

Guidance for specialists and renal units on prescribing antiviral medicine to children with renal failure during the swine flu pandemic.

The following has been agreed between the Royal College of Paediatrics and Child Health, the British Association for Paediatric Nephrology and the Department of Health.

The symptoms of influenza and serious bacterial infections (especially in children under one year old) may be confused and difficult to differentiate. For this reason, a general practitioner should see all children under one year old who are unwell with fever or influenza-like symptoms. In addition if a febrile child is immunosuppressed or at particular risk of specific infections (e.g. peritonitis if on peritoneal dialysis or line sepsis if on haemodialysis) he or she should be assessed in the usual way according to the local renal unit policy.

Clinical management guidelines for pandemic H1N1 influenza in adults and children have been prepared by the Department of Health at

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_107769

This guidance should be consulted for information on general management of patients, while this document should be used as the consensus document for the prescription of anti-viral medicines in children with renal impairment.

There is a national stock of two antiviral medicines: oseltamivir (Tamiflu) and zanamivir (Relenza). The management of this stock is being co-ordinated by the Primary Care Trusts and is being distributed through Anti-Viral Collection Points. Hospital Pharmacy departments will need to negotiate with their local Primary Care Trusts (PCT's) to obtain appropriate drug supplies for the treatment of in-patients and those outpatients who require non-standard doses (e.g. renal patients)

For access to antiviral therapy, adults and the carers of most children in the community, who have symptoms of influenza, should contact the National Pandemic Flu Service (NPFS)

- by telephone on 0800 1 513 513 or
- via the internet on <http://www.direct.gov.uk/pandemicflu>.

Patients attending a specialist renal clinic should be advised to contact the NPFS and obtain their supply of anti-viral medication via the Anti-Viral Collection Points in the community. This will avoid delays in accessing anti-viral treatment.

The NPFS is an automated process based on clinical algorithms which have been developed to authorise collection of these two medicines in the community. All users will be asked if the patient attends "a specialist kidney or renal clinic for the care of kidney or renal failure". For the purpose of authorising the safest medicine, the NPFS will presume that a patient who attends such a clinic has some degree of renal failure.

Zanamivir is the drug of choice for most patients with renal failure. It is administered by inhalation and is provided in a powder form contained in "blisters for inhalation". It is licensed for use in children aged 5 years and older, pregnant women, and adults with and without renal failure (GFR of <30ml/min). Patients aged 5 years and older who attend a clinic for renal failure will be authorised to receive zanamivir. Some of these children will not be able to effectively inhale zanamivir and they will require an adjusted dose of oseltamivir.

Patients under five years old who attend a clinic for renal failure will be authorised to receive oseltamivir. Parents and carers will be told to give the first dose of oseltamivir without delay and will be directed to contact their usual renal team for advice on ongoing dosage. It is important that subsequent and remaining doses are adjusted according to the degree of renal failure.

The NPFS cannot assess the degree of renal failure, the ability to use the zanamivir inhaler nor make renal dose adjustments for oseltamivir. Taking the first dose of oseltamivir without renal adjustment is considered safe in the context of managing influenza in high risk patients during a pandemic, and can be considered a loading dose.

All children with an eGFR of $<30\text{ml}/\text{min}/1.73\text{m}^2$ who cannot take inhaled zanamivir will require oseltamivir and must have the subsequent doses of oseltamivir adjusted according to their clinical status (see tables).

They must have the correct dose of oseltamivir recommended by a renal specialist. Non-standard doses may need to be dispensed by the hospital pharmacy. There is no alternative mechanism for non-standard doses of oseltamivir to be distributed from antiviral collection points in the community.

Local renal units will know these children. It is the responsibility of each renal unit to inform carers about the process for receiving the right dose of the right medicine. At the early stages of the pandemic all dialysis patients should be sent a letter informing them what to do if they need antiviral treatment.

Oseltamivir is available in a variety of formulations: Oral solution (15mg/ml), oral suspension (Tamiflu; 12mg/ml), 30mg capsules (Tamiflu), 45mg capsules (Tamiflu) and 75mg capsules (Tamiflu). Doses have been rounded to reserve liquid formulations for infants less than 1 year old where possible; however older children with eGFR $\leq 10\text{ml}/\text{min}/1.73\text{m}^2$, and those on dialysis will require liquid formulations because of the necessary dose reductions. If children are unable to swallow capsules, the capsules can be opened and mixed with a small amount of sweet food (e.g. chocolate syrup, apple sauce, yoghurt). This will help to mask the bitter taste.

Patients on Dialysis

Home peritoneal dialysis patients should not be required to attend their renal unit, but the non-standard dose of oseltamivir may need to be prescribed and dispensed from a hospital pharmacy.

Renal transplant patients

As renal transplant patients are usually significantly immunosuppressed by transplant anti-rejection medication, they will usually require a ten-day course of antiviral treatment rather than the licensed five-day course.

Renal transplant patients should be dosed based on their eGFR. Renal units might consider an advanced letter to these patients, reminding them that they may need to contact their renal unit to discuss their need for a longer course of treatment or prophylaxis, and reassuring them that there is no interaction known with any of their immunosuppressive drugs. If their eGFR is $<30\text{ml}/\text{min}/1.73\text{m}^2$, the dose of oseltamivir should be reduced accordingly.

Prophylaxis for children with renal disease and immune deficiency

The purpose of providing prophylaxis is to reduce morbidity and mortality in people who are at particularly high risk of the complications of flu, usually due to significant immune suppression. Prophylaxis with antiviral medicine should not routinely be given to contacts of a case of pandemic (H1N1) 2009 influenza infection. This includes most children with uncomplicated renal failure where prompt treatment of symptomatic illness is preferred. However there are circumstances where clinical judgement may be used to offer a course of prophylaxis. For example renal dialysis alone is not a criterion for prophylaxis but a decision could be made based on a risk assessment carried out by the clinician overseeing the patient in the light of that individual's circumstances at the time.

Prophylaxis can be considered when an individual with renal disease **and** immune suppression has been close contact with a person with flu symptoms. Close contact usually means within one metre for at least one hour within the last 7 days.

Children with renal conditions who should be considered for prophylaxis would include those who:

- have nephrotic syndrome (either persistent nephrosis or on immunosuppressive drugs-see below)
- are on steroids at a dose of 1mg/kg body weight per day or more; or more than 20mg absolute dose if body weight greater than 20kg; whichever is the lesser
- are on immunosuppressants such as ciclosporin, tacrolimus and sirolimus
- are on biological therapies such as infliximab, etanercept, anakinra or similar agents
- are on antiproliferative immunosuppressants such as azathioprine and mycophenolate 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)

These 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.

Most if not all these children will be receiving frequent reviews and treatment from specialist health services. In these cases, clinicians should assess the risk that the current influenza virus would pose to the health of each individual in their care at an early opportunity.

If the assessment shows that infection with influenza could pose a serious risk to the child'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 prompt review and treatment with antiviral medicine.

(b) This advice should also include whether or not the patient should receive prophylactic antiviral medicine if they have had close contact with a person with flu symptoms within seven days.

Renal Doses for Prophylaxis

For the prevention of influenza in patients without renal failure, the standard dose of oseltamivir is given once daily for 10 days, i.e. increasing the dose interval and duration from the treatment schedule. It is not known what the prophylactic dose of oseltamivir is for children with renal failure. Renal treatment doses have been extrapolated from adult data to reduce the risk of accumulation by increasing the dose interval. Further increases in dose interval are likely to reduce efficacy. In renal patients, a pragmatic approach to prophylaxis would be to accept that where the treatment dose would be reduced or the interval extended to reflect renal impairment, then the same dose schedule should simply be given but extended for a total period of ten days.

In some patients with a GFR of < 10ml/min/1.73m² and/or on peritoneal dialysis, only one dose of oseltamivir is being recommended to cover a five-day period of therapy. For prophylaxis in these few patients, a specialist may consider it reasonable to give a further dose after seven days to prolong the period of antiviral cover.

Use of antiviral medicine for children under one year

As with most medicines with recently granted marketing authorisations there is only limited evidence to support the use of oseltamivir in children under the age of 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 H1N1 pandemic influenza in this age group.

Following advice from the European Medicines Agency, The European Commission recently decided to change the dose of oseltamivir (Tamiflu) for children under one year of age.

Age	Oseltamivir Treatment Dose
Up to 1 month of age	2mg/kg/dose twice a day for 5 days
Over 1 month up to 3 months of age	2.5mg/ kg/dose twice a day for 5 days
Over 3 months and under 1 year of age	3mg/ kg/dose twice a day for 5 days

The doses of oseltamivir will be revised in other age groups as new data on the pharmacodynamics of oseltamivir in young children emerges.

The CHMP noted that there was less evidence to support the use of oseltamivir for the prevention of influenza in children under one year old. 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.

Limitations to this guidance

Prescribers should be aware of the following limitations to this guidance:

The manufacturers of oseltamivir (Tamiflu[®] - Roche) state in their Summary of Product Characteristics "there is insufficient clinical data available in children with renal impairment to be able to make any dosage recommendation". The renal doses of oseltamivir advised in this guidance are not evidence based. They have been extrapolated from the doses recommended for adults with impaired renal function and informed by the European Commission decision on dosage change for children under one year of age, published in November 2009.

The British National Formulary for Children states that “for most drugs the adult maximum dose should not be exceeded”, when prescribing for children by weight. Neither the manufacturers nor the Department of Health have included maximum doses in their guidance on anti-viral therapy with oseltamivir for children under 1 year of age. As a point of good clinical practice we advise that the maximum dose in children less than 1 year of age should not exceed the dose recommended for children aged 1 year to less than 3 years.

Adult doses are based on actual GFR. For the purposes of this guidance actual GFR and eGFR (corrected to body surface area) are treated as equivalent.

Doses for peritoneal dialysis are extrapolated from recommended (adult) doses in Continuous Ambulatory Peritoneal Dialysis (CAPD). In the absence of any other information, it is suggested that the same dosage adjustments are applied to other types of peritoneal dialysis.

Reference sources consulted in the preparation of this guidance

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Anti-viral therapy - Dose guidance for the treatment & prophylaxis of swine flu in children with renal failure

Patient	Drug & formulation	Treatment Dose & frequency	Prophylaxis Dose & frequency	Comments
eGFR > 30ml/min/1.73m²				
Oseltamivir- Standard dose and interval				
Up to 1 month of age	Oseltamivir oral liquid	2mg/kg/dose by mouth twice daily for 5 days	2mg/kg/dose by mouth once daily for 10 days	Maximum 30mg/dose Consult DH guidance on dose and dose volumes.
Over 1 month up to 3 months of age	Oseltamivir oral liquid	2.5mg/kg/dose by mouth twice daily for 5 days	2.5mg/kg/dose by mouth once daily for 10 days	
Over 3 months and under 1 year of age	Oseltamivir oral liquid	3mg/kg/dose by mouth twice daily for 5 days	3mg/kg/dose once daily for 10 days	
1 year old and less than 3 years of age (under 15kg)	Oseltamivir (Tamiflu [®]) 30mg capsule	One 30mg capsule by mouth twice daily for 5 days	One 30mg capsule by mouth once daily for 10 days	
3 years old and less than 7 years of age (15-23kg)	Oseltamivir (Tamiflu [®]) 45mg capsule	One 45mg capsule by mouth twice daily for 5 days	One 45mg capsule by mouth once daily for 10 days	
7 years old and less than 13 years of age (23-40kg)	Oseltamivir (Tamiflu [®]) 30mg capsule	Two 30mg capsules (60mg) by mouth twice daily for 5 days	Two 30mg capsules (60mg) by mouth once daily for 10 days	
13 years old and older (over 40kg)	Oseltamivir (Tamiflu [®]) 75mg capsule	One 75mg capsule by mouth twice daily for 5 days	One 75mg capsule by mouth once daily for 10 days	
eGFR ≥ 10 - 30ml/min/1.73m²				
Adults and Children 5 years and older, with no respiratory problems, and able to use the diskhaler effectively	Zanamivir (Renza [®]) Containing four 5mg blisters of powder for inhalation	Two 5mg blister inhalations (10mg), to be inhaled via the diskhaler, twice daily for 5 days	Two 5mg blister inhalations (10mg), to be inhaled via the diskhaler, once daily for 10 days	Preferred therapy in all appropriate patients with CKD stage 4 & 5
Or Oseltamivir – Standard Dose Increased Interval				
Up to 1 month of age	Oseltamivir oral liquid	2mg/kg/dose by mouth once daily for 5 days	2mg/kg/dose by mouth on alternate days for 10 days	Maximum 30mg/dose
Over 1 month up to 3 months of age	Oseltamivir oral liquid	2.5mg/kg/dose by mouth once daily for 5 days	2.5mg/kg/dose by mouth on alternate days for 10 days	
Over 3 months and under 1 year of age	Oseltamivir oral liquid	3mg/kg/dose by mouth once daily for 5 days	3mg/kg/dose by mouth on alternate days for 10 days	
1 year old and less than 3 years of age (under 15kg)	Oseltamivir (Tamiflu [®]) 30mg capsule	One 30mg capsule by mouth once daily for 5 days	One 30mg capsule by mouth on alternate days for 10 days	
3 years old and less than 7 years of age (15-23kg)	Oseltamivir (Tamiflu [®]) 45mg capsule	One 45mg capsule once daily for 5 days	One 45mg capsule by mouth on alternate days for 10 days	
7 years old and less than 13 years of age (23-40kg)	Oseltamivir (Tamiflu [®]) 30mg capsule	Two 30mg capsules (60mg) by mouth once daily for 5 days	Two 30mg capsules (60mg) by mouth on alternate days for 10 days	
13 years old and older (over 40kg)	Oseltamivir (Tamiflu [®]) 75mg capsule	One 75mg capsule by mouth once daily for 5 days	One 75mg capsule by mouth on alternate days for 10 days	

Patient	Drug & formulation	Treatment Dose & frequency	Prophylaxis Dose & frequency	Comments
eGFR <10 ml/min/1.73m²				
Zanamivir – preferred option as above				
Or Oseltamivir – standard dose increased interval				
Up to 1 month of age	Oseltamivir oral liquid	2mg/kg/dose by mouth (single dose only)	1mg/kg/dose by mouth weekly to complete a course of two doses in total	Maximum 30mg/dose- all ages. Patients who have received their first dose of antiviral medication in the community will not require any further doses to complete a treatment course. For prophylaxis a second adjusted dose should be given one week later as described.
Over 1 month up to 3 months of age	Oseltamivir oral liquid	2.5mg/kg/dose by mouth (single dose only)	1.25mg/kg/dose by mouth weekly to complete a course of two doses in total	
Over 3 months and under 1 year of age	Oseltamivir oral liquid	3mg/kg/dose by mouth (single dose only)	1.5mg/kg/dose by mouth weekly to complete a course of two doses in total	
1 year old and less than 3 years of age (under 15kg)	Oseltamivir 30mg capsule	One 30mg capsule by mouth (single dose only)	1mg/kg/dose by mouth weekly to complete a course of two doses in total. Maximum single dose = age related treatment dose.	Patients who have received their first dose of antiviral medication in the community will not require any further doses to complete a treatment course. For prophylaxis a second adjusted dose should be given one week later as described.
3 years old and less than 7 years of age (15-23kg)	Oseltamivir 45mg capsule	One 45mg capsule by mouth (single dose only)		
7 years old and less than 13 years of age (23-40kg)	Oseltamivir 30mg capsule	Two 30mg capsules by mouth (60mg) single dose only		
13 years old and older (over 40kg)	Oseltamivir (Tamiflu[®]) 75mg capsule	One 75mg capsule by mouth (single dose only)		

Patient	Drug & formulation	Treatment Dose & frequency	Prophylaxis Dose & frequency	Comments
Patients on peritoneal dialysis				
Zanamivir – preferred option as above				
Or Oseltamivir – reduced dose increased interval				
Up to 1 month of age	Oseltamivir oral liquid	1mg/kg/dose by mouth (single dose only)	1mg/kg/dose by mouth weekly to complete a course of two doses in total	Maximum 30mg/dose (all ages)
Over 1 month up to 3 months of age	Oseltamivir oral liquid	1.25mg/kg/dose by mouth (single dose only)	1.25mg/kg/dose by mouth weekly to complete a course of two doses in total	Patients in this category who have received their first dose of antiviral medication in the community will not require any further doses to complete a treatment course. For prophylaxis a second adjusted dose should be given one week later as described
Over 3 months and under 1 year of age	Oseltamivir oral liquid	1.5mg/kg/dose by mouth (single dose only)	1.5mg/kg/dose by mouth weekly to complete a course of two doses in total	
1 year old and less than 3 years of age (under 15kg)	Oseltamivir oral liquid	1mg/kg/dose by mouth (single dose only)	1mg/kg/dose by mouth weekly to complete a course of two doses in total	
3 years old and less than 7 years of age (15-23kg)	Oseltamivir oral liquid	1mg/kg/dose by mouth (single dose only)		
7 years old and less than 13 years of age (23-40kg)	Oseltamivir oral liquid	1mg/kg/dose by mouth (single dose only)		
13 years old and older (over 40kg)	Oseltamivir (Tamiflu[®]) One 30mg capsule	One 30mg capsule by mouth (single dose only)	One 30mg capsule by mouth weekly to complete a course of two doses in total	

Patient	Drug & formulation	Treatment Dose & frequency	Prophylaxis Dose & frequency	Comments
Patients on haemodialysis				
Zanamivir – preferred option as above				
Or Oseltamivir – reduced dose increased interval				
Up to 1 month of age	Oseltamivir oral liquid	1mg/kg/dose by mouth after each haemodialysis session for 5 days	1mg/kg/dose by mouth after each haemodialysis session for 10 days	Maximum 30mg/dose In all ages
Over 1 month up to 3 months of age	Oseltamivir oral liquid	1.25mg/kg/dose by mouth after each haemodialysis session for 5 days	1.25mg/kg/dose by mouth after each haemodialysis session for 10 days	
Over 3 months and under 1 year of age	Oseltamivir oral liquid	1.5mg/kg/dose by mouth after each haemodialysis session for 5 days	1.5mg/kg/dose by mouth after each haemodialysis session for 10 days	
1 year old and less than 3 years of age (under 15kg)	Oseltamivir oral liquid	1mg/kg/dose by mouth after each haemodialysis session for 5 days	1mg/kg/dose by mouth after each haemodialysis session for 10 days	
3 years old and less than 7 years of age (15-23kg)	Oseltamivir oral liquid	1mg/kg/dose by mouth after each haemodialysis session for 5 days	1mg/kg/dose by mouth after each haemodialysis session for 10 days	
7 years old and less than 13 years of age (23-40kg)	Oseltamivir oral liquid	1mg/kg/dose by mouth after each haemodialysis session for 5 days	1mg/kg/dose by mouth after each haemodialysis session for 10 days	
13 years old and older (over 40kg)	Oseltamivir (Tamiflu®) 30mg capsule	One 30mg capsule by mouth after each haemodialysis session for 5 days	One 30mg capsule by mouth after each haemodialysis session for 10 days	

Patient	Drug & formulation	Treatment Dose & frequency	Prophylaxis Dose & frequency	Comments
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Patients on Haemodiafiltration (HDF)/High Flux (haemodialysis)				
Zanamivir – preferred option as above				
Or Oseltamivir – standard dose increased interval				
Up to 1 month of age	Oseltamivir oral liquid	2mg/kg/dose by mouth after each haemodialysis session for 5 days	2mg/kg/dose by mouth after each haemodialysis session for 10 days	Maximum 30mg/dose
Over 1 month up to 3 months of age	Oseltamivir oral liquid	2.5mg/kg/dose by mouth after each haemodialysis session for 5 days	2.5mg/kg/dose by mouth after each haemodialysis session for 10 days	
Over 3 months and under 1 year of age	Oseltamivir oral liquid	3mg/kg/dose by mouth after each haemodialysis session for 5 days	3mg/kg/dose by mouth after each haemodialysis session for 10 days	
1 year old and less than 3 years of age (under 15kg)	Oseltamivir(Tamiflu®) 30mg capsule	One 30mg capsule by mouth after each haemodialysis session for 5 days	One 30mg capsule by mouth after each haemodialysis session for 10 days	
3 years old and less than 7 years of age (15-23kg)	Oseltamivir(Tamiflu®) 45mg capsule	One 45mg capsule by mouth after each haemodialysis session for 5 days	One 45mg capsule by mouth after each haemodialysis session for 10 days	
7 years old and less than 13 years of age (23-40kg)	Oseltamivir(Tamiflu®) 30mg capsule	Two 30mg capsules (60mg) by mouth after each haemodialysis session for 5 days	Two 30mg capsules (60mg) by mouth after each haemodialysis session for 10 days	
13 years old and older (over 40kg)	Oseltamivir(Tamiflu®) 75mg capsule	One 75mg capsule by mouth after each haemodialysis session for 5 days	One 75mg capsule by mouth after each haemodialysis session for 10 days	

Note: Caution Oseltamivir liquid is available in two strengths.

Suggested template for renal units to send to parents of patients with renal conditions, which may be adapted for local use

What to I do if my child has a fever and I am concerned about swine flu?

You are aware that swine flu is a concern at present. The symptoms can be non-specific and could be similar to other less important viruses or sometimes other significant infections. Some children will require treatment for swine flu and if their kidney function is reduced they may need an adjusted dose of antiviral medicine. We also need to take steps to prevent spread to patients on the renal unit and would ask that you follow the guidelines below.

Transplant patients

Patients on dialysis

Patients attending a chronic kidney disease clinic

Patients with Nephrotic Syndrome

If you are unsure if your child is included in these groups please ask a nurse or doctor.

If your child has a fever and a cough/runny nose we need to consider whether this is due to swine flu or whether there is another cause. We would like you to phone the community nurse or the renal ward. A member of the nursing or medical staff will speak to you to discuss your child's symptoms with them.

If we feel that your child needs to be reviewed in hospital you will be asked either to be reviewed in your local hospital or at the Renal Unit. At the..... your child will be seen in the Emergency Department and **not** on the ward. The Emergency Department will know that you are coming and will know all about your child.

Please do not bring your child to a routine clinic or the ward if he/she has a fever until we have talked to you and made arrangements for the best place for your child to be seen.

If your child needs treatment with an antiviral medicine and their kidney function is abnormal we may need to adjust the dose of medicine and we will advise on this. Children aged 5 years and over will be offered zanamivir (Relenza). The dose of this does NOT need to be changed in kidney failure. It is provided via an inhaler. If your child is under 5 years old or is unable to use an inhaler then he/she will need oseltamivir (Tamiflu). The dose of this may need adjustment and the kidney unit will advise on the dose of this. This oseltamivir must be dispensed by a hospital pharmacy, it cannot be issued by anti-viral collection points in the community.

All other patients.

If your child has any symptoms of flu; fever, runny nose, sore throat, aching muscles, you should contact the National Pandemic Flu Service for advice

- by telephone on 0800 1 513 513 or
- via the internet on <http://www.direct.gov.uk/pandemicflu>.

They will give you advice on how to help manage your child at home or the next steps if further treatment is required.

A GP should see all children under 1 year of age, who are unwell with fever or flu-like symptoms

For patients already admitted to the ward, family and friends should be asked not to visit if they have respiratory symptoms, or if they been in contact with confirmed flu cases even if they do not have symptoms themselves.

Treatment of contacts of known cases

Now that swine flu is widespread, treatment of contacts with known cases is not generally recommended. However, if your child's immunity is reduced or they are particularly at risk of infections then he/she might benefit from a preventative course- this should be discussed with the doctor from the renal unit.

Contact numbers:

Renal Unit:

Community: