

# Antivirals and Vaccine

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# Antivirals

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# Quick Facts on Antivirals

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- It's not too late after 48 hours
  - Hospitalized patients
  - Severe illness not improving
- Many 2009 H1N1 patients can benefit from antiviral treatment
  - Hospitalized
  - Moderately ill with risk factors
  - Worsening illness

# More Quick Facts

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- No risk factors does not mean no antiviral treatment
- Treatment shouldn't wait until laboratory confirmation
- Capsules can ease oseltamivir suspension shortage

# The day-to-day supply chain

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- Intact
- Manufacturers
  - Shortage of Tamiflu Suspension
- Distributors
  - Spot shortages reported
  - Some allocation limits
- Local Pharmacies
  - Spot shortages

# NC Stockpile

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- TREATMENT ONLY
- 75 mg Tamiflu - >500,000 regimens
- Pediatric Tamiflu - ~15,000 regimens
- Relenza - >120,000 regimens

# April 2009 SNS allocation

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- Received April 30-May 2, 2009
- Ten 53 foot tractor trailers
- Antivirals
  - Tamiflu - >200,000 regimens 75mg and >35,000 regimens pediatric
  - Relenza - >70,000 regimens
- PPE
  - N95s, gowns, gloves, surgical masks, face shields

# Resistance

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- ~20 novel H1N1 influenza viruses resistant to oseltamivir have been detected
- Oseltamivir resistant novel H1N1 influenza viruses remain isolated at this time
- Sensitive (susceptible) to zanamivir
- No evidence of genetic reassortment
- WHO and CDC recommend judicious use of antivirals
- Surveillance for the detection of antiviral resistance is ongoing

# Emergency Use Authorization (EUA)

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- <http://www.cdc.gov/h1n1flu/eua/>
- Approved April 27, 2009
- Allows either the use of an unapproved medical product or an unapproved use of an approved medical product
- Must provide EUA fact sheets with every product

# Expiring Antivirals from SNS

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- Tamiflu Suspension dated 6/09 has been extended to 6/11
- Tamiflu 75 mg dated 10/09 use extended to April 26, 2010
- EUA Fact Sheets are updated to indicate new dating and eliminate the need to re-label

# Peramivir

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- IV Neuraminidase inhibitor
- Authorized for emergency use for the treatment hospitalized patients with 2009 H1N1 influenza.
- Patients not responding to either an oral or inhaled antiviral therapy and patients without a dependable route of delivery
- Dose – 600 mg daily for 5-10 days for adults
  - Pediatric dosing is based on AGE
- Should not be used in patients with known or suspected oseltamivir resistance

# Vaccine

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# Pandemic H1N1 Vaccine

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- Monovalent vaccine
  - Separate from seasonal vaccine
- Five manufacturers
  - Live attenuated vaccine available
  - LAIV and prefilled syringes (~15%) supply
- Produced by same method as seasonal flu

# Vaccine Distribution

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- Centralized via McKesson
  - ~2600 sites in NC
  - Ancillary supplies shipped to same site

# Availability

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- As much as 600 million doses available over time
  - Ages 10 and up only need 1 dose
- ~3% allocated to NC
- Pandemic vaccine providers submitted by Local Health Departments
- Reporting of aggregate data weekly required

# Pandemic Vaccine: Target Groups

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- Pregnant women
- People who live with or care for children younger than 6 months of age
- Health care and emergency medical services workers
- Persons 6 months through 24 years of age
- People 25 through 64 years of age at high risk for complications of influenza

# Administration of Seasonal and H1N1 Vaccines at Same Visit

Vaccine combination	Give at same visit?
Inactivated seasonal and inactivated H1N1	Yes
Inactivated seasonal and live attenuated H1N1	Yes
Live attenuated seasonal and inactivated H1N1	Yes
Live attenuated seasonal and live attenuated H1N1	No

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