



Department of  
**Health, Social Services  
and Public Safety**

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An Roinn

**Sláinte, Seirbhísí Sóisialta  
agus Sábháilteachta Poiblí**

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[www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)

**NORTHERN IRELAND (NI) OPERATIONAL  
FRAMEWORK FOR STOCKPILING, DISTRIBUTING  
AND USING ANTIVIRAL MEDICINES FOR PATIENT  
TREATMENT IN THE EVENT OF PANDEMIC  
INFLUENZA**

**DECEMBER 2005**

## Purpose

1. This framework sets out arrangements for the storage and distribution of antiviral medicines from regional stockpiles and provides advice and information to support the development of effective local plans for making those medicines available to treat patients in the event of an influenza pandemic. It supplements the guidance contained in the Department's Interim Influenza Pandemic Contingency Plans and should be read in conjunction with those documents. ([http://www.dhsspsni.gov.uk/phealth/pandemic/pandemic\\_contingency.asp](http://www.dhsspsni.gov.uk/phealth/pandemic/pandemic_contingency.asp)).

## Aim

2. The overall aim is to ensure that antiviral medicines are available to treat patients suffering from influenza within 24-48 hours of the onset of symptoms. This framework therefore aims to:
  - arrange the secure storage, maintenance and when necessary distribution of supplies of antiviral medicines to local level
  - make initial supplies available at local access points throughout NI within 24 hrs of a decision to distribute to those points
  - distribute additional supplies as the pandemic progresses in a way that mirrors its development, optimises clinical benefit and helps maintain availability over its entire period
  - monitor use, ensuring available stocks are used in clinically effective and equitable ways that comply with nationally agreed clinical protocols and published control measures
  - support the development of local arrangements that ensure antiviral medicines are accessible, supplies are used optimally over the whole pandemic and additional burdens on the healthcare system – particularly primary care - are minimised.

## Principles

3. The principles guiding the release and use of antiviral medicines support the general principles for managing an influenza pandemic.
4. Antiviral medicines from regional stockpiles are for **patient treatment purposes only** unless initial prophylactic use to limit or slow the spread of infection is specifically authorised by Chief Medical Officers (CMOs). Local plans should be developed on that basis. The protection of essential workers falls outside the scope of these arrangements.

## Organisational Responsibilities and Action Required

5. As an integral part of their influenza pandemic preparations:-

### DHSSPS will

- **Lead and co-ordinate the public health response**
- **Develop and disseminate regional policy on the use on anti-viral medication in the context of an influenza pandemic**
- **Authorise release of anti-virals from central supplies**

- **Prioritise supplies and release to regulate consumption**
- **Monitor availability of anti-virals**
- **Provide up to date information on anti-virals, their use and availability for health professionals and the public**

HSS Boards in Northern Ireland should develop, maintain and periodically test multi-agency contingency plans that ensure effective arrangements are in place for:

- supplying information on local antiviral access arrangements to the DHSSPS in the event of a raised pandemic alert level
- providing public information on antiviral access as an integrated part of a local pandemic communications plan
- making the medicine available at the various access point locations, acute hospitals and other settings determined in plans
- providing suspension for children ( see paragraphs 19-20)
- making specific provision for closed communities such as residential homes and prisons
- monitoring availability/use and reporting to Boards daily
- ensuring supplies are used strictly in accordance with national guidance and in the most clinically effective and equitable ways
- consulting partners – including local authorities/police/voluntary sector - at all stages in the planning process
- compile and forward information on local antiviral arrangements and access points to the DHSSPS if the pandemic alert level is raised
- provide communication support and public information advice on antiviral arrangements to Trusts and Primary Health care Providers
- ensure Public Health and local Resilience cover arrangements
- coordinate operational arrangements, forwarding daily reports on stock levels/consumption to DHSSPS as the pandemic develops

**All HPSS Trusts, Primary Care Providers and other supporting health agencies/organisations** should review their ability to maintain core services and their capacity to support HSS boards in fulfilling the key requirements of this framework by ensuring maximum flexibility in the use of premises, facilities and staff.

**The NI Regional Procurement Pharmaceutical Service will liaise with The NHS Purchasing and Supply Agency (PaSA)** in England will make and maintain contractual arrangements on behalf of DHSSPS for the storage of antiviral stockpiles and distribution when authorised by the CMO.

**The Health Protection Agency (HPA)** will support the operational health response and has a major role in checking for antiviral

resistance, monitoring the virus' susceptibility and assessing effectiveness in reducing complications/deaths.

**The Medicines and Healthcare products Regulatory Agency (MHRA)** is responsible for monitoring the safety of medicinal products, evaluating the balance of benefits-risks and taking appropriate regulatory action if required. Reports of suspected adverse reactions should be reported to MHRA via the 'Yellow Card' scheme'.

### **Background and key planning assumptions for use of antiviral supplies**

6. An influenza pandemic might consist of one or more waves, perhaps weeks or months apart, the first lasting up to 17 weeks. For planning purposes, the most likely scenario is a cumulative attack rate affecting 25% of the total population by the end of the pandemic. A suitable vaccine is unlikely to be available at the start of a pandemic and its development could take 4-6 months or more.
7. Used for patient treatment in the absence of - or as an adjunct to - vaccination, antiviral medicines may lessen the severity and duration of illness, reduce the need for antibiotics and lower demand for hospital care. Making best use of supplies over the entire pandemic period is therefore critical to the provision of effective patient care.
8. The stock levels of antiviral medicines normally available would be inadequate in a pandemic scenario and high international demand makes rapid post-event supply unlikely. DHSSPS are therefore building stockpiles of the antiviral medicine oseltamivir phosphate (Tamiflu), comprising 400,000 treatment courses - including powder for children - when completed.
9. Antiviral stockpiles will be sufficient to treat all influenza patients who might benefit at a cumulative clinical attack rate of 25%. CMO may authorise small amounts to be used to control or limit spread in the initial phases. All plans must assume severe pressure on stocks and measures to avoid waste and ensure that supplies are used only in accordance with national guidelines must form important elements.
10. A pandemic is likely to affect all localities. To ensure equity, each HSS BOARD should assume its maximum cumulative allocation of antivirals to be no more than required to treat 25% of its total resident population. Until adult and child stock levels are fully established - and/or if the clinical attack rate proves higher than 25% - it may be necessary to determine clinical priorities nationally and cascade to HSS boards and clinicians as alert levels increase.
11. To inform and assist contingency planning an '*as fast as is reasonable*' temporal profile of the likely health impact and spread of a pandemic has been derived from historical data on previous pandemics. (Annex A). This provides working estimates of the additional workload expected over time as the pandemic develops. If a pandemic starts

abroad better information on the attack rate, speed of spread and patient impact may be available before it reaches the UK.

12. Arrangements for antivirals must allow for initial uncertainties in these key areas and be flexible enough to adapt approaches as definitive data become available. Plans must also recognise that the response needs sustaining over a significant period and adjusting to match expected variation in additional workload as the pandemic develops.

#### **Who should receive antiviral treatment?**

13. Although a pandemic virus is likely to affect some groups more severely than others, it will be impossible to identify them until the virus starts circulating. National decisions on treatment priorities will be taken if consumption threatens to exceed available supplies but plans should assume that antiviral treatment will initially be available for all patients – including non residents and other nationals – who have:

- an acute influenza-like illness **and**
- fever(>38<sup>0</sup>C) **and**
- have been symptomatic for no more than 2 days.

14. Those considered most at clinical risk from influenza related complications in seasonal outbreaks are listed in Annex B. that list will provide the basis for setting national treatment priorities. CMOs will monitor use and provide regular information and advice to health professionals on antiviral priorities as the pandemic develops.

#### **Prescribing information, cautions and side effects**

15. Oseltamivir is an orally administered neuraminidase inhibitor excreted mainly through the kidneys. It is licensed for treating influenza A and B in those above 1 year of age when influenza is circulating in the community. Efficacy has been demonstrated when treatment is started within 48 hours of the onset of symptoms.

16. Oseltamivir (capsules or suspension) is contraindicated in persons with a history of hypersensitivity to the active substance or to any of the excipients in the formulations. A reduction in the daily dose is needed in persons with severe renal insufficiency (creatinine clearance < 30 ml/min).
17. Caution is necessary if recipients are breast-feeding or pregnant. Among the adverse reactions that may occur are gastro intestinal symptoms, skin/hypersensitivity reactions, hepatic function disorders, headache, fatigue, insomnia, dizziness, conjunctivitis, epistaxis and rash.
18. Tamiflu capsules are pre-packed in adult treatment courses. The recommended dose for persons of 40 kg or more is 75mg taken twice daily for five days. Those with severe renal insufficiency (creatinine clearance < 30 ml/min) should take 75 mg once daily for 5 days.
19. The recommended dose for children of between 24 and 40kg bodyweight is 60mg taken twice daily. Although **the use of adult dose capsules for children is outside the licence**, children over 23 kg (usually at or over 5 years of age) could be given 75 mg twice daily (i.e. adult dose capsules) for treatment in a pandemic scenario.
20. Children below 5 years of age or < 24 kg body weight must be referred to a clinician. In order to treat children below 24kg but over one year old, HSS boards will receive an allocation - based on 4.5% of total resident population - of their antiviral supply as oseltamivir phosphate powder. ***The SPC for Tamiflu suspension should be consulted for dosing instructions.***
21. Instructions for preparation as a suspension by hospital pharmacies will be provided. **Although the preparation of suspension from bulk powder falls outside the medicine's licence** such arrangements are necessary to meet prescribing demand in a pandemic scenario.
22. **Tamiflu is not currently licensed for use in children under one year of age** but - as with any unlicensed use of medicines - clinicians may need to consider treatment in those under that age on a named patient basis if the child is so ill as to alter the risk-benefit argument in favour of doing so. More detailed clinical guidance for the management of paediatric patients with pandemic influenza is currently being developed.

#### **Initial alert and stockpile release arrangements**

23. Release of antiviral stocks will require specific authorisation and CMO may decide to provide initial supplies to HSS Boards' initial access points if alert levels increase (UK levels 1+). *They should not be further distributed unless authorised.* At alert level 2+ an initial supply will be delivered within 24 hours for immediate distribution to additional access points.

<b>UK ALERT LEVELS</b>	
<b>No cases worldwide</b>	<b>Level 0</b>
<b>Virus/cases only outside the UK</b>	<b>Level 1</b>
<b>Virus isolated in the UK</b>	<b>Level 2</b>
<b>Outbreak(s) in the UK</b>	<b>Level 3</b>
<b>Widespread activity across the UK</b>	<b>Level 4</b>

24. Initial supplies - based on anticipated consumption over the first two weeks – will be supplemented by further deliveries that may become more frequent as the pandemic reaches its peak (See Annex C). To conserve stocks and ensure equitable distribution, subsequent releases will take account of expert advice, the pandemic’s progress and reported usage.

#### **Developing local plans for making antivirals available to patients**

25. Providing safe storage and rapid access to antiviral medicines - without adding to pressures on health systems, encouraging spread of infection or allowing multiple doses to be obtained against one case – should form key elements of response plans.

26. Boards should identify a location for the receipt and storage of antivirals and plan for onward distribution. Secure facilities are essential, preferably using hospital pharmacies with a qualified pharmacist in attendance. Police and other local partners must be involved in developing plans and appropriate security and control arrangements included at all stages.

27. Plans should determine the optimal numbers and locations of access points from which antiviral medicines will be available and how those locations will be publicised. Numbers should be restricted to balance ease of access with the need to maintain rigorous stock control and distribution. Arrangements are also required for supplying acute care facilities, residential accommodation and other closed establishments.

28. In determining the optimal numbers and locations of access points, HSS boards will need to take account of population density, public transport links and similar factors. HSS boards have the flexibility to use locally derived service specifications and any agreements with general practices or community pharmacies should be based on level of provision. DHSSPS will provide further guidance on specifying service levels. Plans should also provide for daily monitoring and reporting consumption.

29. HSS Boards will compile and forward information on local antiviral access arrangements in the event of any increased pandemic alert level.
30. Antiviral medicines are normally available only on prescription and patients – or others seeking medication on their behalf - are likely to present at surgeries, hospital emergency departments, walk in centres, community pharmacies and other health care establishments, accelerating the spread of the disease and risking serious detriment from their normal functions.

31. Whilst health care facilities might provide sufficient surge capacity to cope with the initial additional workload, response needs to be sustained and acute pressure is particularly likely over a 6-8 week period. Many – if not most – patients with influenza are unlikely to be well enough to attend health care facilities, GP capacity to undertake home visits will be severely limited, thresholds for hospital admission will be raised and there will be acute pressure on all providers of health and social care.
32. Supplementary and flexible arrangements will be necessary to ensure 24X7 patient access to antiviral medicines whilst allowing hospitals and GPs to focus on greatest clinical need. As an integral part of plans, HSS boards should consider alternative mechanisms for access that suit the geography, topography and requirements of their areas. Locally determined options might include:
- the use of telephone diagnosis and remote supply
  - pharmacists and other health professionals supplying antiviral medicines following clinical protocols and authorised by a Patient Group Direction (PGD) or Patient Specific Direction (PSD)
  - utilising minor injuries units
  - home visiting teams, utilising a range of health professionals and following agreed algorithms to assess and supply by PGD / PSD
  - designating additional community outlets where the medicine can be made available for specific local catchment areas
33. DH (L) is developing model PGDs and Patient Specific Directions (PSDs) to allow for supply and administration within defined clinical protocols by pharmacists, nurses and other suitably qualified/trained health professionals in a pandemic scenario. HSS BOARD plans should assume that model PGDs, PSDs and other arrangements to facilitate remote supply will become available on Health Department websites for adoption by health organisations.
34. DH (L) also intends exploring options to use web based real time information systems to register and manage the distribution of antivirals and DHSSPS will also be looking at the options for monitoring. However it is likely to prove difficult to eliminate the scope for misuse. Supply arrangements must include a requirement for clear patient identification and provide for basic documentation. HSS boards should also consider additional controls such as compiling/sharing lists and checking against electoral registers.
35. Plans should also allow for the identification and treatment of patients for whom treatment with Tamiflu is not recommended and for providing advice on recognising and dealing with antiviral side effects.

## **Conclusion**

36. Strategies for the rapid delivery and effective use of antiviral medicines are crucial to a successful health response to any influenza pandemic. Expert opinion suggests that they can lessen the severity of illness and may reduce demand for acute hospital beds by up to 50%. Local influenza pandemic arrangements must aim to make them readily available to those patients who will benefit whilst conserving stock and ensuring their best use over the entire pandemic period.
  
37. As clinical knowledge is constantly advancing and vaccine development on-going, guidance on arrangements for the delivery and use of antiviral medicines will be subject to continuing review. Revisions or updated information will be published on Health Department websites as new information emerges.

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## Annex A

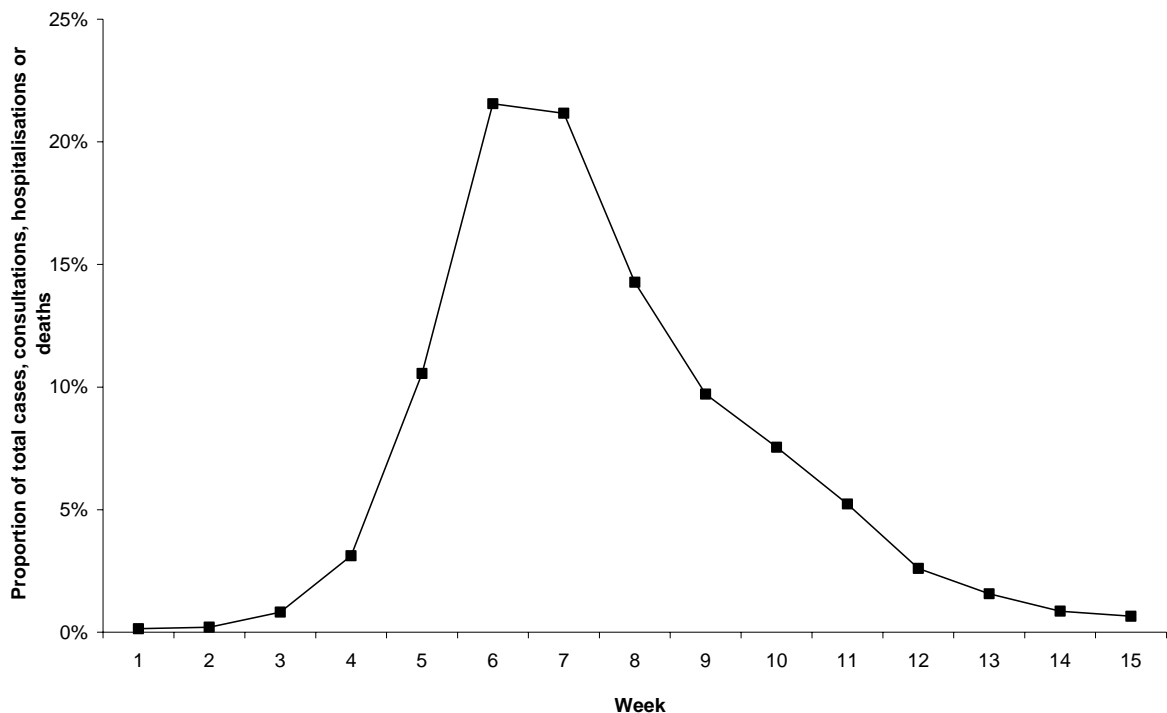
### “AS FAST AS IS REASONABLE” TEMPORAL PROFILE FOR PANDEMIC FLU

#### i) Weekly percentages summarising the temporal component of UK data from the three 20<sup>th</sup> century pandemics

wk 1	wk 2	wk 3	wk 4	wk 5	wk 6	wk 7	wk 8	wk 9	wk 10	wk 11	wk 12	wk 13	wk 14	wk 15
0.1%	0.2%	0.8%	3.1%	10.6%	21.6%	21.2%	14.3%	9.7%	7.5%	5.2%	2.6%	1.6%	0.9%	0.7%

\*Figures are percentages of the total for the outbreak as a whole. They may represent percentages of the total number of clinical cases, GP consultations, hospitalisations or deaths.

#### ii) Illustration of the “as fast as is reasonable profile” showing proportion of new clinical cases, consultations, hospitalisations or deaths by week.



\*These percentages are derived from historical data on previous pandemics. The temporal profile they represent is considerably “faster” than the theoretical profile that has been used for health impact modelling. Antiviral treatment reduces the infectious period, thus slowing the spread of disease -and shifting the temporal profile to a slower one, with a relatively low peak and a relatively long base. This profile is therefore as “fast” as might reasonably be expected for a UK outbreak of pandemic flu and is particularly useful for operational planning where timescales are important. Plans designed with this fast profile in mind should perform well if, as seems likely, the actual profile proves to be somewhat slower.

## Annex B

### PATIENTS AT HIGH-RISK OF INFLUENZA-RELATED COMPLICATIONS

CLINICAL RISK CATEGORY	EXAMPLES
<b>Chronic respiratory disease, including asthma</b>	This includes chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema, and such conditions as bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Asthma requiring continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission. Children who have previously been admitted to hospital for lower respiratory tract disease.
<b>Chronic heart disease</b>	This includes congenital heart disease, hypertension with cardiac complications, chronic heart failure and individuals requiring regular medication and/or follow-up for ischaemic heart disease.
<b>Chronic renal disease</b>	Including nephrotic syndrome, chronic renal failure, renal transplantation.
<b>Chronic liver disease.</b>	Including cirrhosis
<b>Diabetes</b>	Diabetes mellitus requiring insulin or oral hypoglycaemic drugs.
<b>Immunosuppression</b>	Due to disease or treatment. Including asplenia or splenic dysfunction, HIV infection at all stages. Patients undergoing chemotherapy leading to immunosuppression. Individuals on or likely to be on systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age ) or for children under 20kg a dose of 1mg or more per kg per day. <i>However, some immunocompromised patients may have a suboptimal immunological response to the vaccine.</i>
<b>Long-stay residential care homes residents</b>	This does <u>not</u> include prisons, young offender institutions or university halls of residence.
<b>Aged 65 years or older</b>	
<b>Others</b>	Doctors retain discretion to offer immunisation to some additional individual patients who they identify as at high risk of serious illness should they develop influenza, for example children on long term aspirin who are at increased risk of Reye's syndrome

## Annex C

**Estimated weekly totals for the amount of antivirals required to treat all cases given a 25% clinical attack rate.**

Period	% of total clinical cases	Requirements per 100,000 population	
		Adult treatment courses <sup>1</sup>	Treatment courses for children under 23 kg <sup>2</sup>
Week 1	0.1%	34	2
Week 2	0.2%	49	2
Week 3	0.8%	196	9
Week 4	3.1%	745	35
Week 5	10.6%	2,519	119
Week 6	21.6%	5,146	242
Week 7	21.2%	5,052	238
Week 8	14.3%	3,407	161
Week 9	9.7%	2,319	109
Week 10	7.5%	1,801	85
Week 11	5.2%	1,249	59
Week 12	2.6%	622	29
Week 13	1.6%	374	18
Week 14	0.9%	206	10
Week 15	0.7%	156	7
<b>All weeks</b>	<b>100%</b>	<b>23,875</b>	<b>1,125</b>

<sup>1</sup> The adult treatment course is 10 pre-packed Tamiflu capsules.

<sup>2</sup> For children over 1 year old and under 24 kg, Tamiflu will be supplied as bulk powder, which will then need to be made into suspension. In the table above, each treatment course for children under 24 kg represents the maximum dose (0.66 grams of powder) Prescribed dose will be weight adjusted.