically active by regular exercise, and developing good sleep habits help your immune system stays strong.
If consumer with flu symptoms visits pharmacy then pharmacist should guide consumer as follows:

- **Pharmacist must note that patient with flu like symptoms who has travelled from affected areas in past 10 days and his close contacts with similar symptoms should be considered as suspected case of Novel Influenza A (H1N1) [swine flu] and pharmacist should ask these people to contact Outbreak Monitoring Cell, NICD (National Institute of Communicable Diseases), New Delhi. or call: 011-23921401. or nearby Government Hospital.**

- **If patient live in areas where influenza A H1N1 cases have been identified and become ill with influenza like symptoms, pharmacist should instruct such patients to contact nearby Government Hospital/District CMO/ Influenza H1N1 Control Room or State Nodal officers (Refer Page. No. 103)/ Identified Isolation/Critical Care Facilities (Refer Page No.108)/ NICD (Phone: 011-23921401).**

- **If patients with flu-like symptoms who have not travelled from affected area and who are not close contacts of suspected/probable or confirmed case of novel influenza or no case of swine flu has been detected is in their area should not worry, pharmacist should ask such patient to contact GP.**

- Ask patient to cover his nose and mouth with a tissue while coughing or sneezing. Instruct patient to throw the tissue in the trash after use. Ask him to clean hands immediately after contact with respiratory secretions.

- Instruct patient to take plenty rest. drink clear fluids (such as water, broth, sports drinks, electrolyte beverages for infants) to keep from being dehydrated

- Ask patient to stay home and keep away from work, school or crowds for 7 days after symptoms begin or until patient have been symptom-free for 24 hours, whichever is longer. Staying at home means that patient should not leave home except to seek medical care.

- Instruct patient if he is leaving the house to seek medical care or if he is sharing common space with other household members at home, wear a facemask, if available and tolerable.
Instruct patients and their caretakers at home to watch out below mentioned emergency warning signs and ask them to seek medical attention on urgent basis.

**In children, emergency warning signs that need urgent medical attention include:**

- Fast breathing or trouble breathing
- Bluish or gray skin colour
- Not drinking enough fluids
- Severe or persistent vomiting
- Not waking up or not interacting
- Being so irritable that the child does not want to be held
- Has signs of dehydration, in infants, a lack of tears when they cry
- Flu-like symptoms improve but then return with fever and worse cough

**In adults, emergency warning signs that need urgent medical attention include:**

- Difficulty breathing or shortness of breath
- Has purple or blue discoloration of the lips
- Pain or pressure in the chest or abdomen
- Has signs of dehydration such as dizziness when standing, absence of urination
- Confusion, incoherent speech
- Loss of consciousness
- Severe or persistent vomiting and unable to keep liquids down
- Flu-like symptoms improve but then return with fever and worse cough
- Has seizures (for example, uncontrolled convulsions)
In particular, patients with co-morbid condition (hypertension, diabetes, bronchial asthma, chronic bronchitis or Obstructive airway diseases etc) need to be observed for worsening of symptoms.

**Hand Hygiene**

Hand hygiene is the most important measure to reduce the risk of transmitting infectious organism from one person to other. Hand hygiene is especially important in combating the spread of swine influenza and pharmacist should guide consumers the importance of following good hand hygiene routines.

Pharmacist should guide people upon hand hygiene as follows:

All members of a household should wash their hands -
- Before eating or handling food
- After touching the mouth and nose (after blowing nose, coughing, sneezing if individual is sick).
- After contact with respiratory secretions or such contaminated surfaces.
- After going to the toilet
- After handling general waste and garbage

Pharmacist should educate individuals regarding hand washing technique as follows:

- Wash hands often with soap and running water or antiseptic hand wash, especially after coughing or sneezing, and dry them thoroughly by using disposable tissue, paper or towel. Pharmacists should emphasise individuals that washing hands properly takes about as long as singing "Happy Birthday" twice!
• Alcohol-based hand cleaners and gel sanitizers are also effective; use it if don’t have immediate access to soap and water.

• If using gel, rub hands until the gel is dry. The gel doesn’t need water to work; the alcohol in it kills the germs on hands.

For steps in washing hands properly see Annexure 7.1 (Page No.-82). Community pharmacist must display this as poster in their setting or can distribute same as PIL to create awareness among people.

**Respiratory and Cough Etiquette**

It is very important that community pharmacist should convey consumers that serious respiratory illnesses like influenza, respiratory syncytial virus (RSV), whooping cough, and severe acute respiratory syndrome (SARS) are spread by: Coughing or sneezing and Unclean Hands.

In order to stop help stop the spread of germs, Pharmacist must advise consumers to

• Cover mouth and nose with a tissue while coughing or sneezing. Ask him to clean hands immediately after contact with respiratory secretions.
• Ask patient to put used tissue in the waste basket and clean hands properly.
• Clean hands after coughing or sneezing Wash with soap and water. Or Clean with alcohol-based hand cleaner.
• Guide patient that if tissue is not available close by while coughing or sneezing, he should cover his mouth as much as possible with the crook of his elbow.
**Cleaning Measures at Home**

Influenza virus is destroyed by heat (167-212°F [75-100°C]). Pharmacist should ascertain consumers that germs can be spread when a person touches something that is contaminated with germs and then touches his or her eyes, nose, or mouth. Droplets from a cough or sneeze of an infected person move through the air. Germs can be spread when a person touches respiratory droplets from another person on a surface like a desk, for example, and then touches their own eyes, mouth or nose before washing their hands. To prevent the spread of influenza virus it is important to keep household surfaces (especially bedside tables, surfaces in the bathroom, kitchen counters and toys for children) clean regularly by wiping them down with soap and water or sodium hypochlorite solution or with household bleach (5%) solution or a household disinfectant according to directions on the product label. Improve airflow in your living space by opening windows as much as possible.

**Role of Pharmacist in training person taking care of suspected, probable or confirmed case of Novel Influenza A (swine flu) at home:**

According to WHO the majority of people who contract the virus experience the milder disease and recover without antiviral treatment or medical care. Supportive care at home - resting, drinking plenty of fluids and using a pain reliever for aches - is adequate for recovery in most cases. Keeping this in mind community pharmacist has major and vital role to play in educating persons taking care of patient with flu symptoms, suspected or confirmed case of swine flu. Pharmacist should instruct caretakers as follows:

- Pharmacist must instruct to caretaker and patients how to take medicines (before or after food) [Medicines should be taken only on advice of the health care provider], how to store medicines and important instruction if any. Pharmacist should ask caretaker and patient to inform doctor/pharmacist or nurse if patient experiences adverse effects due to medicine.
• Pharmacist must instruct patients and their caretakers/close contacts at home to watch out above mentioned emergency warning signs in children and adults and ask them to seek medical attention on urgent basis. [Patient should be referred to nearest identified health facility (See Page No.-108)]. In particular, patients with co-morbid condition (hypertension, diabetes, bronchial asthma, chronic bronchitis or Obstructive airway diseases etc) need to be observed for worsening of symptoms.

• Pharmacist must instruct caretaker the most important ways to protect himself and others who are not sick when providing care to a household member who is sick with influenza as follows:

  • Patient should wear three layer surgical mask all the time. If mask is not readily available, mouth and nose should be covered with a piece of cloth/handkerchief/tissue paper.
  • Instruct patient to avoid smoking.
  • Caretaker should ask patient to stay home and keep away from work, school or crowds for 7 days after symptoms begin or until patient have been symptom-free for 24 hours, whichever is longer. Staying at home means that patient should not leave home except to seek medical care.
  • Instruct caretaker to keep the sick person away from other people as much as possible. If inevitable maintain an arms length.
  • Patient and household members should void having visitors at home.
  • Instruct caretaker if there is individual who belongs to high risk group (Refer Page No.43 to see Groups at high risk for complications) for complications from influenza, should attempt to avoid close contact (within 6 feet) with household members who are sick with influenza.
  • Ask caretaker to remind the sick person to cover their coughs, and clean their hands with soap and water or an alcohol-based hand rub often, especially after coughing and/or sneezing
  • Instruct everyone in the household clean their hands often, using soap and water or an alcohol-based hand rub. Children may need reminders or help keeping their hands clean.

Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)
• Strictly warn caretaker that infants should not be cared for by sick family members.
• Instruct caretaker to keep the sick person in a room separate from the common areas of the house. (For example, a spare bedroom with its own bathroom, if that's possible.) Keep the sickroom door closed.
• If the living space is small and more than one person need to sleep in a room, ensure that the head end of patient and others sleeping in that room are in opposite direction (head to toe).
• Instruct caretaker to throw away tissues and other disposable items used by the sick person in the trash. Washing hands properly after touching used tissues and similar waste is must.
• Instruct caretaker to keep surfaces (especially bedside tables, surfaces in the bathroom, and toys for children) clean by wiping them down with a household disinfectant according to directions on the product label.
• Linens, eating utensils, and dishes belonging to those who are sick do not need to be cleaned separately, but importantly these items should not be shared without washing thoroughly first.
• Advise caretaker to wash linens (such as bed sheets and towels) by using household laundry soap and tumble dry on a hot setting. Avoid “hugging” laundry prior to washing it to prevent contaminating himself. Cleaning hands with soap and water or alcohol-based hand rub right after handling dirty laundry is mandatory.
• Eating utensils should be washed either in a dishwasher or by hand with water and soap.

Pharmacist should advise caretakers to follow below mentioned instructions to protect himself:

• Avoid being face-to-face with the sick person. Use mask if feasible and possible.
• When holding small children who are sick, place their chin on shoulder so that they will not cough in face.
• Clean hands with soap and water or use an alcohol-based hand rub after touching the sick person or handle used tissues, or laundry.

• Chemoprophylaxis to house hold contacts and caretaker would be as per the policy decision taken by the Government. House hold contacts having co morbid conditions would be put on chemoprophylaxis

Pharmacist should instruct caretaker/close contacts/household members of suspected/probable/confirmed case of novel influenza to

(i) Remain at home (home quarantine) for at least 7 days after the last exposure with a case.
(ii) Initiate self-health monitoring for the development of fever (regular temperature charting, twice a day) or respiratory symptoms (cough, sore throat, running nose, difficulty in breathing etc.) for 7 days after the last exposure to the case patient.
(iii) If fever or respiratory symptoms develop must inform the identified Local Health Official/ Government Hospital/District CMO/ Influenza H1N1 Control Room or State Nodal officers (Refer Page. No. 103)/ Identified Isolation/Critical Care Facilities (Refer Page No.108)/ NICD (Phone: 011-23921401).

**Role of Pharmacist in Educating Consumers Proper Use of Mask:**

In the community, the benefits of wearing masks has not been established, especially in open areas, as opposed to enclosed spaces while in close contact with a person with influenza-like symptoms. Nonetheless, many individuals may wish to wear masks in the home or community setting, particularly if they are in close contact with a person with influenza-like symptoms, for example while providing care to family members. Furthermore, using a mask can enable an individual with influenza-like symptoms to cover their mouth and nose to help contain respiratory droplets, a measure that is part of cough etiquette. In management of confirmed cases of swine influenza
patients and close contacts (e.g. caretaker, driver of ambulance taking confirm case to hospital etc) should wear a three layer surgical mask. Pharmacist can advise consumers and patients

Role of pharmacist in training on the correct and proper use of masks in vital because *Using a mask incorrectly, may actually increase the risk of transmission, rather than reduce it.* Pharmacist should train consumers the proper use and disposal of mask as follows

Instruct consumers-

- to place mask carefully to cover **mouth and nose** and tie securely to minimize any gaps between the face and the mask
- while in use, avoid touching the mask
to clean hands by washing with soap and water or using an alcohol-based handrub whenever consumer touches a used mask, e.g. when removing or washing
- to replace masks with a new clean, dry mask as soon as they become damp/humid
- not to re-use single-use masks
- to discard single-use masks after each use and dispose of them immediately upon removing.

Although some alternative barriers to standard medical masks are frequently used (e.g. cloth mask, scarf, paper masks, rags tied over the nose and mouth), there is insufficient information available on their effectiveness.
Pharmacist should not encourage using such alternatives if such alternative barriers are used, they should only be used once or, in the case of cloth masks, should be cleaned thoroughly between each use (i.e. wash with normal household detergent at normal temperature). They should be removed immediately after caring for the ill. Hands should be washed immediately after removal of the mask.

82

*Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)*
Annexure 7.1: How to Wash Your Hands Properly?\textsuperscript{58}

\textbf{How to Handwash?}

\textit{WASH HANDS WHEN VISIBLY SOILED! OTHERWISE, USE HANDBRUB}

\begin{itemize}
  \item \textbf{0} Duration of the entire procedure: 40-60 seconds
  \item \textbf{1} Wet hands with water;
  \item \textbf{2} Apply enough soap to cover all hand surfaces;
  \item \textbf{3} Rub hands palm to palm;
  \item \textbf{4} Right palm over left dorsum with interlaced fingers and vice versa;
  \item \textbf{5} Palm to palm with fingers interlaced;
  \item \textbf{6} Backs of fingers to opposing palms with fingers interlocked;
  \item \textbf{7} Rotational rubbing of left thumb clasped in right palm and vice versa;
  \item \textbf{8} Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;
  \item \textbf{9} Rinse hands with water;
  \item \textbf{10} Dry hands thoroughly with a single use towel;
  \item \textbf{11} Use towel to turn off faucet;
  \item \textbf{12} Your hands are now safe.
\end{itemize}

\textsuperscript{58} Courtesy: World Health Organization. Copied for fair use in public interest. \url{http://www.who.int/gpsc/5may/How_To_HandWash_Poster.pdf}

Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)
Annexure 7.2: Cover Your Cough^59

Stop the spread of germs that make you and others sick!

Cover your Cough

Cover your mouth and nose with a tissue when you cough or sneeze or cough or sneeze into your upper sleeve, not your hands.

Put your used tissue in the waste basket.

You may be asked to put on a surgical mask to protect others.

Clean your Hands after coughing or sneezing.

Wash hands with soap and warm water for 20 seconds or dry with alcohol-based hand cleaner.

^59 Courtesy: Centers for Disease Control and Prevention (CDC). Copied for fair use in public interest.

Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)
Annexure 7.3: Do’s and Don’ts for Community

DO’S AND DON'TS FOR THE COMMUNITY

DO

* Wash your hands
* Avoid crowded places
* Stay more than an arm's length from persons afflicted with flu
* Get plenty of sleep
* Do exercise regularly
* Drink plenty of water and eat nutritious food

DO NOT

* Shake hands or hug in greeting
* Spit in public
* Take medicines without consulting a physician

FOR PEOPLE WHO ARE SICK:

* Stay home and limit contacts with others as much as possible
* Rest and take plenty of liquids
* Cover your mouth and nose when you cough or sneeze
* Seek medical advice if needed.

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Annexure 7.4: Influenza A (H1N1) How to Protect Yourself and Others61
POSTER FOR DISPLAY IN PHARMACY FOR PUBLIC AWARENESS

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Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)
Annexure 7.5: How to use Mask Properly

Use your mask properly.

Using a mask incorrectly, may actually increase the risk of transmission, rather than reduce it.

cover mouth and nose with new, clean and dry mask carefully and tie it
check and try to minimise gap between face and mask

while in use, avoid touching the mask
whenever you touch the mask wash wash your hands properly

change mask when it becomes humid or dump
do not re-use single-use mask
discard single-use masks after each use and dispose of them immediately upon removing

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8. Vaccination

Vaccines are one of the most valuable ways to protect people from getting the disease during influenza epidemics and pandemics. So far, evidence suggests that it is unlikely that seasonal influenza vaccines will be protective against the new pandemic virus. Till date there is no effective vaccine is available against novel influenza A (H1N1) [Swine flu] virus but work is already under way to develop such a vaccine. According to WHO making new influenza vaccines ready to immunize people generally takes five to six months after first identification of the pandemic virus. The pandemic influenza A (H1N1) 2009 virus was identified at the end of April 2009. The very first doses of influenza A (H1N1) vaccine usable to immunize people, from one or more manufacturers, are expected as early as September 2009. In India depending upon the availability, the at-risk population would be prioritized for vaccination.

WHO has identified a global network of manufacturers that includes Serum Institute of India Ltd. (212/2, Hadapsar, Off Soli Poonawalla Road, Pune-411 028, Maharashtra India Phone no: +91 -20-26993900 Fax no: +91-20-26993921 e-mail id:contact@seruminstitute.com).

According to WHO people should continue to seek seasonal influenza vaccination like any other year. Inactivated influenza vaccine can be given at the same time as other injectable non-influenza vaccines, but the vaccines should be administered at different injection sites. Specific studies will need to be conducted to assess whether there is any interference between seasonal influenza vaccines and adjuvanted-pandemic vaccines. However it must be noted that seasonal influenza is not considered a public health problem in India, there is no policy for seasonal influenza vaccine. Such a policy can only be evolved, if the morbidity and mortality due to seasonal influenza is known.

Pharmacist should note that studies suggest that seasonal influenza vaccines could sometimes be associated with an increased risk of Guillain-Barré syndrome on the order of one to two cases per million vaccinated persons. During the 1976 influenza vaccination campaign in the United States of

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63* Guillain-Barré Syndrome (GBS) is an acute disorder of the nervous system. It sometimes develops following a variety of infections, including influenza.
Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)

America, about 10 persons per million vaccinated persons developed GBS which stopped the vaccination campaign and led to the withdrawal of the vaccine. The reason why GBS developed in association with that specific vaccine has never been firmly established. The potential for the development of a similar risk with future vaccines can never be firmly excluded. However, according to WHO, the influenza A (H1N1) vaccine will be manufactured according to established standards and post marketing surveillance will be conducted to monitor potential development of any serious adverse events following administration of vaccine.
9. Infection Control Measures at Healthcare Facility

Role of Hospital Pharmacist

Environmental/engineering controls, such as basic HCF infrastructure\textsuperscript{64}, adequate environmental ventilation, proper patient placement and adequate environmental cleaning can help reduce the spread of some pathogens during health care. To prevent the transmission of all respiratory infections in healthcare settings, including influenza, the following infection control measures should be implemented and hospital pharmacist should play role to implementation of these measures in hospital.

Hospital pharmacist should take initiative in posting visual alters in healthcare setting. Hospital pharmacist should post visual alerts (in appropriate local languages) at the entrance to outpatient facilities (e.g., emergency departments, physician offices, outpatient clinics) instructing patients and persons who accompany them (e.g., family, friends) to inform healthcare personnel (doctor/pharmacist) of symptoms of a respiratory infection immediately and to practice respiratory hygiene/cough etiquette. (See Annexure 9.1 Page No.-92) Hospital pharmacist while dispensing should guide patients orally about hand hygiene technique and respiratory etiquette.

Visual alters for those who have returned from affected areas and experiencing flu-like symptoms should be displayed instructing patients to contact hospital pharmacist immediately and wear mask along with general precautionary measures. Hospital pharmacist should guide such patients on proper use of three layered surgical mask.

Hospital pharmacist should ensure easy availability of masks, tissues, alcohol based hand-rubs, soap, disposable towels, and no-touch dust bins in waiting area. When space and chair availability permit, encourage coughing persons to sit at least three feet away from others in common waiting areas.

Healthcare persons including hospital pharmacist should observe “Droplet Precautions” as follows

- Wear a mask, if working within or ≤ 1 metre of the patient.
- Hand hygiene before and after patient contact, and immediately after removal of mask.

Along with Standard Precautions, when examining or close contact a patient with symptoms of a respiratory infection, particularly if fever is present.

As per ‘Standard Precautions’, for procedures with a risk for splashes onto the face and body, PPE should include the use of:

- Facial protection (either a medical mask and eye-visor or goggles, or a face shield).
- A gown and clean gloves; and
- Hand hygiene before and after patient contact, and after PPE removal.

These precautions should be maintained until it is determined that the cause of symptoms is not an infectious agent that requires Droplet Precautions.

**Decontaminating contaminated surfaces, fomites and equipments:**

- Cleaning followed by disinfection should be done for contaminated surfaces and equipments.

- Use phenolic disinfectants, quaternary ammonia compounds, alcohol or sodium hypochlorite. Patient rooms/areas should be cleaned at least daily and terminally after discharge. In addition to daily cleaning of floors and other horizontal surfaces, special attention should be given to cleaning and disinfecting frequently touched surfaces.

- To avoid possible aerosolization of AI virus, damp sweeping should be performed.
• Clean heavily soiled equipment and then apply a disinfectant effective against influenza virus before removing it from the isolation room/area.

• When transporting contaminated patient-care equipment outside the isolation room/area, use gloves followed by hand hygiene. Use standard precautions and follow current recommendations for cleaning and disinfection or sterilization of reusable patient-care equipment.

**Guidelines for Waste Disposal:**

• All the waste has to be treated as infectious waste and decontaminated as per standard procedures

• Articles like swabs/gauges etc are to be discarded in the Yellow coloured autoclavable biosafety bags after use, the bags are to be autoclaved followed by incineration of the contents of the bag.

• Waste like used gloves, face masks and disposable syringes etc are to be discarded in Blue/White autoclavable biosafety bags which should be autoclaved/microwaved before disposal

• All hospitals and laboratory personnel should follow the standard guidelines (Biomedical waste management and handling rules, 1998) for waste management.
Annexure 9.1: Notice to All Patients in Hospital

**IMPORTANT NOTICE TO ALL PATIENTS**

Please tell staff immediately if you have flu symptoms

Flu symptoms include fever, headache, tiredness, dry cough, sore throat, nasal congestion and body aches.

**1. Cover Your Cough and Sneeze**
- Use a tissue to cover your mouth and nose when you cough or sneeze.
- Drop your used tissue in a waste basket.
- You may be asked to wear a mask if you are coughing or sneezing.

**2. Clean Your Hands**
- Wash your hands with soap and warm water or clean with gels or wipes with alcohol.
- Cleaning your hands often keeps you from spreading germs.

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10. Health Facility Managing the Human cases of Novel Influenza A (H1N1) [Swine Flu]

**During Pre Hospital Care:**

- Standard precautions are to be followed while transporting patient to a health-care facility. The patient should also wear a three layer surgical mask.

- Aerosol generating procedures should be avoided during transportation as far as possible.

- The personnel in the patient’s cabin of the ambulance should wear full complement of PPE including N95 masks, the driver should wear three layered surgical mask.

- Once the patient is admitted to the hospital, the interior and exterior of the ambulance and reusable patient care equipment needs to be sanitized using sodium hypochlorite / quaternary ammonium compounds.

- Recommended procedures for disposal of waste (including PPE used by personnel) generated in the ambulance while transporting the patient should be followed.

**During Hospital Care:**

- The patient should be admitted directly to the isolation facility and continue to wear a three layer surgical mask.

- Hospital pharmacist should advise to the close contacts of patient regarding basic facts of novel influenza A (H1N1) and not to panic. Should limit visitors for patients in isolation for novel H1N1 infection.
• The identified medical, nursing and paramedical personnel attending the suspect/ probable / confirmed case should wear full complement of PPE (including N95 mask). If splashing with blood or other body fluids is anticipated, a waterproof apron should be worn over the PPE.

• Aerosol-generating procedures such as endotracheal intubation, nebulised medication administration, induction and aspiration of sputum or other respiratory secretions, airway suction, chest physiotherapy and positive pressure ventilation should be performed by the treating physician/nurse wearing full complement of PPE with N95 respirator on.

• Sample collection and packing should be done under full cover of PPE.

• Perform hand hygiene before and after patient contact and following contact with contaminated items, whether or not gloves are worn.

• Until further evidence is available, infection control precautions should continue in an adult patient for 7 days after resolution of symptoms and 14 days after resolution of symptoms for children younger than 12 years because of longer period of viral shedding expected in children.

• If the patient insists on returning home, after resolution of fever, it may be considered, provided the patient and household members follow recommended infection control measures. At this point hospital pharmacist has an important role to play in educating preventive and infection control measures to the patients, caretakers and their household members. (Refer Chapter No. 7 “Prevention” Page No.-72) Community pharmacist should play pro-active role in monitoring such cases in community also should re-emphasize importance of hand hygiene, cough/respiratory etiquettes and should ensure patients and his close contacts are following instructions.
• The virus can survive in the environment for variable periods of time (hours to days). Cleaning followed by disinfection should be done for contaminated surfaces and equipments.

• The virus is inactivated by a number of disinfectants such as 70% ethanol, 5% benzalkonium chloride (Lysol) and 10% sodium hypochlorite. Patient rooms/areas should be cleaned at least daily and finally after discharge of patient. In addition to daily cleaning of floors and other horizontal surfaces, special attention should be given to cleaning and disinfecting frequently touched surfaces. To avoid possible aerosolization of the virus, damp sweeping should be performed. Horizontal surfaces should be dusted by moistening a cloth with a small amount of disinfectant.

• Clean heavily soiled equipment and then apply a disinfectant effective against influenza virus (mentioned above) before removing it from the isolation room/area. If possible, place contaminated patient-care equipment in suitable bags before removing it from the isolation room/area.

• When transporting contaminated patient-care equipment outside the isolation room/area, use gloves followed by hand hygiene. Use standard precautions and follow current recommendations for cleaning and disinfection or sterilization of reusable patient-care equipment.

• All waste generated from influenza patients in isolation room/area should be considered as clinical infectious waste and should be treated and disposed in accordance with national regulations pertaining to such waste. When transporting waste outside the isolation room/area, gloves should be used followed by hand hygiene.

Healthcare personnel, who develop a febrile respiratory illness and have been working in areas of the hospital where swine influenza patients are present, should be excluded from work for 7 days or until symptoms have resolved, whichever is longer.
Use of PPE:

Rational use of available personal protective equipment (PPE) and appropriate hand hygiene also help reduce spread of infection.

- The medical, nurses and paramedics attending the suspect/probable/confirmed case should wear full complement of PPE (Annexure-10.1 Page No.-97).

- Use N-95 masks during aerosol-generating procedures.

- Perform hand hygiene before and after patient contact and following contact with contaminated items, whether or not gloves are worn.

- Sample collection and packing should be done under full cover of PPE.
Annexure 10.1: Standard Operating Procedures on Use of PPE

Personal Protection Equipments

PPE reduces the risk of infection if used correctly. It includes:

- Gloves (nonsterile),
- Mask (high-efficiency mask) / Three layered surgical mask,
- Long-sleeved cuffed gown,
- Protective eyewear (goggles/visors/face shields),
- Cap (may be used in high risk situations where there may be increased aerosols),
- Plastic apron if splashing of blood, body fluids, excretions and secretions is anticipated.

Goggles  N-95 Mask  OR

Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)

Gown (must for lab work)  Triple layer Mask

Gloves  Shoe covers

The PPE should be used in situations where regular work practice requires unavoidable, relatively closed contact with the suspected human case/poultry.

Correct procedure for applying PPE in the following order:

1. Follow thorough hand wash
2. Wear the coverall.
3. Wear the goggles/shoe cover/head cover in that order.
4. Wear face mask
5. Wear gloves

The masks should be changed after every six to eight hours.
Remove PPE in the following order:

• Remove gown (place in rubbish bin).

• Remove gloves (peel from hand and discard into rubbish bin).

• Use alcohol-based hand-rub or wash hands with soap and water.

• Remove cap and face shield (place cap in bin and if reusable place face shield in container for decontamination).

• Remove mask - by grasping elastic behind ears – do not touch front of mask

• Use alcohol-based hand-rub or wash hands with soap and water.

• Leave the room.

• Once outside room use alcohol hand-rub again or wash hands with soap and water.

**Used PPE should be handled as waste as per waste management protocol**
11. Guidance to Travellers and Role of Pharmacists

WHO is not recommending travel restrictions related to the outbreak of the influenza A (H1N1) virus. Scientific research based on mathematical modelling shows that restricting travel would be of limited or no benefit in stopping the spread of disease. Historical records of previous influenza pandemics, as well as experience with SARS, validate this.

Travellers at high risk for complications include:

- Children less than 5 years of age
- Persons aged 65 years or older
- Pregnant women
- Adults and children who have chronic pulmonary, cardiovascular, hepatic, hematological, neurologic, neuromuscular, or metabolic disorders
- Adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV)

Pharmacist should advise consumers –

- to defer non essential travel to affected areas and to delay travel plan if they are ill.
- to protect themselves and others by following simple prevention practices that apply while travelling and in daily life.
- Pharmacist by means of display and PILs should appeal people who have travelled from Mexico, USA and Canada in past 10 days and show symptoms of flu like fever, cough or sore throat and difficulty in breathing should immediately contact ‘Outbreak Monitoring Cell, National Institute of Communicable Diseases, New Delhi, Phone: 011-23921401

Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)
Annexure 11.1: Travel Advice! Swine Flu

Pharmacist should display below mentioned poster at their retail counters.

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67 Courtesy: MOHFW GOI Copied for fair use in public interest. Travel Advisory to Public
http://www.mohfw.nic.in/SWINEFLU.htm
12. Role of Government in Current Pandemic Situation of Novel Influenza A (H1N1) [Swine Flu] and Contact Information form Pharmacists and other Healthcare Professionals

Since WHO has declared current Novel Influenza A (H1N1) as pandemic, the national government is the natural leader for overall coordination and communication efforts.

In its leadership role, the central government should:

- Identify, appoint, and lead the coordinating body for pandemic preparedness and response; enact or modify legislation and policies required to sustain and optimize pandemic preparedness, capacity development, and response efforts across all sectors;
- Prioritize and guide the allocation and targeting of resources to achieve the goals as outlined in a country’s Pandemic Influenza Preparedness Plan;
- Provide additional resources for national pandemic preparedness, capacity development, and response measures; and
- Consider providing resources and technical assistance to countries experiencing outbreaks of influenza with pandemic potential.

Pharmacist must visit [http://www.mohfw.nic.in/SWINEFLU.htm](http://www.mohfw.nic.in/SWINEFLU.htm) to receive latest Novel Influenza updates in Indian context.
## Novel Influenza A (H1N1) [Swine Flu]

List of State Nodal Officers and contact details of Control Room

<table>
<thead>
<tr>
<th>STATE</th>
<th>CONTROL ROOM (ADD. &amp; CONTACT)</th>
<th>NODAL OFFICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANDHRA PRADESH</td>
<td>Office of The Addl. Director (Health Services), Hyderabad. 040-24656852(T) [24x7]</td>
<td>Dr. Ramswarup [09989923781]</td>
</tr>
<tr>
<td>ARUNACHAL PRADESH</td>
<td>SSU IDSP, Directorate of Health Services, Naharlagun, Arunachal Pradesh. Tel: 0360-2245460 Telefax:: 0360-2244271 (During office hours)</td>
<td>Dr. L. Jampa [09436055743] [24x7]</td>
</tr>
<tr>
<td>ASSAM</td>
<td>Office of the Director (Health Services), Guwahati. 0361-2235577 0361-2261630 0361-2261089 [24x7]</td>
<td>Dr. Doley 0361-2642008 09854066560</td>
</tr>
<tr>
<td>BIHAR</td>
<td>Office of the Executive Director, State Health Society, Sheikhpura, Patna. 0612-2280562 0612-2281232 0612-2290322(F) [24x7]</td>
<td>Mr. Santosh Mathew (IAS) Dr. D K Gupta (Addl. Nodal officer)- 09430057795 Control Room In-charge (Dr BK Singh: 9470003023)</td>
</tr>
<tr>
<td>CHHATISHGARH</td>
<td>State Surveillance Unit (IDSP), Directorate Health services, Old Nurses Hostel, DKS Mantralya Campus, Raipur 0771-2220011 [24x7]</td>
<td>Dr. T K Agarwal (Deputy Director, Epidemic)- Nodal officer: 09926624162 Dr S N M Murti (Addl. N.O) 09425564418</td>
</tr>
<tr>
<td>GUJARAT</td>
<td>Office of Dy. Director (Epid) Commisionerate of Health Services Block No:5, Dr Jivaraj</td>
<td>Dr. S. J. Gandhi [09825342899]</td>
</tr>
</tbody>
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68 [http://www.mohfw.nic.in/SWINEFLU.htm](http://www.mohfw.nic.in/SWINEFLU.htm) accessed 27th July 2009
<table>
<thead>
<tr>
<th>State/Region</th>
<th>Contact Information</th>
<th>Officer(s)</th>
</tr>
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<tbody>
<tr>
<td>GOA</td>
<td>Call Centre: 0832- 2458458 [24x7]</td>
<td>Dr. Tamba (09822123801)</td>
</tr>
<tr>
<td>HARYANA</td>
<td>Office of the Director (Health Services), Sector-6, Panchkula 0172-2587346 [During office hours]</td>
<td>Dr. Aparajita Sondh (Nodal Officer) 09417931024 [24x7]</td>
</tr>
<tr>
<td>JAMMU-KASHMIR</td>
<td>Office of DHS, Srinagar, J&amp;K Tel/Fax. No (0194) 2452697 (main) 2452052, 2454706, 2430141 (24x7)</td>
<td>Dr. M. Ahmed (09419012355) Dr. Bashir Ahmed Dar (Addl. N.O) (09419017716)</td>
</tr>
<tr>
<td>JHARKHAND</td>
<td>RIMS, RANCHI Chamber of Dr. A. K. Mathur (HOD Medicine) (09431176496) (RIMS acting as Control Room)</td>
<td>Dr. C. B Sharma (094311740820) Dr. Pradeep Baski (09431102461)</td>
</tr>
<tr>
<td>KERALA</td>
<td>Office of Addl. DHS (Public Health), Near Govt. General Hospital Trivandrum TF:(0471) 2466828 [24x7]</td>
<td>Dr. Amar 09447451846 DR. SHAUKAT ALI (Joint Director, NICD)-09447702444 Dr K K Mohammad-09447327569</td>
</tr>
<tr>
<td>KARNATAKA</td>
<td>Office of the Director (Health and Family Welfare), Anand Rao Circle, Bangalore-9 Phone no: 080-1056 [24x7]</td>
<td>Dr. Chelluraj 09901060584 Dr. Vasudev Murthi 09880024329</td>
</tr>
<tr>
<td>MAHARASHTRA</td>
<td>Room no.137, First Floor, Swasthya Bhawan, Mumbai. 022-22029070 022-22025830</td>
<td>Dr. Gawande (09420711426) Dr. Awate-09423337556</td>
</tr>
</tbody>
</table>

**Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)**

Mehta Bhawan, Old Sachivalaya, Ahmedabad, Gujarat
Tel: 079-23253334 Fax: 079-23250818 [24x7]
<table>
<thead>
<tr>
<th>State</th>
<th>Contact Information</th>
<th>Phone Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pune</td>
<td>Office of the Joint Director (Health Services), Central Building, Pune 020-26124299 [24X7]</td>
<td>Dr. Desai-09822429266</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dr. Suresh Bohatre</td>
</tr>
<tr>
<td></td>
<td></td>
<td>09881364656</td>
</tr>
<tr>
<td>MEGHALAYA</td>
<td>Office of DHS, Medical Institutions Nokrek Bldg. 3rd Secretariat, Shillong, Meghalaya TF:(0364)2506498</td>
<td>Dr.R.R.Lanong,</td>
</tr>
<tr>
<td></td>
<td>[Office hour only]</td>
<td>(09436102763)</td>
</tr>
<tr>
<td></td>
<td>Control room no 0364-2505842</td>
<td></td>
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<tr>
<td></td>
<td>Civil hospital Shilling</td>
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<tr>
<td></td>
<td>[24x7]</td>
<td></td>
</tr>
<tr>
<td>MANIPUR</td>
<td>Medical Directorate, Office of DHS, Manipur Room no-23 Lamphelpat Manipur-795004 0385-2411668 (9am-6pm)</td>
<td>Dr Bhubon Chandra</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[09436021607]</td>
</tr>
<tr>
<td>MADHYA</td>
<td>State Surveillance Unit, Directorate Health Services, Satpura Bhavan, Bhopal 0755-4094192(TF)</td>
<td>Dr. B N Chauhan</td>
</tr>
<tr>
<td>PRADESH</td>
<td>[Office hours only]</td>
<td>09826282249</td>
</tr>
<tr>
<td>MIZORAM</td>
<td>Civil hospital Aizwal 0389-2322318 102</td>
<td>Dr Sangawalar</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0389-2313721</td>
</tr>
<tr>
<td>NAGALAND</td>
<td>SSU IDSP, Directorate of Health Services &amp; FW, T.R. Hill, KOHIMA-797001. Tel:(0370)2245016 [24x7]</td>
<td>Dr.Kebichusa</td>
</tr>
<tr>
<td></td>
<td>[Office hours only]</td>
<td>(09436000463)</td>
</tr>
<tr>
<td>ORISSA</td>
<td>State Surveillance Unit, Director of Health Services, Heads of the Department</td>
<td>Dr. V. Patnaik</td>
</tr>
<tr>
<td></td>
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<td>0674-2390466</td>
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Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)
<table>
<thead>
<tr>
<th>State</th>
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<th>Nodal Officer</th>
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<tbody>
<tr>
<td>PUNJAB</td>
<td>Buildings, Bhubaneshwar, 0674-2390466 (TF)</td>
<td>Dr. Deepak Bhatia 09814302403 [24x7]</td>
</tr>
<tr>
<td></td>
<td>Pariwar Kalyan Bhawan, Sector-34A, Chandigarh. Tel:(0172) 2621506</td>
<td>0172-2621506(0)/0172-2620234(Fax)</td>
</tr>
<tr>
<td>RAJASTHAN</td>
<td>Office of the Director (Public Health), Swasthaya Bhawan, Jaipur. 0141-2225624</td>
<td>Mr. R K Meena ,IAS, Principal Sect.(Health)- Nodal Officer</td>
</tr>
<tr>
<td></td>
<td>0141-2224831(F) [</td>
<td>Dr. O P Gupta(Addl.Nodal Officer)-0141-2229858</td>
</tr>
<tr>
<td>SIKKIM</td>
<td>SSU IDSP, Health &amp; F.W. Govt. of Sikkim 03592-204199 [Office hours only]</td>
<td>Dr.Y.D.Chingappa (09832079576) Tel:(03592)204199</td>
</tr>
<tr>
<td>TRIPURA</td>
<td>DHS building PN Building Gurkha Basti Agartala Tel/Fax:(0381) 2215879</td>
<td>Dr P Chatterjee (09436120711)</td>
</tr>
<tr>
<td></td>
<td>Dr.R.K. Dhar (09436137652)</td>
<td></td>
</tr>
<tr>
<td>TAMILNADU</td>
<td>Office of the Director (Public Health &amp;Preventive Medicine), Central Malaria Laboratory, 359,Annasalai,Chennai-6 044-24321569 (TF) [24x7]</td>
<td>DR. Elango, DHS, (09940610123)</td>
</tr>
<tr>
<td>UTTARAKHAND</td>
<td>Office of DHS, IDSP, 107,Chander Nagar, Dehradun TF: 0135-2721792 0135-2729897 [Office Hours only]</td>
<td>Dr.Pankaj Jain(09412969502) [24x7]</td>
</tr>
<tr>
<td>UTTAR PRADESH</td>
<td>Swasthaya Bhawan,Luknow Control Room No- Tel:(0522)2616482 Fax:(0522)2622819 [24x7]</td>
<td>Dr Pyaremoohan Srivastava 0522-2629106(TF) (09415181629)</td>
</tr>
<tr>
<td>WEST BENGAL</td>
<td>Chamber of Joint Director (Health Services), Swasthaya Bhawan, Sector-5,GN Block, Kolkata-91</td>
<td>Dr.Bhaskar Bhattacharya, Jt.DHS 033-23330180 (09831187818)</td>
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**Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)**
<table>
<thead>
<tr>
<th>Location</th>
<th>Contact Information</th>
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</thead>
<tbody>
<tr>
<td>ANDAMAN AND NICOBAR</td>
<td>G.B. Pant Hospital, Port Blair Tel: 03192-230622, 233473 Dr. Abhijit Roy, Dy. Director (H) (09474269315) T/F: (03192-232797)</td>
</tr>
<tr>
<td>CHANDIGARH</td>
<td>Govt. Multispecialty Hospital, Sector-16, Chandigarh. Call Centre: 102 Tel: (0172) 2700255 Mr. H.C. Gera (09988212139) (0172)-2740408</td>
</tr>
<tr>
<td>DADRA AND NAGAR HAVELI</td>
<td>Office of DHS, Silvassa. T/F (0260) 2642061, 2641759 Dr. L.M. Patra DHS (09426117593)</td>
</tr>
<tr>
<td>DAMAN AND DIU</td>
<td>CHC, Daman. Tel: (0260) 2230080 Fax: (0260) 2230570 Dr. B. Hansraj (Daman) (09825142600) Dr. Das (Silvassa) Tel: 0260-6242961, 62422120</td>
</tr>
<tr>
<td>DELHI</td>
<td>DHS Office Tel: 22307145 (24X7) Dr. R.P. Vashist (09212222456)/22305657(O), 23646049(O), 23646173(F)</td>
</tr>
<tr>
<td>LAKSHADWEEP</td>
<td>Office of DHS, Tel: (04896) 262316 [Office hours only] Dr. K P Hamza Koya (DHS)-Nodal officer (09496429027, 04896-262113) 04896-262089, 04896-262209(F) Dr. K. Attakoya (Addl. Nodal officer) - 04896-262109, 262317</td>
</tr>
<tr>
<td>PUDUCHERRY</td>
<td>Call Centre: (24X7) Tel: (0413) 1070 (0413) 1077 Dr. G.S. Naidu (09443729783) Tel: (0413) 2249357</td>
</tr>
</tbody>
</table>
### Novel Influenza H1N1 (Swine Flu)

List of airports along with identified Isolation/Critical care Facilities in India

<table>
<thead>
<tr>
<th>City Airports</th>
<th>Isolation/Critical Care Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyderabad (Andhra Pradesh)</td>
<td>Govt. General and Chest Diseases Hospital, Erragadda, Hyderabad, Andhra Pradesh 040-23814939 [Dr. Prasad – 9849902995]</td>
</tr>
<tr>
<td>Ahmedabad (Gujarat)</td>
<td>Civil Hospital attached to Medical College, Asarwa, Ahmedabad, Gujarat-380016 [Dr. Ancheliah – 09426347531]</td>
</tr>
</tbody>
</table>
| Goa                           | 1. Cottage Hospital, Chikalem, Goa (Isolation Ward) [0832-2540864]  
2. Goa Medical College & Hospital, Panjim, Goa (Critical Care) [Dr. Suhas - 09011025066]                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Srinagar (Jammu & Kashmir)    | 1. Govt Medical College, Sri Maharaja Hari Singh Hospital, Karan Nagar, Srinagar-190010, J&K [SMHS - Dr. Wasim Qureshi – 09419000231] (both isolation and critical care)  
2. Sher-e-Kashmir Institute of Medical Sciences, Srinagar, Jammu & Kashmir [Prof. Dr Bhukhari 09419000318]                                                                                                                                                                                                                                                                                                                                                           |
| Thiruvananthapuram (Kerala)   | 1. General Hospital, Thiruvananthapuram, Kerala-695025 [Dr. Suresh - 09447030291] {Isolation and Critical care}  
2. District Hospital, Manjeri; District-Malappuram, Kerala Dr. Ramani – 09447157128, Krishna – 9388014526 {Isolation}                                                                                                                                                                                                                                                                                                                                                           |

69 [http://www.mohfw.nic.in/SWINEFLU.htm](http://www.mohfw.nic.in/SWINEFLU.htm) List of Isolation Facilities issued by Ministry of Health & Family Welfare (Govt. of India) accessed on 18th July 2009
### Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)

**Bangalore (Karnataka)**
- **1.** Dr. Rajiv Gandhi Institute of Chest Diseases and SDS TB Hospital Hosur Road, Near NIMHANS, Bangalore-29, Karnataka
  - Isolation and critical care
  - Dr. S. Buggi - 09448042579
  - Dr. Nagraj - 09448057093

**Mangalore (Karnataka)**
- **2.** District Wenlock Hospital, Mangalore, Karnataka
  - Isolation and critical care
  - Dr. Prabhudev - 09480015944
  - Dr. Jagannath - 09448166113
  - Fax – 08242445664

**Mumbai (Maharashtra)**
- Kasturba Hospital, Sane Guruji Marg, Mumbai-11, Maharashtra
  - Isolation and critical care
  - Dr. Umesh Aigal – 09820935680, 022-23083901, 02,03,04

**Pune (Maharashtra)**
- Dr. Naidu Infectious Disease Hospital, Pune, Maharashtra
  - Isolation and critical care
  - Dr. Barathe – 09923130909

**Nagpur (Maharashtra)**
- Govt Medical College and Hospital, Nagpur, Maharashtra-444003
  - Isolation and critical care
  - Swine Flu Ward: 0712-2750730
  - GMC- MS -0712- 2750427, 2749311,
  - Dr. Khade- 09422139720

**Amritsar (Punjab)**
- Jallian Wala Bagh Memorial Civil Hospital, Ram Bagh, Amritsar, Punjab
  - Dr. Kakkar – 09815576862

**Jaipur (Rajasthan)**
- Infectious District Hospital, Near Charak Bhawan, SMS Medical College, Jaipur, Rajasthan
  - Dr. P. D.Vyas - 0141-2564434, 518392
  - 2605148
  - Dr. Sen - 9887806450,
  - Dr. Girdhari - 9414772483
  - Dr. Somundra – 9829620508

**Chennai (Tamil Nadu)**
- **1.** Communicable Disease Hospital, 87, T.H. Road, Tondiarpet, Chennai, Tamil Nadu (Isolation Facility)
  - Dr. Lakshmi- 044-25912688. M- 09841250567
- **2.** Annal Gandhi Memorial Hospital, Puthur, Trichy-17, Tamil Nadu
  - Isolation and Critical care
  - Dr. Veerapande – 09443913446
<table>
<thead>
<tr>
<th>(Tamil Nadu)</th>
<th>Coimbatore (Tamil Nadu)</th>
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<tbody>
<tr>
<td>3.</td>
<td>Dist. Headquarter Hospital, Mannapari {Isolation Facility}</td>
</tr>
<tr>
<td></td>
<td>[Dr. Veerapande – 09443913446]</td>
</tr>
<tr>
<td>4.</td>
<td>Coimbatore Medical College Hospital, Trichy Road, Coimbatore, Tamil Nadu</td>
</tr>
<tr>
<td></td>
<td>{Isolation and Critical care}</td>
</tr>
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<td></td>
<td>[Dr. Kumaran – 09442012555]</td>
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</table>

<table>
<thead>
<tr>
<th>Lucknow (Uttar Pradesh)</th>
<th>Varanasi (Uttar Pradesh)</th>
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<tbody>
<tr>
<td>1.</td>
<td>Balrampur District Hospital, Lucknow, Uttar Pradesh-226001 {Isolation and Critical care}</td>
</tr>
<tr>
<td></td>
<td>[Dr. P. N. Srivastva – 9415181629]</td>
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<tr>
<td>2.</td>
<td>Shree Shiv Prasad Gupta District Hospital, Kabir Chaura, Varanasi</td>
</tr>
<tr>
<td></td>
<td>Uttar Pradesh {Isolation and critical care}</td>
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<tr>
<td></td>
<td>[Dr. Kanta Prasad - 9451006046, Dr. R. S. Verma – 09415301513]</td>
</tr>
<tr>
<td>3.</td>
<td>Pandit Deen Dayal Upadhya Govt Hospital, Pandeypur, Varanasi, Uttar Pradesh</td>
</tr>
<tr>
<td></td>
<td>{Isolation and Critical care}</td>
</tr>
<tr>
<td></td>
<td>[Dr. Kanta Prasad - 9451006046, Dr. R. S. Verma – 09415301513]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kolkata (West Bengal)</th>
<th>Beliaghata Infectious Diseases Hospital, 57, Beliaghata, Main Road, Kolkata</th>
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<tbody>
<tr>
<td></td>
<td>{Isolation and Critical Care}</td>
</tr>
<tr>
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<td>[Dr. Vishwanath 09433392182 Dr. Vishwas -09434009077]</td>
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<table>
<thead>
<tr>
<th>DELHI</th>
<th>Yellow Fever Quarantine Centre, Near AAI Residential Colony, New Delhi</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[APHO- 25652129, Dr S.K Singh:09868252314]</td>
</tr>
<tr>
<td></td>
<td>Influenza Ward, Ward no 5, Second Floor, New Building, RML Hospital, Delhi-1</td>
</tr>
<tr>
<td></td>
<td>[RML- 24525211,23404328,23365525- Ext 4328]</td>
</tr>
</tbody>
</table>

**Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)**
13. FAQ: NOVEL INFLUENZA A (H1N1) [Swine Flu]

- **What is influenza – A (H1N1)?**

  Influenza – A (H1N1) (earlier known as swine flu) is a new influenza virus causing illness in people. First detected in California in April, 2009, it has spread to many countries in the World.

- **Are there human/infections with influenza – A (H1N1) in India?**

  Yes

- **Is it safe to take pork items?**

  Pigs have nothing to do with this disease. Pork products are absolutely safe if properly cooked. There is no need to cull pigs. Do not panic if some pigs die in the community due to natural disease.

- **Is this flu virus contagious?**

  Influenza A (H1N1) virus is contagious and spreading from human to human.

- **What are the signs and symptoms of influenza-A (H1N1) in people?**

  The symptoms of swine flu in people are similar to the symptoms of regular seasonal flu and include fever, cough, sore throat, body aches, headache, chills and fatigue. Some people have reported diarrhoea and vomiting associated with influenza-A (H1N1)

- **How does influenza-A (H1N1) spread?**

  Flu viruses are spread mainly from person to person through droplets created while coughing or sneezing by a person infected with the influenza-A (H1N1).
• **How can someone with the flu infect someone else?**

Infected person may be able to infect others beginning one day before symptoms develop and up to seven or more days after becoming sick.

• **How to keep away from getting the flu?**

_First and most important:_ Follow simple steps as cough etiquettes (covering mouth & nose with handkerchief or tissue paper while coughing), stay at least an arm’s length from persons coughing or sneezing, avoid gathering and wash your hands frequently. Try to stay in good general health. Get plenty of sleep, be physically active, manage your stress, drink plenty of fluids and eat nutritious food.

• **Are there medicines to treat this flu?**

Yes. Necessary medicines in sufficient quantity are available. The Government has in the designated hospitals stored medicines if required. It is strongly advisable not to take medicines of your own, as it will lower your immunity.

• **What can I do to protect myself from getting sick?**

(a) Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue in the trash after you use it.
(b) Wash your hands often with soap and water, especially after you cough or sneeze. Alcohol-based hand cleaners are also effective.
(c) Avoid touching your eyes, nose or mouth. Germs spread this way.
(d) Try to avoid close contact with people having respiratory illness.
(e) If one gets sick with influenza, one must stay at home, away from work or school and limit contact with others to keep from infecting them. However, if one is having any respiratory distress, one should report to a nearby hospital.
What steps Government of India taking to prevent outbreak of this flu in India?

(1) The strategy is basically to detect early cases among the passengers coming from the affected countries either by air, road or ship.
(2) The Government has launched a massive mass media campaign to inform and educate people on dos and don’ts.
(3) Sharing information with public through media.

APPEAL

People who have travelled from the affected countries in the past ten days and show symptoms of influenza A (H1N1) like fever, cough, sore throat and difficulty in breathing should immediately contact the telephone number given below or the nearby Government Hospital.

IMPORTANT CONTACT NUMBERS:

Outbreak Monitoring Cell (Control Room, NICD): 011-23921401

National Institute of Communicable Diseases
Directorate General of Health Services
22, Sham Nath Marg
New Delhi-110 054
India
Phone: +91-11-23946893 (PS To Director)
+91-11-23971 272/060/344/524/449/326 (Board Numbers)
Fax: +91-11-23922677
E-mail: dirnicd@bol.net.in, dirnicd@del3.vsnl.net.in
Important Websites: www.mohfw.nic.in; www.nicd.nic.in
14. Pandemic Update

Status as on: Dated 29th July, 2009

World Health Organization has reported 94,512 laboratory confirmed cases of Novel Influenza A (H1N1) infection from 135 countries as on 6th July 2009. There have been 429 deaths. According to WHO, at this point, further spread of the pandemic, within affected countries and to new countries, is considered inevitable. WHO will no longer issue the global tables showing the numbers of confirmed cases for all countries.

Current update: India

Twenty three positive cases are reported on 29th July 2009

- Delhi -5
- Pune-11
- Cochin -2
- Calicut- 1
- Hyderabad-1
- Chandigarh UT-1
- Roorkee-1
- Gurgaon-1

2252 persons have been tested so far out of which 498 are positive for Novel Influenza A H1N1 [Swine Flu]. 481 out of the 2252 persons have been identified through entry screening, 351 through contact tracing and the rest were self reported.

Of the 498 positive cases, 273 have been discharged. Rest of them remains admitted to the identified health facility.

The situation is being monitored by GOI, MOHFW.

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70 GOI, MOHFW http://mohfw.nic.in/press_releases_on_swine_flu.htm
Bibliography

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Guiding Principles for Pharmacists to fight against Swine Flu (H1N1)


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