Antiviral prophylaxis

Guidance on the use of prophylaxis with antiviral medicines during the H1N1 (swine flu) pandemic

Prepared by the Department of Health

October 2009

DH INFORMATION READER BOX

Policy	Estates
HR / Workforce	Commissioning
Management	IM & T
Planning /	Finance
Clinical	Social Care / Partnership Working

Document Purpose	Best Practice Guidance
Gateway Reference	12703
Title	Antiviral prophylaxis:Guidance on the use of prophylaxis with antiviral medicines during the H1N1 (swine flu) pandemic
Author	Department of Health
Publication Date	06 Oct 2009
Target Audience	PCT CEs, NHS Trust CEs, SHA CEs, Foundation Trust CEs , Medical Directors, Directors of PH, GPs, Emergency Care Leads,
Circulation List	Department of Health and Wellbeing of the Scottish Government; Department of Health and Social Services of the Welsh Assembly Government; Department of Health, Social Services and Public Safety of the Northern Ireland Assembly; Royal College of Physicians; Royal College of General Practitioners; Royal College of Paediatrics and Child Health; Faculty of Public Health Medicine of the Royal College of Physicians; British Medical Association; Health Protection Agency
Description	This guidance sets out the circumstances in which it may be appropriate to offer a course of prophylactic antiviral medicine to patients with a serious underlying medical condition or who are pregnant during the H1N1 (swine flu) pandemic
Cross Ref	N/A
Superseded Docs	N/A
Action Required	N/A
Timing	**N/A**
Contact Details	The Pandemic Influenza Preparedness Team Department of Health 451C Skipton House, 80 London Road London SE1 6LH 0207 972 2000 pandemicflu@dh.gsi.gov.uk
For Recipient's Use	

Contents

Introduction

- **Prophylaxis with antiviral medicine should not routinely be given to contacts of a case of pandemic (H1N1) 2009 influenza infection.**

- **In most cases prompt and early treatment of symptomatic illness is the preferred course.**

- **However, in certain situations, where individuals with a serious underlying condition (see annex A) or who are pregnant have been in close contact with an infectious case, clinical judgement may be used to offer a course of prophylaxis.**

Purpose of prophylaxis

The purpose of providing prophylaxis in the following settings is primarily to reduce morbidity and mortality in people who are at particularly high risk of the complications of flu.

Situations in which prophylaxis may be considered include:

- **In a household setting:** where there has been close contact[1] between an individual with a serious underlying condition and a person with flu symptoms.

- **In an institutional setting:** where individuals with serious underlying conditions are, in the clinician's judgement, particularly vulnerable and are living in close proximity to each other and sharing common facilities. Prophylaxis may be offered where there has been close contact with a person, including another resident or a member of staff, with flu symptoms.

  In this setting, prophylaxis may be considered -

  - to protect vulnerable groups of people, for example in certain types of school where there may be many children with serious underlying conditions, or

  - for the prevention and control of an outbreak where some or all of the residents have serious underlying conditions and are, in the clinician's judgement, particularly vulnerable.

  The decision to provide prophylaxis in an institutional setting should be made on an incident by incident basis and should be made in consultation with the local Health Protection Unit who will be able to advise on local arrangements for access to supplies

[1] close contact usually means within one metre for at least one hour within the last 7 days

of antiviral medication for prophylaxis. The HPA has produced guidance for the management of incidents in care homes including a recommendation that testing should be considered in early cases within each care home in order to inform any therapeutic interventions.

When to consider prophylaxis

For patients with serious underlying conditions who are not in frequent contact with specialist health services the decision about whether to provide antivirals as prophylaxis or to provide them only should the patient become symptomatic is one to be made by the patient's primary care clinician following a risk assessment.

The clinician may wish to consult another appropriate expert as necessary, such as a paediatrician, renal physician or a specialist overseeing the care of, for example, an immunosuppressed patient. In each case the decision on antiviral prophylaxis should be based on a risk assessment appropriate to the individual and their particular underlying condition.

However, many patients with serious underlying conditions will be receiving frequent reviews and treatment from specialist health services. In these cases, in the course of the review clinicians should assess the risk that the current influenza virus would pose to the health of each individual in their care. For example, not all patients receiving dialysis will require prophylaxis but the decision will be based on a risk assessment carried out by the clinician overseeing the patient's care in the light of that individual's circumstances at the time.

If the assessment shows that infection with influenza could pose a serious risk to the patient's health then -

(a) advice should be given to the patient to contact a named person or service at the first sign of influenza symptoms. This will enable an immediate review to be conducted and treatment with antivirals started as early as possible,

(b) this advice should also include whether or not the patient should receive prophylactic antivirals if they have had close contact, within the last 7 days[2], with a person with flu symptoms.

Pregnant women

Similar advice applies for pregnant women for whom prophylaxis may be indicated. This may include women with co-morbid conditions or those who are morbidly obese. In these cases the decision about whether to provide antivirals as prophylaxis or to provide them only should the patient become symptomatic is one to be made by the patient's primary care clinician following a risk assessment. Similarly, where the woman is under the care of specialist health services the primary care clinician may wish to consult the specialist overseeing her care.

[2] the figure of 7 days is based on current understanding and may be subject to change.

Repeated doses of prophylaxis

Occasionally, clinicians may need to consider providing more than one 10-day prophylactic course of antiviral medicine (see also paragraph below on the appropriate dose to be given) if an individual who is assessed as requiring prophylaxis has a series of close contacts with people with flu symptoms. The need for each course must be assessed individually, based on the particular circumstances each time a course of prophylaxis may be indicated.

Antivirals are not licensed for long-term continuous use although oseltamivir can be used continuously for up to 6 weeks. In each case the risk assessment will need to include an assessment of the risks and benefits of repeated courses. When a decision is made that prophylaxis should be provided, where appropriate the individual, or their parent or carer, should be provided with information about the potential side effects of the medication prescribed.

In an institutional setting, where an institution has more than one outbreak then, depending on the risk assessment undertaken by the local Health Protection Unit, repeated prophylaxis may be considered subject to the HPA guidance on testing, mentioned above.

Travel

There is no plan to provide ‘standby’ courses of antiviral medicine to people who are planning to travel abroad and antiviral medicines cannot be issued for this purpose.

Authorising the supply of antivirals for prophylaxis and arrangements for their distribution

Details of the arrangements for authorising the supply of antiviral medicines for prophylaxis for individual patients and the distribution of antivirals for prophylaxis can be found at Annex B. Different UK countries may use different arrangements.

Which antiviral should be used for prophylaxis?

Reference should be made to the British National Formulary or the British National Formulary for Children as appropriate as well as evidence from the latest available research. Oseltamivir is indicated for the majority of patients while zanamivir is currently recommended for patients with chronic kidney disease stage 4 or 5. Zanamivir is recommended as first choice (although either medicine can be used) for pregnant women for whom prophylaxis may be indicated following a risk assessment, for example those with co-morbid conditions or those who are morbidly obese.

Dose

For prevention of influenza a single dose of antiviral is to be given each day for 10 days (the doses of oseltamivir and zanamivir for prophylaxis can be found in the British National Formulary (or for children the British National Formulary for Children); doses are also clearly laid out in the antiviral authorisation vouchers). On receiving the voucher annotated **for prophylaxis** the collection point will label the medicine for each individual with a label displaying the correct dose for prophylaxis.

Use of antiviral medicine for children under one year

In early 2009 the European Committee for Medicinal Products for Human Use (CHMP) considered the risks and benefits of antiviral medicines for children under the age of one year. They concluded that there was evidence that oseltamivir was effective, and that there was no evidence of harm from its use (other than already-recognised side-effects). They therefore endorsed the use of oseltamivir for treatment of AH1N1 influenza in this age group.

The committee noted that there was less evidence to support the use of oseltamivir for the prevention of influenza. Doctors should therefore consider very carefully the benefits and risks of prophylactic antiviral medicine for each child, and may wish to take advice from a specialist in the care of young children.

Annex A - Meaning of 'serious underlying condition' for the purpose of this guidance

1. Individuals with a serious underlying condition will usually be those within the known at risk groups who will be particularly vulnerable to developing a severe illness, with potential rapid decline, leading to serious or life threatening complications. Almost all of these patients will be receiving frequent secondary and tertiary care and some will live in institutions.

2. These individuals will fall into one of the following groups –

Group A: Those with depleted immunity who will be less able to cope with secondary bacterial infection after pandemic flu

This will include adults and children who -

- are immunosuppressed secondary to chemotherapy for cancers;
- are on steroids:
    - for children at a dose of 1mg/kg body weight per day or more; or more than 20 mg absolute dose if body weight greater than 20kg; whichever is the lesser
    - for adults receiving greater than 20mg prednisolone daily;
- are on multiple immunosuppressants such as cyclosporin, tacrolimus and sirolimus;
- are on biological therapies such as infliximab, etanercept, anakinra or similar agents;
- are on antiproliferative immunosuppressants such azathioprine and mycophenalate mofetil;
- are on transplant immunosuppression;
- have hypogammaglobulinaemia, although this is rare and should be treated already with immunoglobulin;
- have neutrophil abnormalities, although these are rare and patients will be under specialist care;
- have serious illness related to being HIV positive;
- have primary immunodeficiency (all types).

Group B: Those identified following clinical assessment as having advanced chronic illness, which would be destabilised by a severe viral illness

This will include adults and children identified within the following groups as being particularly vulnerable. The following examples are to assist decision-making, but the ultimate decision remains with the clinician following an individual assessment as the list cannot cover every eventuality -

- **Chronic hepatic failure**
    - Awaiting transplantation;

  - Recent hospital admissions with hepatic failure.
- **Renal Conditions**
  - Nephrotic syndrome or on immunosuppression.
- **Cardiac Conditions**
  - Chronic congestive cardiac failure: anyone with current NHYA class III or IV symptoms resulting from a cardiac problem;
  - Current severe impairment of left ventricular function (LV ejection fraction less than 35%) from any cause;
  - Current severe structural heart disease (eg severe non-operated valvular disease, cardiomyopathy);
  - Severe congenital heart disease in adults;
  - Cyanotic congenital heart disease in children;
  - Previous history of severe viral myocarditis.
- **Respiratory Conditions**
  - Cystic fibrosis;
  - Difficult to manage asthma (eg > 2 exacerbations requiring additional treatment /year or regular hospital admission);
  - Difficult to manage COPD (eg > 2 exacerbations requiring additional treatment /year or regular hospital admission or FEV1 < 50% predicted);
  - Difficult to manage bronchiectasis (eg > 2 exacerbations requiring additional treatment per year);
  - Lung cancer on treatment;
  - Interstitial lung disease under hospital follow up.
- **Neurological Conditions**
  - Unstable epilepsy;
  - Severe neurodegenerative diseases, or severe neurodisability, predisposing to aspiration or failure to clear respiratory secretions.
- **Child Specific Conditions**
  - Chronic lung disease of prematurity;
  - Complex neurodisability/cerebral palsy.

Group C: Patients recently discharged from hospital, having been treated for a serious illness, whose recovery would be destabilised by a severe viral illness

Annex B - Authorising the supply of prophylactic antiviral medicines for individual patients and arrangements for distribution in England (different arrangements may apply in Scotland, Wales and Northern Ireland)

1. New vouchers have been designed to enable GPs and other healthcare professionals to authorise antivirals for both treatment and prophylaxis, both for children under one year and those over one year of age. GPs and other healthcare professionals will need to indicate clearly on the voucher whether they are authorising antivirals for treatment or prophylaxis by ticking the appropriate box. The vouchers also include information about treatment and prophylactic doses.

2. This system will enable antiviral collection point (ACP) staff to determine clearly whether the antivirals have been authorised for treatment or prophylaxis and what dose is required for the patient. The ACP staff will be required to attach the appropriate pre-printed label on the antiviral pack of medicines. PCTs already have label templates for treatment doses. Label templates for prophylaxis have been distributed to the NHS for use at ACPs, with the suite of other resources disseminated alongside the guidance on the use of vouchers and FP10s for authorisation and supply of antivirals.

3. GPs will need to be vigilant when authorising antivirals for children 13 years and older and adults using the right hand side of the FP10 prescription form. They will need to ensure that the instructions for supplying antivirals are absolutely clear and unambiguous to non-healthcare staff. Instructions that are not clear may result in delays to patients getting their antivirals. It could also lead to errors and confusion.

4. For oral oseltamivir solution, the labels will be modified to allow ACP staff to write the frequency and the duration of dosage on the label, in addition to including the volume of oseltamivir solution the child will need to take, which the doctor will have indicated on the voucher.