In-Pharmacy Flu Vaccination Programme

Support Pack 2013/14

Pharmacist / Nurse name:

Novartis Vaccines and Diagnostics Limited has developed an In-Pharmacy Flu Vaccination training and support programme as a service to medicine and as a part of their commitment to provide greater access and convenience to those members of the public seeking to protect themselves against flu.

NOVARTIS
VACCINES AND DIAGNOSTICS

UK/FLU/13-0001(2) June 2013

INTRODUCING THE NOVARTIS VACCINES IN-PHARMACY FLU VACCINATION PROGRAMME

Influenza (flu) is a highly infectious disease and an unpredictable pressure that the NHS faces every winter. In England and Wales, it is estimated that 18,500–24,800 deaths are attributable to flu infections annually. Flu has led to 19,000–31,200 hospital admissions and 779,000–1.164 million GP consultations per year.[1] The Department of Health's seasonal flu vaccination programme aims to protect those people deemed more at–risk from the virus (people aged over 65 years or 'at–risk' from serious complications due to a clinical condition or circumstances), by providing free flu vaccinations via GPs. However, uptake rates in 2012/13 were below the government target of 75%, with around 73% of over 65 year olds, and 51% of 'at–risk' groups being vaccinated.[2]

In 2008, Novartis Vaccines and Diagnostics Limited ("Novartis Vaccines") launched an initiative aimed at improving service access in the community to help improve uptake of flu vaccinations. The Novartis Vaccines In–Pharmacy Flu Vaccination Programme provides a comprehensive training and support programme to community pharmacists for the delivery of seasonal flu vaccinations both in and out of the pharmacy setting. Pharmacists can offer this as a private service for anyone wishing to be vaccinated, or via NHS commissioning for those eligible for a free vaccination.

Since the programme began, Novartis Vaccines have provided support and training to more than 7,000 pharmacists and more than 800,000 people have been vaccinated against flu as part of the programme.[3] These figures demonstrate that the convenience and location of community pharmacy provide an accessible option for the public.

Novartis Vaccines are delighted to continue supporting community pharmacy and your campaign against flu and wishes you every success with this year's programme.

Deborah Di Salvo
Marketing Manager Influenza
Novartis Vaccines and Diagnostics Limited

References:

1. *Pitman RJ, Melegaro A, Gelb D, et al. Assessing the burden of influenza and other respiratory infections in England and Wales. J Infect 2007:54 (6):530–8*
2. *Department of Health, Public Health England and NHS England. Flu immunisation programme letter 2013/2014, 5 June 2013. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/205433/130605_Flu_Letter_FINAL.pdf (accessed June 2013)*
3. *Novartis Vaccines and Diagnostics Limited. Data on file: IPFI Statistics for 2012, January 2013*

NOVARTIS VACCINES AND DIAGNOSTICS

CONTENTS SUMMARY

NOVARTIS VACCINES AND DIAGNOSTICS

OPERATIONAL, PHYSICAL AND PROFESSIONAL REQUIREMENTS FOR FLU VACCINATION

OPERATIONAL REQUIREMENTS

- Undertake and successfully complete the online training programme at the grade of 80% or more
- Attendance at the Novartis Vaccines In-Pharmacy Training Programme as applicable
- Administrative staff / Pharmacy Assistant to help the Pharmacist / Nurse with the vaccination process including helping patients with form filling and to assist the Pharmacist / Nurse in the occurrence of an adverse event
- Timetable of clinics available for both walk-in and pre-booked appointments
- Undertake and successfully complete an approved Safeguarding Children Course (if vaccinating patients aged 12-15). In England and Wales contact The Centre for Pharmacy Postgraduate Education (CPPE) and in Scotland contact NHS Education for Scotland

PHYSICAL REQUIREMENTS

Access:

- Disabled access to the pharmacy

Storage:

- In Pharmacy: Vaccine refrigerator with a minimum / maximum thermometer, an annual service certificate and a chart for daily recording of fridge temperature. Storage of flu vaccines must be between +2 °C and +8 °C
- Out of Pharmacy: Vaccines should be transported to the administration location in a cool box with the appropriate insulation to keep the temperature between +2 °C and +8 °C. The vaccines should be kept in their packaging and insulated (e.g. bubble wrap) from the cooling system to avoid the risk of freezing. Vaccines to be stored on site in cool box until required. Any unused vaccines should be returned to pharmacy fridge within 8 hours. It is the Pharmacist's / Nurse's responsibility to keep the vaccines stored between +2 °C and +8 °C at all times

Consultation Room – In Pharmacy:

The private consultation room for vaccination administration should adhere to Principle 3 of the General Pharmaceutical Council's (draft) standards for registered pharmacies in that the premises where pharmacy services are provided, and any associated premises, are safe and suitable[1]

- The premises that pharmacy services are provided from are safe and properly maintained
- The size, design and layout of the premises are suitable for the pharmacy services provided. This includes sufficient space to effectively manage any emergency situations i.e. undertake CPR
- The design and layout of the premises protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services
- The premises are maintained to an appropriate level of cleanliness and hygiene. No food or drink should be consumed in the area. No smoking
- The pharmacy services are accessible to people who want to use them
- The premises are secure and safeguarded from unauthorised access
- Pharmacy services are provided in an environment that is appropriate for the provision of healthcare. This includes keeping the room free of stock, prescriptions and storing any immunisation equipment out of sight from the patient

NOVARTIS VACCINES AND DIAGNOSTICS

OPERATIONAL, PHYSICAL AND PROFESSIONAL REQUIREMENTS FOR FLU VACCINATION

- There should be a cleaning and disinfecting rota in place
- Seating should be provided during vaccination
- Access to emergency support in the form of a telephone or panic button to summon immediate assistance and 999 backup
- Pharmacy audit to be completed

External Room – Out of Pharmacy:

- See section above (Consultation Room)
- External Consultation Room Audit to be completed

Waiting Area:

- The customer should wait for 10 minutes after the vaccination in sight of pharmacy staff, this will allow appropriate treatment in the event of an adverse reaction to the vaccine
- The waiting area should allow privacy in the event of an adverse reaction
- It should be large enough to permit the customer to lie flat and allow staff access to either side of the customer with enough room to undertake CPR if necessary
- Seating should be provided. In the event of an adverse reaction the seat could be used to elevate the customer's legs if appropriate

Waste Disposal:

- Sharps bin for disposal of needles and syringes UN-approved, BS7320
- In Pharmacy: Yellow bag for clinical waste (cotton swabs, plasters etc)
- Out of Pharmacy: There are no additional regulations over and above those applicable in pharmacy when transporting sharps in a robust sharps container. Bags are not permitted so clinical waste should also be deposited in the sharps bin
- Any accidental blood contamination is cleaned immediately and the resulting contaminated waste disposed of in either the clinical waste or the sharps bin

Clinic Documentation (available in Support Pack):

- In Pharmacy: Pharmacy Audit to be completed
- Out of Pharmacy: External Consultation Room Audit Form (to be completed before the flu clinic commences)
- A copy of Immunisation Against Infectious Disease 'The Green Book' or copies of relevant chapters (excerpt from the relevant chapter in the Green Book available in Support Pack)
- Point of sale leaflet with flu vaccination suitability questions (for use if applicable)
- Patient Vaccination Record / Consent Form

  Four copies should be reproduced:

  1 x copy for the patient

  1 x copy for the patient's GP (if the patient consents)

  1 x copy for NHS (e.g. PCO) if required

  1 x copy for the pharmacy (to be retained for 8 years)

NOVARTIS VACCINES AND DIAGNOSTICS

OPERATIONAL, PHYSICAL AND PROFESSIONAL REQUIREMENTS FOR FLU VACCINATION

Sundries:

- Pre-filled Novartis flu vaccines
- Gloves - both latex and latex free (optional)
- Cotton swabs / wool
- Plasters
- Sharps bin
- Clinical waste bags
- Intramuscular adrenaline 1:1000 via
  - auto-injector or
  - ampoules, 2ml graduated syringes and Blue 23G (1 inch) needles
- Face mask / Laerdal (optional)
- Guedel airways (optional)
- Soap / handwash / paper towel (available within the vicinity)

PROFESSIONAL REQUIREMENTS

- Vaccination is not considered an exposure prone procedure (defined as a procedure in which there is a risk of injury to a worker which may expose the patient's open tissues to the blood of the worker). As such the recipient of a vaccination is not considered 'at-risk' of contracting Hepatitis B from the vaccinator. It is, however, possible for the vaccinator to be infected by the person receiving the vaccination. For this reason it is ***recommended*** that all persons delivering the vaccine be immune to Hepatitis B
- Appropriate professional indemnity insurance is in place for the provision of an In-Pharmacy Flu Vaccination Programme in and / or out of the pharmacy setting
- It is recommended that any healthcare professional obtains a DBS certificate where they undertake an activity which requires them to deliver any form of treatment or therapy either unsupervised with children or vulnerable adults or regularly with such category of person

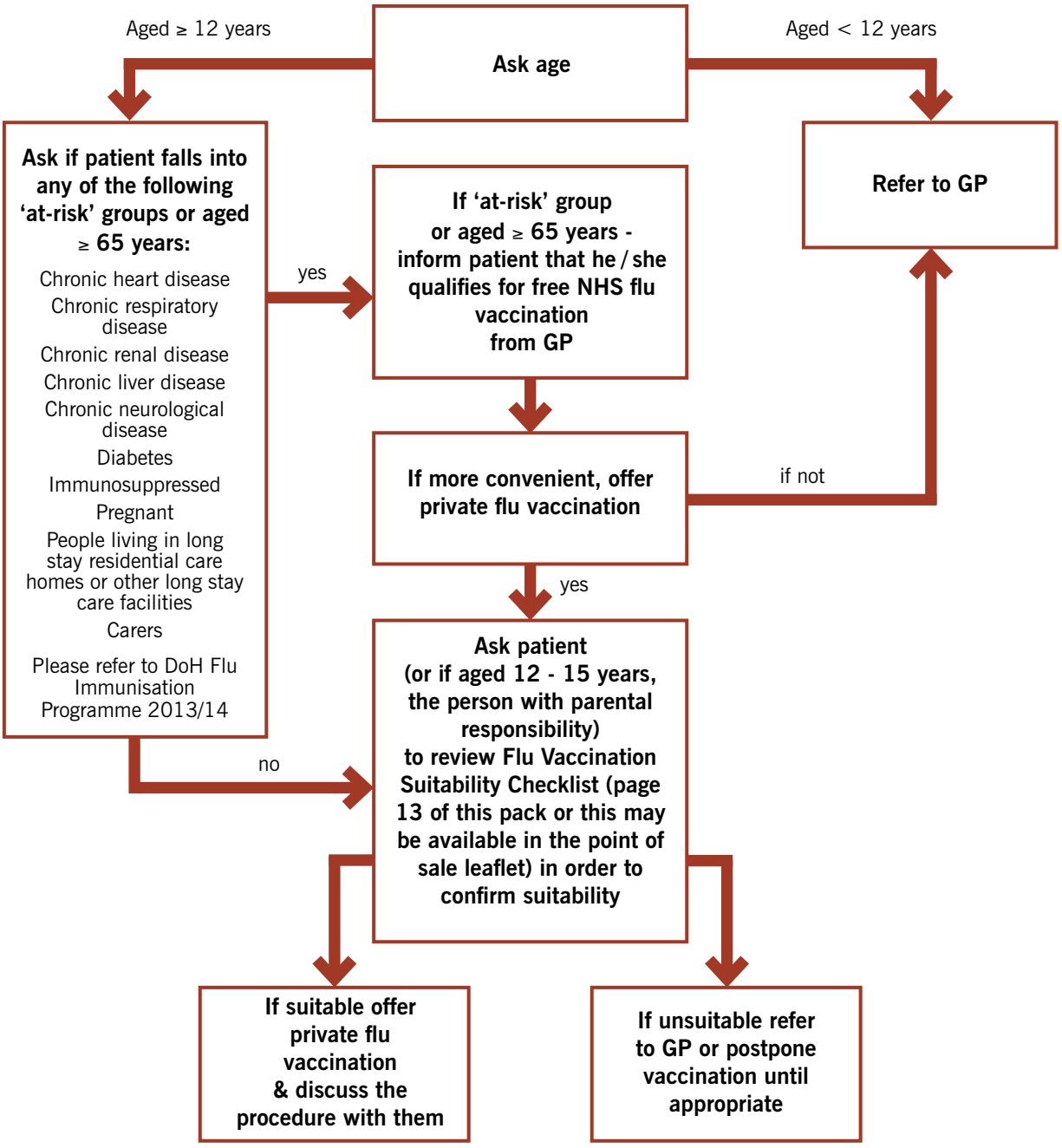
Reference:

1. *General Pharmaceutical Council (GPhC). Modernising Pharmacy Regulation: A consultation on the draft standards for registered pharmacies, February 2012 http://registeredpharmacies.org/files/2012/02/Consultation-8th-Feb.pdf (accessed June 2013)*

NOVARTIS VACCINES AND DIAGNOSTICS

STEP 1 - PATIENT SCREENING PROCESS

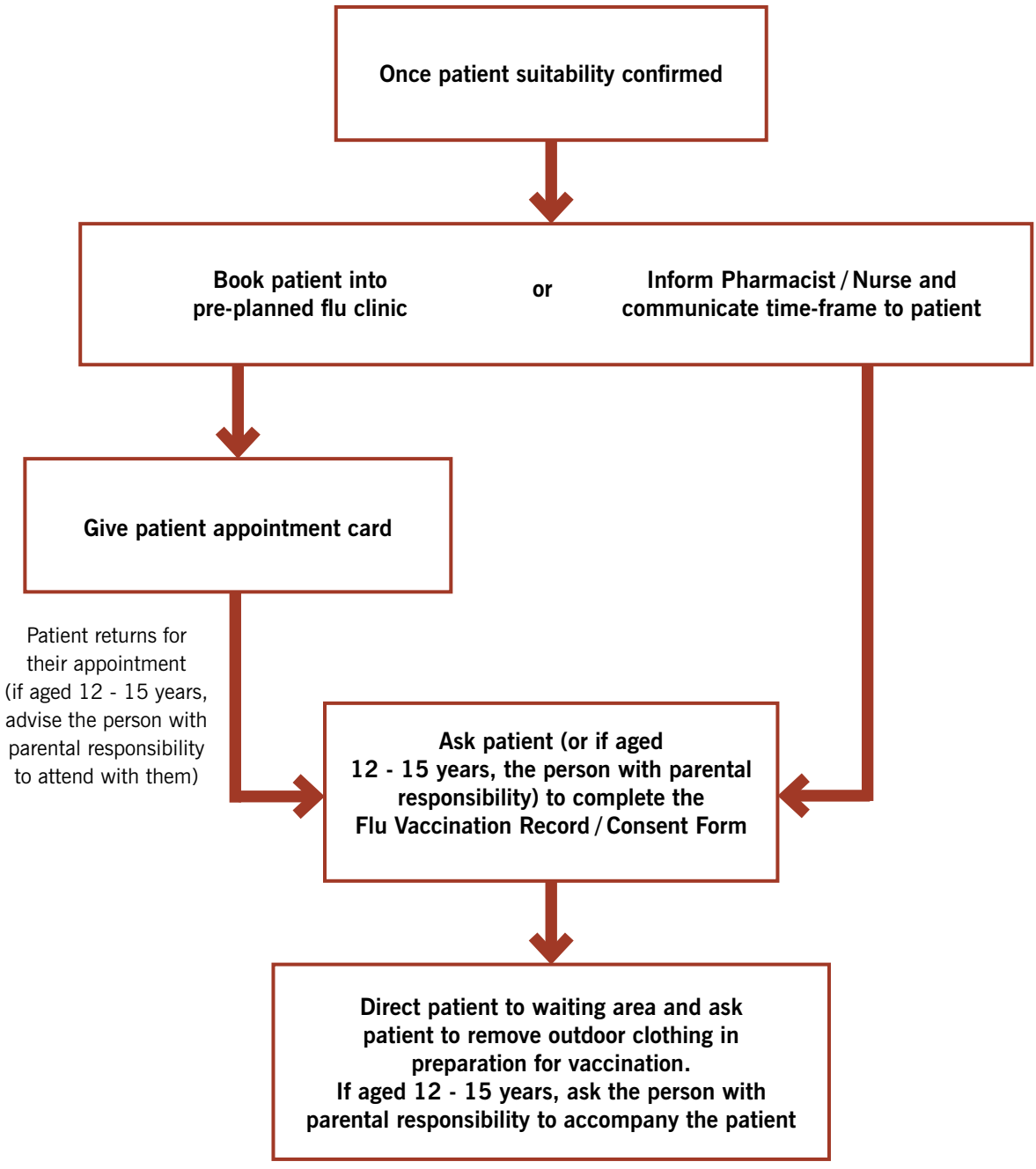
To be undertaken by a Pharmacy Assistant
To assess the suitability for flu vaccination, the below process should be followed.



NOVARTIS VACCINES AND DIAGNOSTICS

STEP 2 - PRE-VACCINATION PROCESS

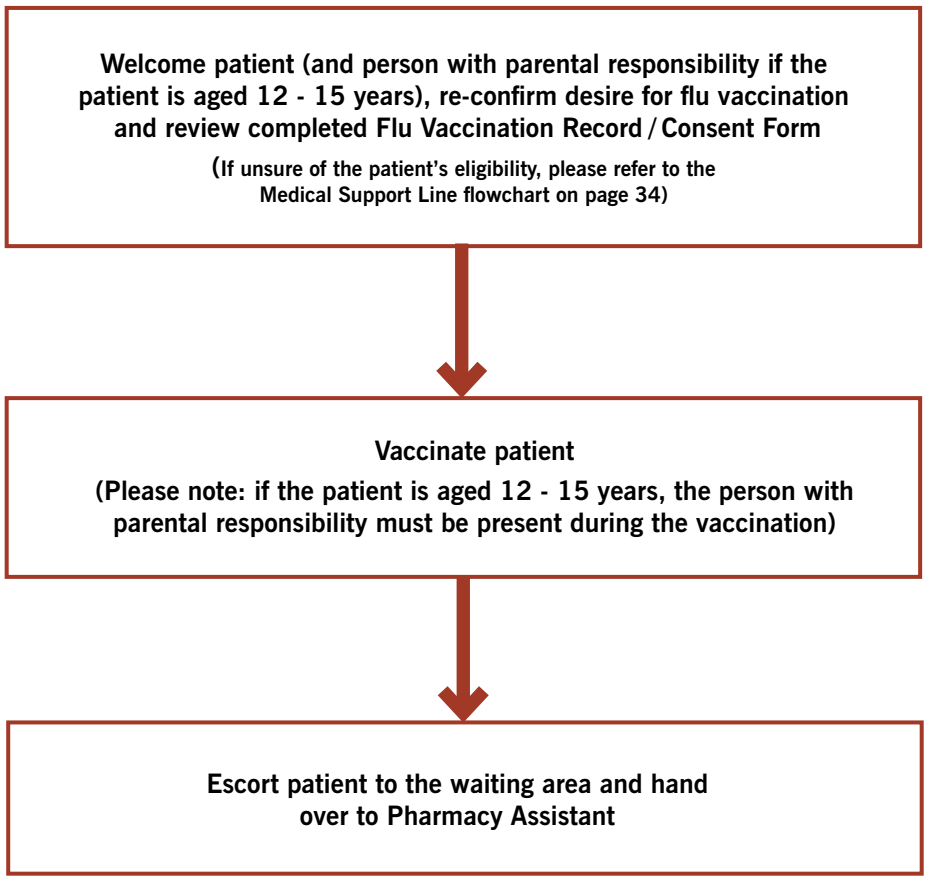
To be undertaken by Pharmacy Assistant



NOVARTIS VACCINES AND DIAGNOSTICS

STEP 3 - THE VACCINATION PROCESS

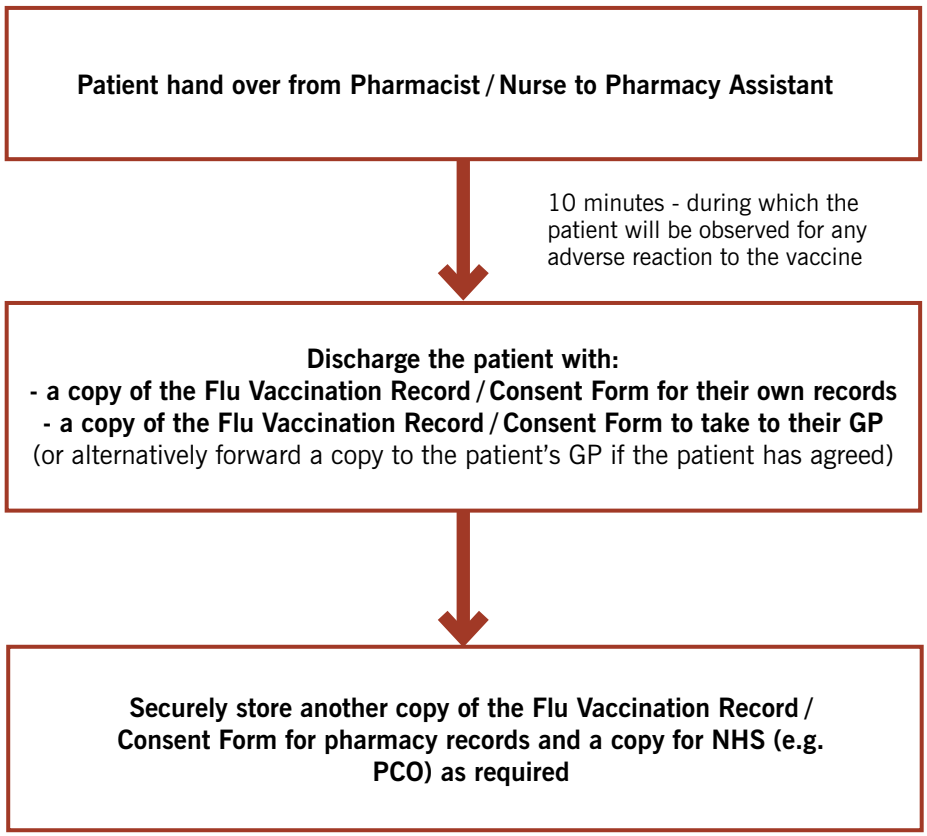
To be undertaken by a Pharmacist / Nurse authorised to administer flu vaccinations



NOVARTIS VACCINES AND DIAGNOSTICS

STEP 4 - POST-VACCINATION PROCESS

To be undertaken by Pharmacy Assistant



NOVARTIS VACCINES AND DIAGNOSTICS

FLU VACCINATION PROTOCOL

Pre-vaccination procedure

1. Undertake patient screening process
2. Patient (or if aged 12 - 15 years, the person with parental responsibility) to review the Flu Vaccination Suitability Checklist (page 13 or this may be available in your flu point of sale leaflet) and suitability confirmed by Pharmacist / Nurse
3. Patient to complete and sign Flu Vaccination Record / Consent Form
   If patient is aged 12 - 15 years, the person with parental responsibility to assist / complete as required and counter sign the Flu Vaccination Record / Consent Form
4. Patient to remove outdoor clothing

Vaccination procedure

(Please note: if the patient is aged 12 - 15 years the person with parental responsibility must be present during the vaccination)

1. Seat patient and ask the patient which is the preferred arm for vaccination
2. Ensure chosen upper arm exposed
3. Prepare tray with vaccine, cotton wool ball, plaster
4. Wash hands (See Hand Washing Guide on page 49)
5. Put on gloves (if required) - if wearing gloves containing latex, confirm again with the patient that he / she is not allergic to latex
6. Check arm for preferred site, avoid lesions, tattoos. Only if physically dirty, clean with soap and water and allow to dry
7. If administering Agrippal® or Fluvirin®, remove the pre-filled syringe from outer packaging.
   If adminstering Optaflu®▼, remove the pre-filled syringe and insert the needle if appropriate
8. Put label on Flu Vaccination Record / Consent Form
9. Stretch skin (bunch skin if emaciated patient with limited muscle mass)
10. Insert needle at 90° angle
11. Inject vaccine into patient in a single smooth action
12. Withdraw needle
13. Ask patient to press over vaccination area with cotton wool ball
14. Discard needle and syringe in sharps bin (**do not re-sheath**)
15. Apply a plaster if appropriate and not allergic to plasters

Post-vaccination

1. Ask patient to remain on premises for 10 minutes so that you can observe the patient for any adverse effects to the vaccine
2. Patient must be told to check out with a member of the pharmacy staff before leaving

NOVARTIS VACCINES AND DIAGNOSTICS

FLU CLINIC PLANNER

Date	Time	Name	Contact Number

FLU VACCINATION SUITABILITY CHECKLIST

TO BE GIVEN TO PATIENT (OR IF PATIENT IS AGED 12 - 15 YEARS, THE PERSON WITH PARENTAL RESPONSIBILITY) TO DETERMINE THEIR ELIGIBILITY FOR A FLU VACCINATION

(copies of this checklist should be available in pharmacy)

Flu Vaccination - Suitability

There are certain circumstances that prevent the Pharmacist/Nurse from administering a flu vaccination.

You (the person being vaccinated or the person with parental responsibility) should be able to confirm the following:

- You (the person being vaccinated) are 12 years of age or over
- You (the person being vaccinated) have not had a seasonal flu vaccination in the past 6 months
- You (the person being vaccinated) are not pregnant and do not think you may be pregnant

If any of the following apply to you (the person being vaccinated), you should discuss your suitability with the Pharmacy Assistant:

- You (the person being vaccinated) have any significant infection at present e.g. chest infection
- You (the person being vaccinated) have had any other immunisations or vaccinations during the last 3 months
- You (the person being vaccinated) have ever fainted or felt dizzy after receiving an injection in the past
- You (the person being vaccinated) are allergic to anything
- You (the person being vaccinated) are taking any medication
- You (the person being vaccinated) are suffering from any medical conditions

Post-Vaccination Advice

After you have had your vaccination...

- If you have a sore arm, apply a cold flannel
- If you have a headache or slight fever, drink plenty of water and painkillers may help
- If your symptoms persist over 48 hours, contact your surgery

NOVARTIS VACCINES AND DIAGNOSTICS

GUIDANCE ON FLU VACCINATION SUITABILITY

TO DETERMINE PATIENT ELIGIBILITY FOR A FLU VACCINATION

The patient should be given the Flu Vaccination Suitability Checklist or flu leaflet containing the checklist to assess their suitability for a vaccination, which should be discussed with the Pharmacy Assistant.

The patient (or if aged 12 - 15 years, the person with parental responsibility) should be able to confirm:

- **Patient is 12 years of age or over**

  If patient is not 12 years of age or over, refer to GP.
  If the patient is under 18 years, administer Fluvirin® or Agrippal®. DO NOT administer Optaflu®▼▼
  If patient is over 65 years of age, inform the patient he / she can qualify for a free flu vaccination on the NHS. However, if more convenient the patient may pay to have a private flu vaccination.

- **Patient has not had a seasonal flu vaccination in the past 6 months**

  If patient aged 12 years or above has had a flu vaccination in the past 6 months, another flu vaccination is not required.

- **Patient is not pregnant or does not think they may be pregnant**

  If patient is pregnant, or thinks they might be pregnant, refer to GP.

The patient (or if aged 12 - 15 years, the person with parental responsibility) should advise if any of the following apply:

- **Patient has a significant infection at present e.g. chest infection**

  Postpone vaccination until after full recovery.

- **Patient has had other immunisations or vaccinations during the last 3 months**

  If a patient has received a BCG vaccination within the past three months use the opposite arm and deltoid muscle.
  If a patient has a sore arm from a previous vaccination, use the opposite arm and deltoid muscle.

- **Patient has fainted or felt dizzy after receiving an injection in the past**

  Make sure the patient is sitting and calm before administration and carefully monitor the patient for 10 minutes after administration.

- **Patient has allergies**

  One of the criteria for exclusion is hypersensitivity to a previous dose.
  If patient is allergic to latex, refer to GP.
  If patient has a known: neomycin allergy or is allergic to egg products or chicken protein, administer Optaflu®; kanamycin allergy, administer Fluvirin® or Optaflu® or thiomersal allergy, administer Agrippal® or Optaflu®.

- **Patient is taking medication**

  There are no reported drug interactions with flu vaccination or adrenaline. However, asking this question will help indicate whether the patient falls into an 'at-risk' category and therefore can qualify for a free flu vaccination on the NHS.

- **Patient is suffering from a medical condition**

  If a patient has a bleeding disorder as a result of illness or medication, e.g. Warfarin or Heparin etc, refer to GP.
  If included in the Department of Health 'at-risk' groups, inform the patient a vaccine is available free of charge at their own GP practice.

NOVARTIS VACCINES AND DIAGNOSTICS

Notification of
Flu Vaccination

Pharmacy Stamp

In-Pharmacy
Flu Vaccination Programme

Date:

Dear Doctor,

Please find attached a Flu Vaccination Record / Consent Form detailing your patient's recent flu vaccination. The vaccine was administered by myself. The patient did not experience any problems during or after the vaccination.

Name of patient:

If you would like to know more about our service, please do not hesitate to contact me.

Yours sincerely,

Name:

Title:

GPhC / NMC registration number:

Read code:-
65E20

Circle as appropriate:
Private service **NHS service**

FLU VACCINATION RECORD / CONSENT FORM

Affix vaccine label here

To be completed by patient (or if aged 12 - 15 years, the person with parental responsibility):

Patient Details

Name: _____

Address: _____

_____

_____

Contact Number: _____

DOB: _____ Age (if under 16 years): _____

GP Details (Optional)

Name: _____

Address: _____

_____

_____

Contact Number: _____

Any Medical Conditions: _____

Current Medication: _____

Allergies: _____

Patient Consent

- ☐ I agree to be given a flu vaccine by a specially trained Pharmacist / Nurse
- ☐ I have received a patient advice leaflet about flu and vaccination
- ☐ I confirm that I have not been previously administered with a seasonal flu vaccine for this coming winter
- ☐ I confirm that I am not pregnant

I am happy for my GP to be informed of this treatment (optional): Yes ☐ No ☐

Signature: _____

(Person with parental responsibility for anyone aged 12 - 15 years) Signature: _____

Print name: _____

To be completed by Pharmacist / Nurse:

Vaccine Details

Flu vaccine (please tick relevant box):

Fluvirin® ☐ Agrippal® ☐ Optaflu®▼ ☐

Manufacturer: **Novartis Vaccines and Diagnostics Limited**

Batch number (from vaccine label above):

_____

Expiry date: _____

Administered by

Signature: _____

Name: _____

GPhC / NMC registration number: _____

Date administered: _____

Injection site

Deltoid muscle:

Left arm ☐ Right arm ☐

Adverse effects: _____

Pharmacy Details

Name: _____

Address: _____

_____

Telephone: _____

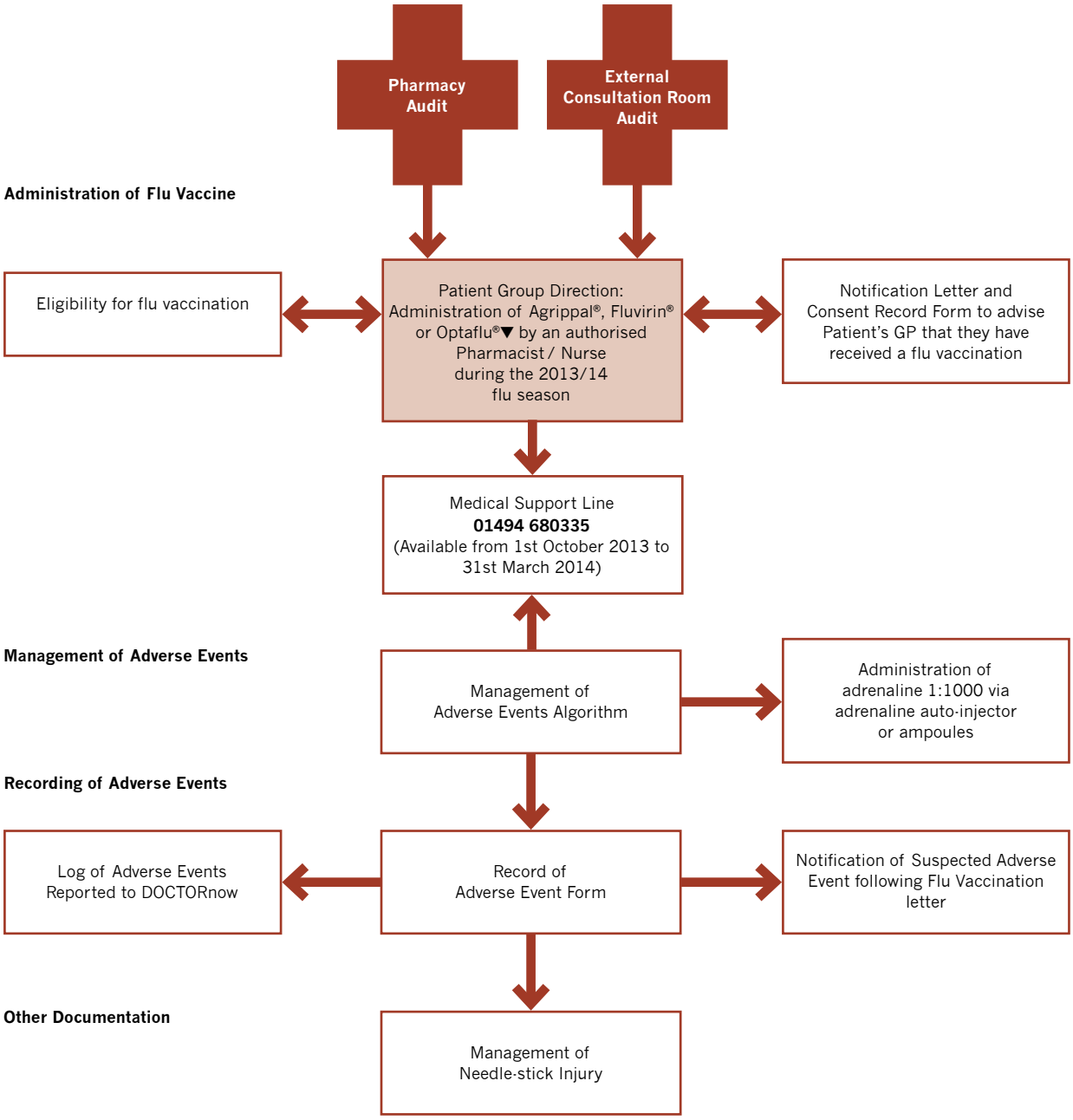
Location at which flu vaccination administered (if external), e.g. business and town

_____

Top copy for GP (if required) | Pink copy for Patient | Yellow copy for Pharmacist / Nurse | Blue copy for NHS (if required)

NOVARTIS VACCINES AND DIAGNOSTICS

CLINICAL GOVERNANCE FRAMEWORK



PHARMACY AUDIT

FOR THE ADMINISTRATION OF FLU VACCINES 2013/14

The responsible person for the Pharmacy must complete the audit.

1. Pharmacy Details

Pharmacy Name: .....

Pharmacy Address: .....

.....

.....

2. Personnel

Any Pharmacist / Nurse administering vaccinations in the pharmacy has read, understood and signed the PGD(s)	Yes ☐	No ☐
Pharmacy support staff identified and appropriately trained / briefed	Yes ☐	No ☐

3. Consultation Area

Consultation area meets the physical requirements (see pages 4 - 6 of the In-Pharmacy Flu Vaccination Programme Support Pack 2013/14)	Yes ☐	No ☐
Immediate access to adrenaline 1:1000 via adrenaline auto-injectors or ampoules	Yes ☐	No ☐
Pharmacist / Nurse is aware of actions to be taken in the event of a used needle-stick injury	Yes ☐	No ☐

4. Professional Standards and Ethics / Indemnity

The Pharmacist / Nurse must ensure they have appropriate professional indemnity insurance in place for the provision of an In-Pharmacy Flu Vaccination Programme in and / or out of the pharmacy setting	Yes ☐	No ☐

Eligibility to participate in the In-Pharmacy Flu Vaccination Programme

If your response is **Yes** to all of the above questions it is appropriate for your pharmacy to participate in the service

If your response is **No** to any of the above questions it is not appropriate for your pharmacy to participate until these issues have been resolved and participation agreed with DOCTORnow and / or the Superintendent Pharmacist

Pharmacist / Nurse name	GPhC Registration number/ NMC PIN number	Signature	Date

Copy to be retained by the responsible person for the premises concerned.

EXTERNAL CONSULTATION ROOM AUDIT

FOR THE ADMINISTRATION OF FLU VACCINES 2013/14

(Please note: this must be completed at the planning stage and prior to the vaccination clinic)

1. Location Details

Location name and address: .....

Contact name and telephone number: .....

.....

2. Accessibility

Easily identifiable (signed)	Yes ☐	No ☐
Easily accessible for the emergency services should they be needed i.e. convenient and close to front of building	Yes ☐	No ☐

3. Consultation Area

Private - i.e. well screened or closable door	Yes ☐	No ☐
Clean	Yes ☐	No ☐
Well-lit	Yes ☐	No ☐

4. Facilities

Hand washing facility with soap (available within the vicinity)	Yes ☐	No ☐
Office desk	Yes ☐	No ☐
Chairs for the clinician and the vaccinee	Yes ☐	No ☐

5. Equipment

Sharps box that meets the BS7320 standard	Yes ☐	No ☐
2ml graduated syringes and Blue 23G (1 inch) needles	Yes ☐	No ☐
Handwash	Yes ☐	No ☐
Cotton wool balls	Yes ☐	No ☐
Plasters	Yes ☐	No ☐
Adrenaline 1:1000 via adrenaline auto-injectors or ampoules	Yes ☐	No ☐
Landline telephone in room with outside line facility i.e. to call 999 or mobile telephone (fully charged with guaranteed adequate signal)	Yes ☐	No ☐
In-Pharmacy Flu Vaccination Support Pack, Clinical Governance Handbook with signed PGDs and administration support documents	Yes ☐	No ☐

DOCTORnow

EXTERNAL CONSULTATION ROOM AUDIT

FOR THE ADMINISTRATION OF FLU VACCINES 2013/14 (CONTINUED)

6. Waiting Area

Convenient seating area to review the flu vaccination leaflet and complete the Flu Vaccination Record / Consent Form prior to vaccination. The waiting area is also compulsory for the patient's 10 minute wait post-vaccination Yes ☐ No ☐

Adequate floor space for patient to be able to be laid flat and for persons to kneel either side in the event of an adverse reaction (emergency procedure as per company policy) Yes ☐ No ☐

Eligibility to operate a flu clinic out of the pharmacy setting

If your response is **Yes** to all of the above questions it is appropriate to proceed with the flu clinic

If your response is **No** to any of the above questions please discuss with DOCTORnow and / or the Superintendent Pharmacist

Pharmacist / Nurse name	GPhC Registration number/ NMC PIN number	Signature	Date

Copy to be retained by the Pharmacist / Nurse responsible, in pharmacy.

DOCTORnow

PATIENT GROUP DIRECTION (PGD) - FLU VACCINATION

ADMINISTRATION OF **AGRIPPAL®** OR **FLUVIRIN®** BY AN AUTHORISED PHARMACIST OR NURSE DURING THE 2013/14 FLU SEASON

Start date: 1st October 2013
End date: 31st March 2014

NOTE: THERE IS A SEPARATE PATIENT GROUP DIRECTION FOR THE ADMINISTRATION OF **OPTAFLU®▼** - REFER TO PAGE 26

Start date: 1st October 2013
End date: 31st March 2014

PATIENT GROUP DIRECTION - FLU VACCINATION

ADMINISTRATION OF **AGRIPPAL**® OR **FLUVIRIN**® BY AN AUTHORISED PHARMACIST OR NURSE DURING THE 2013/14 FLU SEASON

Note: A separate PGD is available for the administration of Optaflu®▼ – refer to page 26

This Patient Group Direction is intended for the administration of Agrippal® or Fluvirin® flu vaccine both in and out of the pharmacy setting. For the avoidance of doubt, any Pharmacist / Nurse working outside of this guidance will be personally / professionally liable, not DOCTORnow.

1. Clinical Condition

Define situation / condition	Prophylaxis of flu by vaccination	
Criteria for inclusion	Patients that are 12 years of age and over	
Criteria for exclusion A Flu Vaccination Suitability Checklist to determine eligibility must be reviewed. If there is any doubt surrounding a patient's eligibility, please refer to the Frequently Asked Questions (FAQs) on pages 32 & 33, or failing this please call the DOCTORnow Medical Support Line on **01494 680335** for guidance.	**Patients that are:**	**Action:**
	• Under the age of 12 years old • Actually or potentially pregnant • Known to have a bleeding disorder	Ineligible, refer to GP
	• Patients that are hypersensitive to any of the active substances, excipients or residues found in the vaccine to be administered (Agrippal® or Fluvirin®)	Ineligible, refer to GP
	• Patients that are hypersensitive to latex	Ineligible, refer to GP
	• Patients with febrile illness or acute infection	Ineligible, refer to GP

2. Characteristics of Staff

Qualifications and registration requirements	• Pharmacist currently registered with the General Pharmaceutical Council / Nurse currently registered with the Nursing and Midwifery Council • Attendance at an In-Pharmacy Flu Vaccination Training Programme for the Flu Vaccination Service, including management of anaphylaxis and basic cardio-pulmonary resuscitation (as applicable) • Undertake and successfully complete the online training programme at the grade of 80% or above • Completion of a recognised 'Safeguarding Children' Course (CPPE or NES) if vaccinating children aged 12-15 years
Additional requirements	The Pharmacist / Nurse must: • Agree to be professionally accountable for this work • Have read and understood the current immunisation recommendations as listed in Immunisation Against Infectious Disease – 'The Green Book'[1] and either the Department of Health, Public Health England and NHS England flu immunisation programme letter concerning the 2013/14 NHS flu campaign or the Scottish Chief Pharmaceutical Officer letter concerning the 2013/14 NHS flu campaign, as applicable • Have read and understood the General Pharmaceutical Council document 'Standards of Conduct, ethics and performance'[2] • Have read and understood the recommendations for vaccination against Hepatitis B and taken all the necessary steps to ensure there is minimum risk of cross contamination as per the Hepatitis B SOP • Possess the appropriate professional indemnity insurance • Have undertaken and signed off the Pharmacy Audit • Have undertaken and signed off the External Consultation Room Audit Form (if working outside of the pharmacy setting)

Start date: 1st October 2013
End date: 31st March 2014

PATIENT GROUP DIRECTION - FLU VACCINATION

ADMINISTRATION OF **AGRIPPAL**® OR **FLUVIRIN**® BY AN AUTHORISED PHARMACIST OR NURSE DURING THE 2013/14 FLU SEASON

3. Description of Treatment [3]

Name of medicine	Agrippal® or Fluvirin® inactivated flu vaccine. Suspension for injection in pre-filled syringe. The vaccine appears as a clear liquid.
Legal status	Prescription only medicines (POM)
Licence status	Licensed
Dose	Single 0.5ml injection in adults and children aged 12 years and older
Frequency	One dose given annually
Route	Intramuscular (IM) injection into the deltoid muscle
Contraindications	Exclusions and contraindications can be found in the 'Guidance on Flu Vaccination Suitability' document (see page 14). The Summary of Product Characteristics for Agrippal® or Fluvirin® detail the following contraindications for each product: • Patients who have previously reacted to any other vaccines with similar components • Patients with hypersensitivity to egg products, chicken protein or any other constituent of the vaccine, with or without previous anaphylaxis • Patients with current significant febrile illness or acute infection
Adverse reactions observed from clinical trials	All of these reactions have been listed as "common" (that is, reported in more than 1/100 but less than 1/10 cases) and usually disappear within 1-2 days without treatment • Nervous system disorders - headache • Skin and subcutaneous tissue disorders - sweating • Musculoskeletal and connective tissue disorders - myalgia (muscle pain), arthralgia • General disorders - fever, malaise, shivering, fatigue • Local reactions - redness, swelling, pain, ecchymosis (bruising), induration (firm swelling)
Adverse reactions observed from post marketing surveillance	• Blood and lymphatic system disorders - transient thrombocytopenia, transient lymphadenopathy • Immune system disorders - allergic reactions, in rare cases leading to shock, angioedema • Nervous system disorders - neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome • Vascular disorders - vasculitis associated in very rare cases with transient renal involvement • Skin and subcutaneous tissue disorders - generalised skin reactions including pruritus, urticaria or non-specific rash
Overdose	Overdose is unlikely to have any untoward effect
Period of time for patient to be observed post-vaccination	To ensure that any immediate adverse events experienced by a patient can be dealt with by the trained Pharmacist / Nurse, pharmacy staff should advise all patients who have received the flu vaccination to be observed for a minimum of 10 minutes
Management of adverse events	• Refer to the following document in your In-Pharmacy Flu Vaccination Programme Support Pack for clear guidance on the recognition and management of adverse reactions: – Management of Adverse Events Algorithm • In the case of anaphylaxis, adrenaline must be used as detailed on pages 36 - 38 • Mild / common adverse events should be treated as appropriate and patient advised to seek medical opinion if symptoms persist or condition deteriorates
Reporting and recording of adverse events	• All suspected adverse events must be reported to DOCTORnow and your Superintendent Pharmacist within 12 hours of being made aware of the event • Refer to the following documents in your In-Pharmacy Flu Vaccination Programme Support Pack for clear guidance on the reporting of adverse events: – Management of Adverse Events Algorithm – Record of Adverse Event Form – Log of Adverse Events Reported to DOCTORnow • Patient's GP should be notified of any adverse event: – Notification of Suspected Adverse Event following Flu Vaccination letter

DOCTORnow

Start date: 1st October 2013
End date: 31st March 2014

PATIENT GROUP DIRECTION - FLU VACCINATION

ADMINISTRATION OF **AGRIPPAL**® OR **FLUVIRIN**® BY AN AUTHORISED PHARMACIST OR NURSE DURING THE 2013/14 FLU SEASON

4. Other Important Information

Supplies, facilities and precautions	The Pharmacist / Nurse should ensure that: • Vaccination is carried out in an appropriate private consultation room that meets the criteria set out in the Pharmacy Audit • There is immediate access to adrenaline 1:1000 via adrenaline auto-injector or ampoules • There is access to a telephone to call 999 • The vaccine is stored appropriately so that the cold-chain is maintained • Frozen, discoloured or cloudy flu vaccines are not administered and are discarded appropriately
Record keeping	The Pharmacist / Nurse should ensure the following records are securely stored for eight years (in adults) or until 25th birthday in a child (age 26 if an entry made when the young person was 17) [1] • Patient Flu Vaccination Record / Consent Form • Any correspondence with patient's GP • Log and record of suspected adverse event
Audit	DOCTORnow reserves the right to carry out an audit of any premises used to vaccinate patients in the In-Pharmacy Flu Vaccination Programme and inspect Pharmacist / Nurse records relating to this service at any time

5. Eligibility for Flu Vaccination

This document has been designed to provide you with clear guidance on the patients that **are not eligible** for a flu vaccination under this Patient Group Direction.

Although the last 3 patient types detailed in the table below are not excluded from receiving Agrippal® or Fluvirin® in accordance with each product's licence, the administration and supply of these products to these patients is not allowed under the terms of the entitled Patient Group Direction.

Patients not eligible for a flu vaccination under the entitled Patient Group Direction Signature

- Patients with a definite history of severe, local or general reaction to a preceding dose of a vaccine containing similar components (absolute contraindication) [3]
- Patients with hypersensitivity to egg products, chicken protein or any other constituent of the vaccine, with or without previous anaphylaxis (always check the SPC of product for excipients that may cause the patient to be hypersensitive) [3]
- Patients with current significant febrile illness or acute infection (postpone until recovery has occurred – minor infections without fever or systemic upset are not reasons to postpone immunisation) [3]
- Patients under 12 years of age
- Patients who are actually or possibly pregnant
- Patients who are known to have a bleeding disorder

} **Eligible under licence, but not eligible under the terms of this Patient Group Direction**

Please note: Agrippal® is licensed for use in adults and children over 6 months and Fluvirin® is licensed for use in adults and children over 4 years

DOCTORnow

Start date: 1st October 2013
End date: 31st March 2014

PATIENT GROUP DIRECTION - FLU VACCINATION

ADMINISTRATION OF **AGRIPPAL**® OR **FLUVIRIN**® BY AN AUTHORISED PHARMACIST OR NURSE DURING THE 2013/14 FLU SEASON

6. Management of Patient Group Direction

This Patient Group Direction was developed and approved by the following:

	Name	Signature	Date
Clinical Governance Lead (Medic) on behalf of DOCTORnow Ltd	Dr Brian McGirr (MRCGP) Dr Richard Angwin (FRCS)		01/02/13
Clinical Governance Advisor (Pharmacist) on behalf of DOCTORnow Ltd	Anita Hadden (BPharm, Reg. No. 2030014)		01/02/13
Clinical Governance Advisor (Nurse) on behalf DOCTORnow Ltd	Elizabeth D'Arcy-Evans (RGN)		01/02/13
Superintendent Pharmacist on behalf of the pharmacy			

This Patient Group Direction is to be read, agreed to and signed by the participating trained Pharmacist / Nurse, who must keep a copy of this signed Patient Group Direction in their In-Pharmacy Flu Vaccination Programme Support Pack. The Superintendent Pharmacist should retain a record of all participating Pharmacists / Nurses.

This Patient Group Direction will be reviewed 1st April 2014.

I (participating authorised Pharmacist / Nurse) confirm that I have read and understood this Patient Group Direction and that I have been provided with the appropriate training to work within this Patient Group Direction.

Name	GPhC Registration number / NMC PIN number	Signature	Date

References:

1. *Public Health England. Immunisation against infectious disease: the green book. Chapter 19: Influenza, August 2012. Available online https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147958/Green-Book-Chapter-19-v4_71.pdf (accessed June 2013)*
2. *General Pharmaceutical Council (GPhC). Standards of conduct, ethics and performance, July 2012 http://www.pharmacyregulation.org/sites/default/files/Standards%20of%20conduct%20ethics%20and%20performance%20July%202012.pdf (accessed June 2013)*
3. *Novartis Vaccines and Diagnostics Limited - Agrippal®, Fluvirin® or Optaflu®▼ Summary of Product Characteristics available on http://www.medicines.org.uk/emc/ (accessed June 2013)*

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PATIENT GROUP DIRECTION (PGD) - FLU VACCINATION

ADMINISTRATION OF **OPTAFLU®▼** BY AN AUTHORISED PHARMACIST OR NURSE DURING THE 2013/14 FLU SEASON

Start date: 1st October 2013
End date: 31st March 2014

NOTE: THERE IS A SEPARATE PATIENT GROUP DIRECTION FOR THE ADMINISTRATION OF **AGRIPPAL®** AND **FLUVIRIN®** - REFER TO PAGE 21

Start date: 1st October 2013
End date: 31st March 2014

PATIENT GROUP DIRECTION - FLU VACCINATION

ADMINISTRATION OF **OPTAFLU®▼** BY AN AUTHORISED PHARMACIST OR NURSE DURING THE 2013/14 FLU SEASON

Note: A separate PGD is available for the administration of Agrippal® and Fluvirin® · refer to page 21

This Patient Group Direction is intended for the administration of Optaflu® flu vaccine both in and out of the pharmacy setting. For the avoidance of doubt, any Pharmacist / Nurse working outside of this guidance will be personally / professionally liable, not DOCTORnow.

1. Clinical Condition

Define situation / condition	Prophylaxis of flu by vaccination	
Criteria for inclusion	Patients that are over **18 years of age**	
Criteria for exclusion A flu vaccination suitability checklist to determine eligibility must be reviewed. If there is any doubt surrounding a patient's eligibility, please refer to the Frequently Asked Questions (FAQs) on pages 32 & 33, or failing this please call the DOCTORnow Medical Support Line on **01494 680335** for guidance.	**Patients that are:**	**Action:**
	• Above the age of **12 years old** and under the age of **18 years old**	Administer Fluvirin® or Agrippal®
	• Under the age of **12 years old** • Actually or potentially pregnant • Known to have a bleeding disorder	Ineligible, refer to GP
	• Patients that are hypersensitive to any of the active substances, excipients or residues found in the vaccine to be administered (Optaflu®)	Ineligible, refer to GP
	• Patients that are hypersensitive to latex	Ineligible, refer to GP
	• Patients with febrile illness or acute infection	Postpone vaccination until after full recovery

2. Characteristics of Staff

Qualifications and registration requirements	• Pharmacist currently registered with the General Pharmaceutical Council / Nurse currently registered with the Nursing and Midwifery Council • Attendance at an In-Pharmacy Flu Vaccination Training Programme for the Flu Vaccination Service, including management of anaphylaxis and basic cardio-pulmonary resuscitation (as applicable) • Undertake and successfully complete the online training programme at the grade of 80% or above
Additional requirements	The Pharmacist / Nurse must: • Agree to be professionally accountable for this work • Have read and understood the current immunisation recommendations as listed in Immunisation Against Infectious Disease – 'The Green Book'[1] and either the Department of Health, Public Health England and NHS England flu immunisation programme letter concerning the 2013/14 NHS flu campaign or the Scottish Chief Pharmaceutical Officer letter concerning the 2013/14 NHS flu campaign, as applicable • Have read and understood the General Pharmaceutical Council document 'Standards of Conduct, ethics and performance'[2] • Have read and understood the recommendations for vaccination against Hepatitis B and taken all the necessary steps to ensure there is minimum risk of cross contamination as per the Hepatitis B SOP • Possess the appropriate professional indemnity insurance • Have undertaken and signed off the Pharmacy Audit • Have undertaken and signed off the External Consultation Room Audit Form (if working outside of the pharmacy setting)

Start date: 1st October 2013
End date: 31st March 2014

PATIENT GROUP DIRECTION - FLU VACCINATION

ADMINISTRATION OF **OPTAFLU®▼** BY AN AUTHORISED PHARMACIST OR NURSE DURING THE 2013/14 FLU SEASON

3. Description of Treatment [3]

Name of medicine	Optaflu® inactivated flu vaccine. Suspension for injection in pre-filled syringe. Clear to slightly opalescent
Legal status	Prescription only medicines (POM)
Licence status	Licensed
Dose	Single 0.5ml injection in adults
Frequency	One dose given annually
Route	Intramuscular (IM) injection into the deltoid muscle
Contraindications	Exclusions and contraindications can be found in the 'Guidance on Flu Vaccination Suitability' document (see page 14). The Summary of Product Characteristics for Optaflu® details the following contraindications: • Patients who have previously reacted to any other vaccines with similar components • Patients with hypersensitivity to any constituent of the vaccine, with or without previous anaphylaxis • Patients with current significant febrile illness or acute infection
Adverse reactions observed from clinical trials	All of these reactions have been listed as "very common" (more than 1/10) or "common" (more than 1/100 less than 1/10) and usually disappear within 1-2 days without treatment • Skin and subcutaneous tissue disorders - sweating • Musculoskeletal and connective tissue disorders - myalgia (muscle pain), arthralgia • General disorders - erythema, pain, malaise, fatigue, swelling, ecchymosis, induration, fever, shivering, gastrointestinal disorders such as abdominal pain, diarrhoea or dyspepsia • Nervous system disorders - headache
Overdose	Overdose is unlikely to have any untoward effect
Period of time for patient to be observed post-vaccination	To ensure that any immediate adverse events experienced by a patient can be dealt with by the trained Pharmacist / Nurse, pharmacy staff should advise all patients who have received the flu vaccination to be observed for a minimum of 10 minutes
Management of adverse events	• Refer to the following document in your In-Pharmacy Flu Vaccination Programme Support Pack for clear guidance on the recognition and management of adverse reactions: – Management of Adverse Events Algorithm • In the case of anaphylaxis, adrenaline must be used as detailed on pages 36 - 38 • Mild / common adverse events should be treated as appropriate and patient advised to seek medical opinion if symptoms persist or condition deteriorates
Reporting and recording of adverse events	• All suspected adverse events must be reported to DOCTORnow and your Superintendent Pharmacist within 12 hours of being made aware of the event • Refer to the following documents in your In-Pharmacy Flu Vaccination Programme Support Pack for clear guidance on the reporting of adverse events: – Management of Adverse Events Algorithm – Record of Adverse Event Form – Log of Adverse Events Reported to DOCTORnow • Patient's GP should be notified of any adverse event: – Notification of Suspected Adverse Event following Flu Vaccination letter

DOCTORnow

Start date: 1st October 2013
End date: 31st March 2014

PATIENT GROUP DIRECTION - FLU VACCINATION

ADMINISTRATION OF **OPTAFLU®▼** BY AN AUTHORISED PHARMACIST OR NURSE DURING THE 2013/14 FLU SEASON

4. Other Important Information

Supplies, facilities and precautions	The Pharmacist / Nurse should ensure that: • Vaccination is carried out in an appropriate private consultation room that meets the criteria set out in the Pharmacy Audit • There is immediate access to adrenaline 1:1000 via adrenaline auto-injector or ampoules • There is access to a telephone to call 999 • The vaccine is stored appropriately so that the cold-chain is maintained • Frozen, discoloured or cloudy flu vaccines are not administered and are discarded appropriately
Record keeping	The Pharmacist / Nurse should ensure the following records are securely stored for eight years [1] • Patient Flu Vaccination Record / Consent Form • Any correspondence with patient's GP • Log and record of suspected adverse event
Audit	DOCTORnow reserves the right to carry out an audit of any premises used to vaccinate patients in the In-Pharmacy Flu Vaccination Programme and inspect Pharmacist / Nurse records relating to this service at any time

5. Eligibility for Flu Vaccination

This document has been designed to provide you with clear guidance on the patients that **are not eligible** for a flu vaccination under this Patient Group Direction.

Although the last 2 patient types detailed in the table below are not excluded from receiving Optaflu® in accordance with the product's respective licence, the administration and supply of these products to these patients is not allowed under the terms of the entitled Patient Group Direction.

Patients not eligible for a flu vaccination under the entitled Patient Group Direction Signature

- Patients with a definite history of severe, local or general reaction to a preceding dose of a vaccine containing similar components (absolute contraindication) [3]
- Patients with hypersensitivity to latex or any other constituent of the vaccine, with or without previous anaphylaxis (always check the SPC of product for excipients that may cause the patient to be hypersensitive) [3]
- Patients with current significant febrile illness or acute infection (postpone until recovery has occurred – minor infections without fever or systemic upset are not reasons to postpone immunisation) [3]
- Patients under 18 years - if the patient is under 18 years, administer Fluvirin® or Agrippal®, DO NOT administer Optaflu®
- Patients who are actually or possibly pregnant
- Patients who are known to have a bleeding disorder

} **Eligible under licence, but not eligible under the terms of this Patient Group Direction**

Please note: Optaflu® is licensed for use in 18 years and over

Start date: 1st October 2013
End date: 31st March 2014

PATIENT GROUP DIRECTION - FLU VACCINATION

ADMINISTRATION OF **OPTAFLU®▼** BY AN AUTHORISED PHARMACIST OR NURSE DURING THE 2013/14 FLU SEASON

6. Management of Patient Group Direction

This Patient Group Direction was developed and approved by the following:

	Name	Signature	Date
Clinical Governance Lead (Medic) on behalf of DOCTORnow Ltd	Dr Brian McGirr (MRCGP) Dr Richard Angwin (FRCS)		01/02/13
Clinical Governance Advisor (Pharmacist) on behalf of DOCTORnow Ltd	Anita Hadden (BPharm, Reg. No. 2030014)		01/02/13
Clinical Governance Advisor (Nurse) on behalf DOCTORnow Ltd	Elizabeth D'Arcy-Evans (RGN)		01/02/13
Superintendent Pharmacist on behalf of the pharmacy			

This Patient Group Direction is to be read, agreed to and signed by the participating trained Pharmacist / Nurse, who must keep a copy of this signed Patient Group Direction in their In-Pharmacy Flu Vaccination Programme Support Pack. The Superintendent Pharmacist should retain a record of all participating Pharmacist / Nurses.

This Patient Group Direction will be reviewed 1st April 2014.

I (participating authorised Pharmacist / Nurse) confirm that I have read and understood this Patient Group Direction and that I have been provided with the appropriate training to work within this Patient Group Direction.

Name	GPhC Registration number/ NMC PIN number	Signature	Date

References:

1. *Public Health England. Immunisation against infectious disease: the green book. Chapter 19: Influenza, August 2012. Available online https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147958/Green-Book-Chapter-19-v4_71.pdf (accessed June 2013)*
2. *General Pharmaceutical Council (GPhC). Standards of conduct, ethics and performance, July 2012 http://www.pharmacyregulation.org/sites/default/files/Standards%20of%20conduct%20ethics%20and%20performance%20July%202012.pdf (accessed June 2013)*
3. *Novartis Vaccines and Diagnostics Limited - Agrippal®, Fluvirin® or Optaflu® Summary of Product Characteristics available on http://www.medicines.org.uk/emc/ (accessed June 2013)*

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CONSENT

Under the Patient Group Directions: Administration of Agrippal® or Fluvirin® by an authorised Pharmacist or Nurse during the 2013/14 flu season, /Administration of Optaflu®▼ by an authorised Pharmacist or Nurse during the 2013/14 flu season, you have a professional and legal duty to get a patient's consent for the professional services, treatment or care you provide, or to use the patient information.[1]

Consent can be explicit or implied, for the purpose of this vaccination programme, patients ARE required to give consent as detailed on the Flu Vaccination Record / Consent Form.

For consent to be valid the patient must: [1]

- Have the capacity to give consent
- Be acting voluntarily – they must not be under any undue pressure from you or anyone else to make a decision
- Have sufficient, balanced information to allow them to make an informed decision
- Be capable of using and weighing up the information provided

Young people and children:

While the capacity to consent depends more on the patient's ability to understand and consider their decision than their age, for the purpose of this vaccination programme, children under 16 years can only be vaccinated if the person with parental responsibility has countersigned the Flu Vaccination Record / Consent Form.

For further information on consent please refer to the General Pharmaceutical Council 'Guidance on consent'.[1]

Reference:

1. *General Pharmaceutical Council (GPhC). Guidance on consent, February 2012 http://www.pharmacyregulation.org/sites/default/files/GPHC%20Guidance%20on%20consent.pdf#overlay-context=standards/guidance (accessed June 2013)*

DOCTORnow

FREQUENTLY ASKED QUESTIONS (FAQs)

PLEASE READ BEFORE CONTACTING THE MEDICAL SUPPORT LINE

Pre-Vaccination

CONCERN	ADVICE
Air in the syringe	**The air bubble is supposed to be there and is an aid to delivery – do not expel**
Patient has reduced mental capability	If you have any concerns about a person's ability to consent to the procedure (e.g. under influence of alcohol / drugs), refer the patient to their GP
Tattoo	If the tattoo is fresh, then proceed with the vaccination using the patient's opposite arm If the tattoo is long established, proceed with vaccination · where possible insert needle in skin where there is no ink coverage
Vaccination site	If the patient insists the injection is administered anywhere other than the deltoid (e.g. upper thigh), refer the patient to their GP
	If there is no access to the necessary injection site (e.g. patient has arm in a sling), refer the patient to their GP
Age of child / young person	If patient is under 12 years, do not proceed with the vaccination and refer the patient to their GP If patient is under 16 years, consent must be obtained from the responsible person If patient is under 18 years, do not administer Optaflu®▼
Breastfeeding	Proceed with the vaccination
Foreign National	Proceed with the vaccination
Patient is not registered with GP	Proceed with the vaccination
Recent or prospective blood donor	Proceed with vaccination as long as patient feels well

Allergies

Can patients receive a flu vaccine from you if they suffer from the following allergies?

ALLERGY	ADDITIONAL INFORMATION
Constituents of the vaccines	**Do not proceed** with the vaccination and refer the patient to their GP Constituents may include: formaldehyde; cetyltrimethylammonium bromide (CTAB); polysorbate 80; diethylether; polymyxin B; Betapropiolactone; nonoxynol 9
Thiomersal	**Proceed** with the vaccination using **Agrippal® or Optaflu® only**
Eggs	**Proceed** with the vaccination using **Optaflu® only**
Neomycin	**Proceed** with the vaccination using **Optaflu® only**
Kanamycin	**Proceed** with the vaccination using **Fluvirin® or Optaflu® only**
Latex	**Do not proceed** with the vaccination and refer the patient to their GP
Penicillin	**Proceed** with the vaccination
Tetracycline	**Proceed** with the vaccination
Vaccines*	If the patient has previously reacted to any other vaccines with similar components, then **do not proceed** with the vaccination and refer the patient to their GP
Feathers	**Proceed** with the vaccination
Plasters	**Proceed** with the vaccination but do not apply a plaster post-vaccination if required, use a cotton wool ball and micropore tape instead
Antibiotics (excluding those antibiotics listed above)	**Proceed** with the vaccination

* There is no contraindication to administering a seasonal flu vaccination at the same time as any other vaccination

DOCTORnow

FREQUENTLY ASKED QUESTIONS (FAQs)

Medical Conditions

Can patients receive a flu vaccine from you if they suffer from the following medical conditions?

MEDICAL CONDITION	ADDITIONAL INFORMATION
Bleeding disorders	**Do not proceed** with the vaccination and refer the patient to their GP
Diabetes	**Proceed** with the vaccination. However, if concerned, then refer the patient to their GP
Common cold	**Do not proceed** with the vaccination and defer the consultation until the patient's symptoms have subsided
Epilepsy	**Proceed** with the vaccination
Heart condition	**Proceed** with the vaccination. However, if concerned, then refer the patient to their GP
Immunocompromised	**Proceed** with the vaccination. However, if concerned, then refer the patient to their GP
Lupus	**Proceed** with the vaccination
ME / fatigue	**Do not proceed** with the vaccination and refer the patient to their GP
Pregnant	**Do not proceed** with the vaccination and refer the patient to their GP
Recent surgery or medical procedure	**Proceed** with the vaccination. However, if concerned, then refer the patient to their GP If patient presents with history of mastectomy, proceed with vaccination in opposite arm If patient has had bilateral mastectomy, refer to GP
Factor V Leiden deficiency	**Proceed** with vaccination unless the patient is on anticoagulant therapy, then refer patient to their GP
Diagnosed with cancer and undergoing chemotherapy	If the patient is feeling unwell due to their chemotherapy **do not proceed** If the patient is feeling well **proceed** with the vaccination. However, if concerned, then refer the patient to their GP
HIV positive	**Proceed** with the vaccination. However, if concerned, then refer the patient to their GP

Medications

Can patients receive a flu vaccine if they are on / previously received the following medications?

MEDICATION	ADDITIONAL INFORMATION
Antibiotics	**Proceed** with the vaccination. However, if you are concerned that the patient has an active infection, then defer vaccination until their course of antibiotics is finished **Caution:** if you are concerned that the patient has an active infection, then defer vaccination until their course of antibiotics is finished
Aspirin	**Proceed** with the vaccination
Clopidogrel	**Proceed** with the vaccination
Heparin	**Do not proceed** with the vaccination and refer the patient to their GP
Steroids	**Proceed** with the vaccination. However, if you are concerned that the patient is immunocompromised, then refer them to their GP
Vaccines (including travel vaccines)	**Proceed** with the vaccination but use the opposite arm to where the previous vaccination was administered
Warfarin	**Do not proceed** with the vaccination and refer the patient to their GP
Contraceptive implant	**Proceed** with the vaccination

Post-Vaccination

CONCERN	ADVICE
Bleeding	If the patient's injection site is bleeding, apply pressure using a clean swab until the bleeding subsides. This should not take longer than a couple of minutes. If bleeding continues, seek additional medical assistance
Fainting	If the patient has fainted, ensure that they are in no imminent danger and, if judged necessary, put them in the recovery position. Ensure they are monitored until revived and have returned back to their original state. If the patient's condition worsens, seek additional medical assistance, as per algorithm
Pain at the injection site	A small amount of localised pain or discomfort may be experienced. If concerned, monitor the patient. If pain doesn't get any worse, then offer advice and support e.g. cold compress and simple analgesia. If pain worsens, or an anaphylactic type reaction is suspected, then seek medical help as per algorithm
Redness	If there is redness and swelling where you have administered the flu vaccine, then this is a normal localised inflammatory response. If the redness, and / or swelling worsens, monitor and seek additional medical assistance

COMMON REACTIONS
Common reactions are redness, swelling, pain, ecchymosis, induration, fever, malaise, shivering, fatigue, headache, sweating, myalgia, arthralgia. These reactions usually disappear within 1-2 days without treatment [1]

Reference:

1. *Novartis Vaccines and Diagnostics Limited - Agrippal®, Fluvirin® or Optaflu®▼ Summary of Product Characteristics available on http://www.medicines.org.uk/emc/ (accessed June 2013)*

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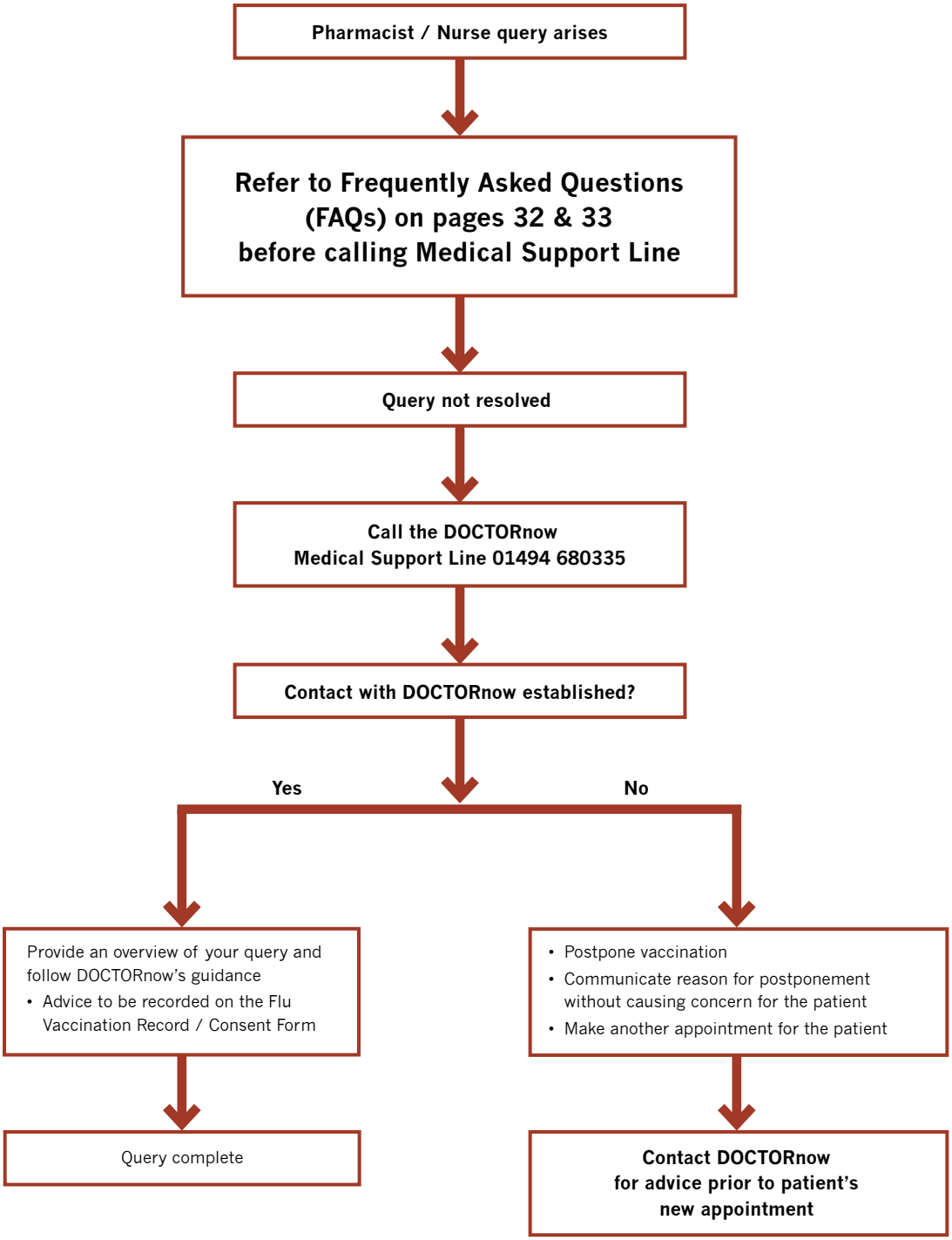
Medical Support Line available:
1st October 2013 to 31st March 2014*

MEDICAL SUPPORT LINE (PHARMACIST / NURSE USE ONLY)



*Any post-vaccination queries after 31st March 2014 - please refer to GP

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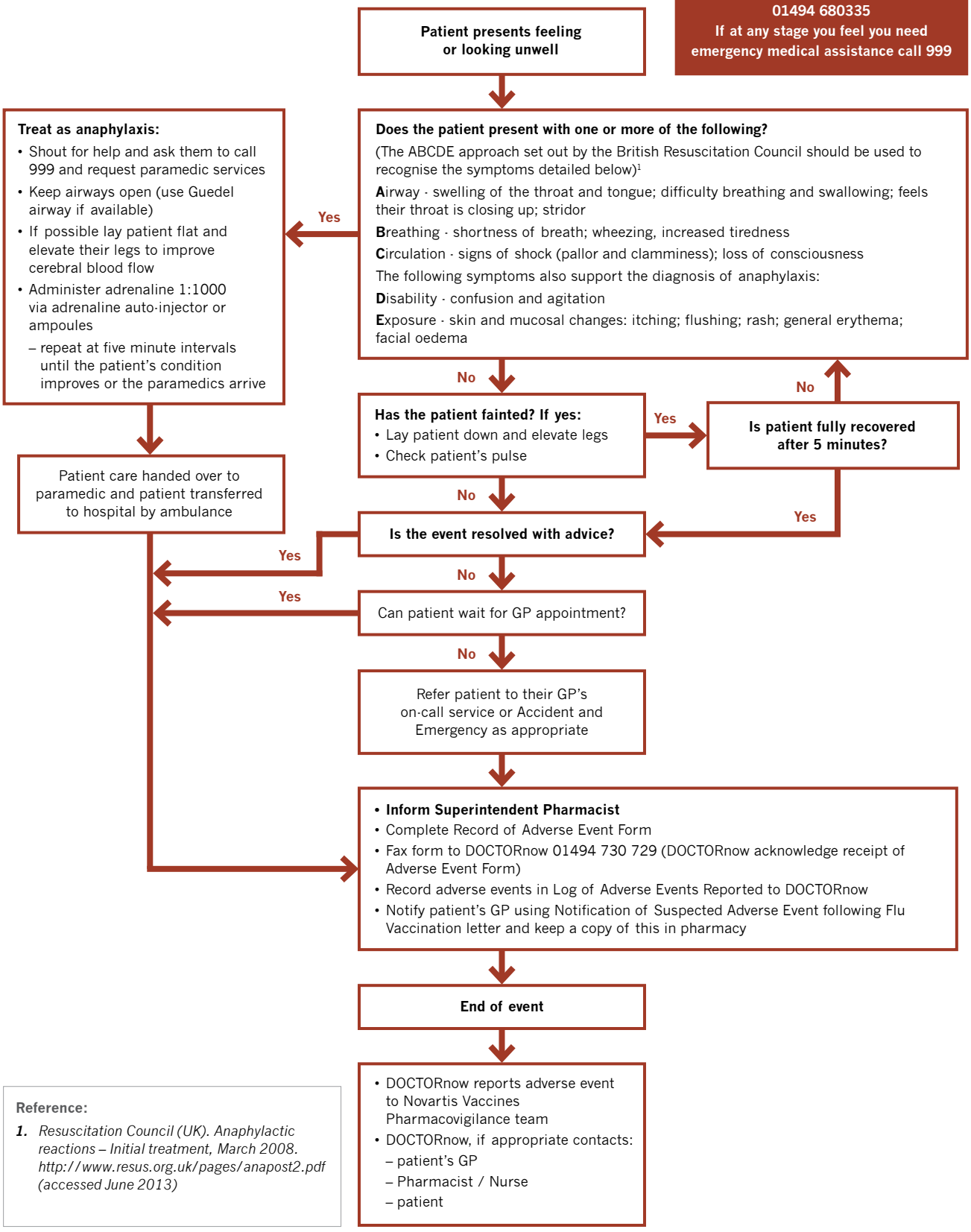
MANAGEMENT OF ADVERSE EVENTS ALGORITHM

TO BE USED IN CONJUNCTION WITH ONLINE / PRACTICAL TRAINING

If at any stage you feel that you need medical advice call the DOCTORnow Medical Support Line on 01494 680335
If at any stage you feel you need emergency medical assistance call 999



Reference:

1. *Resuscitation Council (UK). Anaphylactic reactions – Initial treatment, March 2008. http://www.resus.org.uk/pages/anapost2.pdf (accessed June 2013)*

DOCTORnow

ADRENALINE ADMINISTRATION: EPIPEN® AUTO-INJECTOR 0.3mg

TO BE USED IN CONJUNCTION WITH ONLINE / PRACTICAL TRAINING

Adrenaline is the most important drug for the treatment of an anaphylactic reaction.[1]

Before the healthcare professional administers adrenaline the patient must be assessed and identification of an anaphylactic reaction made (see Management of Adverse Events Algorithm on page 35).

Name of medicine	EpiPen® auto-injector 0.3mg
Dose	The EpiPen® auto-injector delivers a single dose 0.3ml injection equal to 0.3mg adrenaline in adults.
Frequency	The administration of adrenaline may be repeated at five minute intervals until the patient's condition improves or the paramedics arrive.
Route	The EpiPen® auto-injector 0.3mg is administered via an intramuscular injection (IM) into the front / side aspect of the thigh.

Instructions for use

1. Grasp the EpiPen® auto-injector in dominant hand, with thumb closest to grey safety cap
2. With the other hand pull off grey safety cap
3. Hold the EpiPen® at a distance of approximately 10cm away from the outer thigh. The black tip should point towards the outer thigh (no need to remove outer clothing)
4. Jab firmly into the outer thigh so that the EpiPen® auto-injector is at a right angle (at a 90 degree angle) to the outer thigh
5. Hold in place for 10 seconds. The EpiPen® auto-injector should then be lifted off the area and safely discarded in a sharps bin
6. Massage the injected area for 10 seconds

NB: 1.7ml of the EpiPen® contents remains in the device after injection

Reference:

1. *Resuscitation Council (UK). Emergency treatment of anaphylactic reactions: Guidelines for healthcare providers, January 2008. http://www.resus.org.uk/pages/reaction.pdf (accessed June 2013)*

ADRENALINE ADMINISTRATION: JEXT® AUTO-INJECTOR 300mcg

TO BE USED IN CONJUNCTION WITH ONLINE / PRACTICAL TRAINING

Adrenaline is the most important drug for the treatment of an anaphylactic reaction.[1]

Before the healthcare professional administers adrenaline the patient must be assessed and identification of an anaphylactic reaction made (see Management of Adverse Events Algorithm on page 35).

Name of medicine	Jext® auto-injector 300mcg
Dose	The Jext® auto-injector delivers a single dose 0.3ml injection equal to 300mcg adrenaline in adults.
Frequency	The administration of adrenaline may be repeated at five minute intervals until the patient's condition improves or the paramedics arrive.
Route	The Jext® auto-injector 300mcg is administered via an intramuscular injection (IM) into the front / side aspect of the thigh.

Instructions for use

1. Grasp the Jext® auto-injector in dominant hand, with thumb closest to the yellow cap
2. With the other hand pull off the yellow cap
3. Place the black injector tip against the outer thigh, holding the injector at a right angle (approx 90°) to the thigh (no need to remove outer clothing)
4. Push the black tip firmly into the outer thigh until you hear a 'click' confirming the injection has started, then keep it pushed in
5. Hold in place for 10 seconds (a slow count to 10). The Jext® auto-injector should then be lifted off the thigh and safely discarded in a sharps bin. The black tip will extend automatically and hide the needle
6. Massage the injected area for 10 seconds

NB: 1.1ml of the Jext® contents remains in the device after injection

Reference:

1. *Resuscitation Council (UK). Emergency treatment of anaphylactic reactions: Guidelines for healthcare providers, January 2008. http://www.resus.org.uk/pages/reaction.pdf (accessed June 2013)*

ADRENALINE ADMINISTRATION: ADRENALINE 1:1000 (1mg/ml) 1ml AMPOULE

TO BE USED IN CONJUNCTION WITH ONLINE / PRACTICAL TRAINING

Adrenaline is the most important drug for the treatment of an anaphylactic reaction.[1]

Before the healthcare professional administers adrenaline the patient must be assessed and identification of an anaphylactic reaction made (see Management of Adverse Events Algorithm on page 35).

Name of medicine	Adrenaline 1:1000 (1mg/ml) 1ml ampoule
Dose	Adults 0.5ml (500mcg)
Frequency	The administration of adrenaline may be repeated at five minute intervals until the patient's condition improves or the paramedics arrive.
Route	Intramuscular injection (IM) into the front / side aspect of the thigh.
Equipment	1 box (10 ampoules) of adrenaline 1:1000 4 x Blue 23G (1 inch) needles 4 x 2ml graduated syringes

Instructions for use

1. Attach needle to syringe
2. Tap the neck of the ampoule gently until all the liquid is out of the bulb
3. Snap top from adrenaline ampoule, remove sheath from needle
4. Withdraw 0.5ml of ampoule contents into syringe, tilting the ampoule if necessary
5. Replace sheath on the needle* and tap the syringe to dislodge any air bubbles, expel air
6. Change the needle (discard used needle into sharps bin)
7. Remove sheath from new needle, stretch the skin and give by intramuscular injection as taught
8. The needle should be removed from the skin. Both needle and syringe to be immediately discarded in a sharps bin
9. Massage the injected area for 10 seconds

***Note:** replacing the sheath should **not** be confused with resheathing **used** needles*

Reference:

1. *Resuscitation Council (UK). Emergency treatment of anaphylactic reactions: Guidelines for healthcare providers, January 2008. http://www.resus.org.uk/pages/reaction.pdf (accessed June 2013)*

DOCTORnow

Notification of Suspected Adverse Event following Flu Vaccination

Pharmacy Stamp
ATTACH COPY OF FLU VACCINATION RECORD / CONSENT FORM

In-Pharmacy Flu Vaccination Programme

Date:

Dear Doctor,

Patient's Name	Patient's Address	Date of Birth

Your patient, named above, attended our In-Pharmacy Flu Vaccination Service today and on request received a flu vaccine. I would like to inform you that your patient experienced the following adverse event:

Adverse event	Action taken

I have reported the above adverse event to DOCTORnow, who are responsible for managing the reporting of all adverse events relating to the In-Pharmacy Flu Vaccination Programme. If further information is required or needs to be shared, DOCTORnow will contact you directly.

Yours sincerely,

Name:

Title:

GPhC / NMC registration number:

In-Pharmacy Flu Vaccination Programme is provided by General Pharmaceutical Council registered pharmacists/registered Nurses (RN) with current level 1 or 2 NMC registration who have been trained and authorised to supply and administer flu vaccines under the terms of the private Patient Group Directions that have been authorised by DOCTORnow a Care Quality Commission registered Independent Medical Organisation. Registered office: 95 High Street, Great Missenden, Buckinghamshire, HP16 0AL. 01494 410888. Company Registration Number: 05160921. Care Quality Commission Provider ID: 1-101727289

RECORD OF ADVERSE EVENT FORM

(please fax to DOCTORnow – 01494 730729)

Fax date:	
Fax time:	

Pharmacy Details

Pharmacy stamp	Reporting Pharmacist's / Nurse's name
	Telephone

Patient Details

Patient's initials (only)		Patient's date of birth	

Details of Event

Date of event		Time of event	

Novartis vaccine administered (tick / complete as appropriate)	❑ Fluvirin®	❑ Agrippal®	❑ Optaflu®▼
	Dose:	Route:	Batch number:
Description of event			
Details of care / advice provided			
Summary of outcome (please tick as appropriate)	❑ Resolved with advice	❑ Patient referred to GP	❑ Patient care passed to emergency services

Communication Summary

Was the DOCTORnow medic contacted?	❑ Yes ❑ No	If yes, please summarise advice given below and include the name of the medic who gave advice

Was the patient's GP contacted?	❑ Yes ❑ No
Name and address of GP (if known)	

Reporting Pharmacist's / Nurse's signature		Date	

Please attach a copy of this completed form to the Log of Adverse Events, noting the date and time this form was faxed to DOCTORnow

DOCTORnow

LOG OF ADVERSE EVENTS REPORTED TO DOCTORnow

TO BE RETAINED BY PHARMACY / STORE FOR AUDIT PURPOSES

Patient Confidentiality Alert:
This log must be retained in pharmacy and must not be faxed to DOCTORnow

Date of event	Time of event	Patient's full name, address and contact number	Date of birth	Fax date	Fax time

DOCTORnow

MANAGEMENT OF NEEDLE-STICK INJURY (WITH A NEEDLE THAT HAS BEEN USED)

Hypodermic needle-stick injury

There is a very low risk of transferring infection from patient to Pharmacist / Nurse through needle-stick injury, however please follow the instructions below if any injury occurs:

1. Inform patient of the injury immediately
2. Wash wound with plenty of soap and water
3. Press skin around wound while running under water to encourage bleeding
4. Telephone the Medical Support Line (01494 680335) and inform the medic of your injury

- **If possible DOCTORnow will speak to the patient to I. identify if the patient falls into a high risk group for blood born viral infections. II. establish whether or not the patient would be prepared to undertake a blood test to check for Hep B, Hep C or HIV**
- **DOCTORnow will instruct you to attend Accident and Emergency for antiviral advice and possible treatment as well as to take baseline blood samples**
- **DOCTORnow will arrange a follow-up call for further advice / guidance**

5. Inform Superintendent Pharmacist of injury

- Apologise to patients in pharmacy and advise them the flu clinic is suspended
- Rearrange future appointments for patients awaiting their vaccination

- Inform the Superintendent Pharmacist
- Complete Record of Adverse Event Form
- Fax form to DOCTORnow 01494 730729
- Record adverse events in Log of Adverse Events reported to DOCTORnow and attach Record of Adverse Event Form
- Complete the accident book in store / pharmacy

NB: Accidental injury with an unused needle falls outside this guidance. Should this eventuality arise:
i) dispose of the undischarged vaccine as per the sharps protocol
ii) clean and cover the wound appropriately
iii) follow usual in-house accident procedure

DOCTORnow

STANDARD OPERATING PROCEDURES: THE VACCINATION PROCESS **IN PHARMACY**

Delivery, Storage and Transportation

- Novartis Vaccines is responsible for cold chain storage until delivery to the pharmacy of the flu vaccine
- The recipient Pharmacist / Nurse must check the packaging for any tampering or damage and confirm the flu vaccines have been appropriately stored and the cold chain has been maintained
- Report any discrepancies immediately to Novartis Vaccines
- The recipient Pharmacist / Nurse will store the flu vaccines at +2 °C to +8 °C (in a refrigerator). Do not freeze. Fridge temperature should be checked daily and recorded – maximum, minimum and actual
- Protect from light by keeping the flu vaccine in the outer carton
- The flu vaccine should not be used after the expiry date shown on the label

Administration

- Prior to vaccine administration check the vaccine has been stored correctly and the colour and composition of the vaccine. Agrippal® and Fluvirin® should appear as a clear liquid, Optaflu®▼ is opalescent in appearance. Any thickening or cloudiness indicates the vaccine has not been stored correctly and should be discarded
- The patient (or if aged 12 - 15 years, the person with parental responsibility) attending for flu vaccination either at an arranged session or opportunistically will be given a Flu Vaccination Suitability Checklist to review. They will then be seen by the Pharmacist / Nurse in the privacy of the consultation room (if aged 12 - 15 years, the person with parental responsibility must be present)
- The Pharmacist / Nurse will discuss the Flu Vaccination Suitability Checklist with the patient (or if aged 12 - 15 years, the person with parental responsibility). If the Pharmacist / Nurse identifies a reason for refusing the vaccination (please see criteria for exclusion in the PGDs), he / she will advise the individual, or person with parental responsibility, to contact their GP
- If there are no contraindications / exclusions the Pharmacist / Nurse must obtain consent from the patient before administering the vaccine
- There is no legal obligation that consent should be in writing and a signature on a consent form is not proof that consent has been given for a procedure but serves to record the decision and discussion that have taken place. Consent is a process that starts with an explanation of the procedure (in this case administration of a vaccine) including the possible risks / benefits. The patient can give consent orally or by cooperation
- For the purpose of this vaccination programme patients ARE required to give consent as detailed on the Flu Vaccination Record / Consent Form. This represents good clinical practice
- Any patient aged 12 - 15 years will need to be accompanied by a person with parental responsibility who can countersign the Flu Vaccination Record / Consent Form
- When the Pharmacist / Nurse is sure consent has been given from the patient (or if aged 12 - 15 years, the person with parental responsibility) the procedure can take place. The patient should be seated on a chair and asked to expose their upper arm (deltoid area)
- Where possible, when requesting flu vaccination, the patient should be advised to wear short sleeved loose fitting clothing, so that the area where the vaccine is given is easily accessed and viewed. Rolling up sleeves to expose the deltoid often results in a tight band across the arm which acts like a tourniquet causing persistent bleeding post-vaccination
- Prepare tray with cotton wool ball
- Wash hands thoroughly and put on gloves (if required)
- Inspect gloves for signs of damage and cleanliness, change if necessary. Inspect gloves for traces of blood inside the gloves from previously undetected open wounds on the hands. If these are detected the clinic should be cancelled or should be conducted by another qualified person
- The patient should be asked to let their arm hang loosely at their side or rest in their lap
- In most cases there is no need to clean the skin prior to immunisation. If the skin is dirty, soap and water can be used to clean it and the vaccine given when the skin is dry

NOVARTIS VACCINES AND DIAGNOSTICS

STANDARD OPERATING PROCEDURES: THE VACCINATION PROCESS **IN PHARMACY** (CONTINUED)

- Remove vaccine from outer sleeve
- If administering Agrippal® or Fluvirin®, remove the pre-filled syringe from outer packaging. If administering Optaflu®▼, remove the pre-filled syringe and insert the needle if appropriate
- Record the batch number and expiry date of the vaccine vial on the Flu Vaccination Record / Consent Form
- Remove protective sheath. Stretch skin and give by intramuscular (IM) injection as taught
- The needle should be withdrawn from the skin and a piece of cotton wool applied to the site and the patient instructed to press on the cotton wool. The syringe and needle should immediately be discarded in a suitable sharps bin. NEVER RE-SHEATH a used needle.
- Follow the clinical governance documentation and adverse event procedures for dealing with any needle-stick injuries
- Dispose of all cotton wool and clinical waste in the yellow clinical waste bag. Any accidental blood contamination must be cleaned immediately
- There is no evidence to support keeping individuals under observation for long periods although it is advised to monitor the patient for 10 minutes
- They should be observed for any immediate adverse reaction, such as anaphylaxis and this can be done while the Pharmacist / Nurse completes documentation and gives advice on the management of potential after effects
- The patient should be given 2 copies of the Flu Vaccination Record / Consent Form with details of their vaccine:

  - 1 copy for themselves (or if aged 12 - 15 years, the person with parental responsibility)
  - 1 copy to give to their GP (if applicable)

  The remaining 2 copies of the Flu Vaccination Record / Consent Form should be kept / issued as follows:

  - 1 copy for pharmacy
  - 1 copy for NHS (e.g. PCO) if required
- In the event of an episode requiring the administration of adrenaline, the rest of the clinic may need to be postponed because:

  1. The adrenaline stock may be insufficient
  2. Distress could have been caused to all involved in the flu clinic

NOVARTIS VACCINES AND DIAGNOSTICS

STANDARD OPERATING PROCEDURES: THE VACCINATION PROCESS **OUT OF PHARMACY**

Personnel

1. Named trained Pharmacist / Nurse
2. Assistant: The Pharmacist / Nurse must be accompanied by an assistant who does not require formal training. Their primary role is to assist in the event of an emergency. They would also be useful in general administrative tasks such as review of the Flu Vaccination Suitability Checklist and over seeing the waiting area, as well as being available as a chaperone if required

Delivery, Storage and Transportation

- Novartis Vaccines is responsible for cold chain storage until delivery to the pharmacy of the flu vaccine
- The recipient Pharmacist / Nurse must check the packaging for any tampering or damage and confirm the flu vaccines have been appropriately stored and the cold chain has been maintained
- Report any discrepancies immediately to Novartis Vaccines
- The recipient Pharmacist / Nurse will store the flu vaccines at +2°C to +8 °C (in a refrigerator). Do not freeze. Fridge temperature should be checked daily and recorded – maximum, minimum and actual
- Protect from light by keeping the flu vaccine in the outer carton
- The flu vaccine should not be used after the expiry date shown on the label
- Vaccines should be transported to the administration location in a cool box with the appropriate insulation to keep the temperature between +2 °C to +8 °C
- The vaccines should be kept in their packaging and insulated from the cooling system (e.g. bubble wrap) to avoid the risk of freezing
- Vaccines to be stored on site in cool box until required
- Any unused vaccines should be returned to pharmacy fridge within 8 hours
- It is the Pharmacist's / Nurse's responsibility to keep the vaccines stored between +2 °C to +8 °C at all times

Administration

- Prior to vaccine administration check the vaccine has been stored correctly and the colour and composition of the vaccine. Agrippal® and Fluvirin® should appear as a clear liquid, Optaflu®▼ is opalescent in appearance. Any thickening or cloudiness indicates the vaccine has not been stored correctly and should be discarded
- The patient (or if aged 12 - 15 years, the person with parental responsibility) attending for flu vaccination either at an arranged session or opportunistically will be given a Flu Vaccination Suitability Checklist to review. They will then be seen by the Pharmacist / Nurse in the privacy of the consultation room (if aged 12 - 15 years, the person with parental responsibility must be present)
- The Pharmacist / Nurse will discuss the Flu Vaccination Suitability Checklist with the patient (or if aged 12 - 15 years, the person with parental responsibility). If the Pharmacist / Nurse identifies a reason for refusing the vaccination (please see criteria for exclusion in the PGDs), he / she will advise the individual, or person with parental responsibility, to contact their GP
- If there are no contraindications / exclusions the Pharmacist / Nurse must obtain consent from the patient before administering the vaccine
- There is no legal obligation that consent should be in writing and a signature on a consent form is not proof that consent has been given for a procedure but serves to record the decision and discussion that have taken place. Consent is a process that starts with an explanation of the procedure (in this case administration of a vaccine) including the possible risks / benefits. The patient can give consent orally or by cooperation
- For the purpose of this vaccination programme patients ARE required to give consent as detailed on the Flu Vaccination Record / Consent Form. This represents good clinical practice
- Any patient aged 12 - 15 years will need to be accompanied by a person with parental responsibility who can countersign the Flu Vaccination Record / Consent Form
- When the Pharmacist / Nurse is sure consent has been given from the patient (or if aged 12 - 15 years, the person with parental responsibility) the procedure can take place. The patient should be seated on a chair and asked to expose their

NOVARTIS VACCINES AND DIAGNOSTICS

STANDARD OPERATING PROCEDURES: THE VACCINATION PROCESS **OUT OF PHARMACY** (CONTINUED)

upper arm (deltoid area)

- Where possible, when requesting flu vaccination, the patient should be advised to wear short sleeved loose fitting clothing, so that the area where the vaccine is given is easily accessed and viewed. Rolling up sleeves to expose the deltoid often results in a tight band across the arm which acts like a tourniquet causing persistent bleeding post-vaccination
- Prepare tray with cotton wool ball
- Wash hands thoroughly and put on gloves (if required).
- Inspect gloves for signs of damage and cleanliness, change if necessary. Inspect gloves for traces of blood inside the gloves from previously undetected open wounds on the hands. If these are detected the clinic should be cancelled or should be conducted by another qualified person
- The patient should be asked to let their arm hang loosely at their side or rest in their lap
- In most cases there is no need to clean the skin prior to vaccination. If the skin is dirty, soap and water can be used to clean it and the vaccine given when the skin is dry
- Remove vaccine from outer sleeve
- If administering Agrippal® or Fluvirin®, remove the pre-filled syringe from outer packaging. If administering Optaflu®▼, remove the pre-filled syringe and insert the needle if appropriate
- Record the batch number and expiry date of the vaccine vial on the Flu Vaccination Record / Consent Form
- Remove protective sheath. Stretch skin and give by intramuscular (IM) injection as taught
- The needle should be withdrawn from the skin and a piece of cotton wool applied to the site and the patient instructed to press on the cotton wool. The syringe and used needle should immediately be discarded in a suitable sharps bin. NEVER RE-SHEATH a needle
- Follow the clinical governance documentation and adverse event procedures for dealing with any needle-stick injuries
- Dispose of all cotton wool and clinical waste in the sharps bin. Any accidental blood contamination must be cleaned immediately. The sharps bin must be sealed properly at the end of the clinic
- There is no evidence to support keeping individuals under observation for long periods although it is advised to monitor the patient for 10 minutes
- They should be observed for any immediate adverse reaction, such as anaphylaxis and this can be done while the Pharmacist / Nurse completes documentation and gives advice on the management of potential after effects
- The patient should be given 2 copies of the Flu Vaccination Record / Consent Form with details of their vaccine:

  - 1 copy for themselves (or if aged 12 - 15 years, the person with parental responsibility)
  - 1 copy to give to their GP (if applicable)

  The remaining 2 copies of the Flu Vaccination Record / Consent Form should be kept / issued as follows:

  - 1 copy for pharmacy
  - 1 copy for NHS (e.g. PCO) if required
- In the event of an episode requiring the administration of adrenaline, the rest of the clinic may need to be postponed because:

  1. The adrenaline stock may be insufficient
  2. Distress could have been caused to all involved in the flu clinic

NOVARTIS VACCINES AND DIAGNOSTICS

STANDARD OPERATING PROCEDURES: IMMUNITY TO HEPATITIS B

Introduction

Vaccination is not considered an exposure prone procedure (defined as a procedure in which there is a risk of injury to a worker which may expose the patient's open tissues to the blood of the worker). As such the recipient of a vaccination is not considered 'at-risk' of contracting Hepatitis B from the vaccinator. It is, however, possible for the vaccinator to be infected by the person receiving the vaccination. For this reason it is ***recommended*** that all persons delivering the vaccine be immune to Hepatitis B.

Method

It is ***recommended*** that all Pharmacists / Nurses who plan to administer the flu vaccine as part of the In-Pharmacy Flu Vaccination Programme 2013/14 demonstrate that they have had Hepatitis B vaccination within 5 years and that following the vaccination course they had a good antibody response or a poor antibody response followed by a booster vaccination. The following are acceptable evidence of immunity:

- Documented laboratory result
- GP letter
- Current occupational health clearance form or fitness to practice certificate

Responsible persons

- The vaccinator must certify that they have fulfilled the criteria outlined
- Documentation must be checked by the Superintendent Pharmacist or their designate (person responsible for managing the programme) who will store the record for 10 years

Hepatitis B immunisation

- Standard immunisation; immunisation entails a course of 3 injections at 0, 1 and 6 months with subsequent testing of antibody response at 3 months and a booster at 5 years
- Accelerated immunisation; vaccine doses are administered at 0, 1 and 2 months with a fourth dose at 12 months. Antibody levels should be measured 2-3 months after the third dose. A five year booster is required
- Very Rapid immunisation; a schedule of three doses given at 0, 7 and 21 days. A fourth dose is recommended at 12 months. This schedule is licensed for use in adults over 18 years of age at immediate risk. Five year booster is required

Hepatitis B - containing vaccines are inactivated, do not contain live organisms and cannot cause the disease against which they protect.

Response to Hepatitis B vaccine

Antibody responses to Hepatitis B vaccine vary widely between individuals. It is preferable to achieve anti-HBs levels above 100mIU/ml, although levels of 10mIU/ml or more are generally accepted as enough to protect against infection.

***Poor-responders*:** around 10-15% of adults fail to respond to three doses of vaccine or respond poorly. Poor-responders to vaccine (anti-HBs between 10 and 100mIU/ml) will be offered one additional dose of vaccine at that time.
In immunocompetent individuals, further assessment of antibody level is not indicated. A reinforcing booster dose should be given at five years, as for good responders.

***Non-responders*:** An antibody level below 10mIU/ml is classified as a non-response to vaccine, and testing for markers of current or past infection is required. In non–responders, a repeat course of vaccine is recommended, followed by re-testing of antibodies 3 months after the second course.

Notes

Vaccination could be undertaken by local GPs, DOCTORnow, local pharmacies or MASTA if suitable arrangements could be made.

NOVARTIS VACCINES AND DIAGNOSTICS

HEPATITIS B DISCLAIMER

DOCTORnow Hepatitis B Guidelines

We ***recommend*** that vaccinators should ensure they have the right level of immunity. However, any vaccinator classified as a non-responder (defined on page 47), or who chooses not to have a Hepatitis B vaccination course may still participate in the programme.

Non-responders or vaccinators who choose not to have a Hepatitis B vaccination course retain the theoretical risk of contracting Hepatitis B, and will carry out the programme at individual risk.

By signing the 'Patient Group Directions (PGDs)' (page 25 and 30 of the In-Pharmacy Flu Vaccination Programme Support Pack) participants declare that they understand this policy and that DOCTORnow will not be responsible for any Hepatitis B exposure. The vaccinator should pay particular attention to the documentation about needle-stick injury; the risk is small especially if the instructions to prevent needle-stick injuries are followed.

NOVARTIS
VACCINES AND
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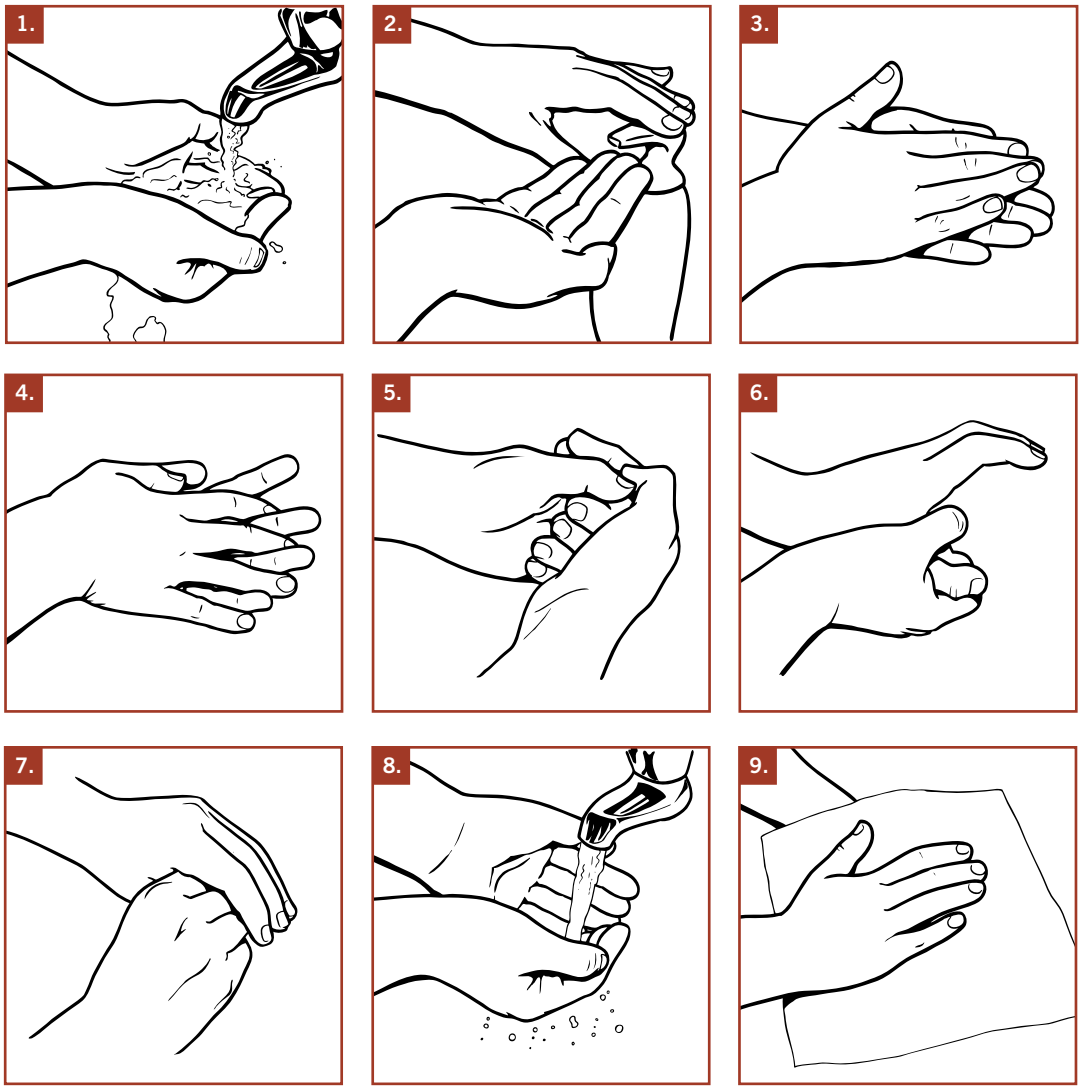
PROCEDURE FOR HAND WASHING



1. Wet hands under running water
2. Apply soap to palm
3. Rub hands together to create a lather
4. Interlace fingers while rubbing palms together then rub soap over back of each hand
5. Work knuckles of each hand into palms
6. Rub thumb (including knuckle) of each hand into palms
7. Work fingertips and thumb tip of each hand into palms. Massage soap into all nail spaces
8. Rinse well under running water
9. Pat dry hands with paper towel. Turn taps off with the paper towel

NOVARTIS
VACCINES AND
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EXTRACTS FROM 'IMMUNISATION AGAINST INFECTIOUS DISEASE - THE GREEN BOOK' (AUGUST 2012)

Under direction from the Department of Health (DH), General Practitioners (GPs) are required to compile a disease register of those at most risk of serious illness or death should they develop flu. The National Health Service (NHS) flu programme provides flu immunisation for these groups who include:

- Adults ≥ 65 years old
- Pregnant women
- Individuals with the following diseases:
  - Chronic respiratory disease including asthma
  - Chronic heart disease
  - Chronic renal disease
  - Chronic liver disease
  - Chronic neurological disease
  - Diabetes
  - Immunosuppression either due to disease or treatment, including asplenia or splenic dysfunction, those on systemic steroids or with HIV infection at any stage.
- People living in long stay residential care homes or other long stay care facilities
- Carers

There are many individuals in the community who would wish to be immunised against flu but are ineligible under the NHS scheme to receive it free. GPs approached by ineligible patients for vaccination, usually advise that they attend private clinics or pharmacies.

Section 58 of the Medicines Act 1968 states:

"No person shall administer (other than to himself) any prescription only medicine unless in accordance with the underlying directions of an appropriate practitioner"

An amendment to the Medicines Act on 9th August 2000 Statutory instrument No 117 – The Prescription Only Medicines Amendment Order introduced Patient Group Directions

The Patient Group Directions (PGDs) are specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up by Doctors, Pharmacists, Nurses and other appropriate professionals and must be approved by the Employer.

It applies to groups of patients who may not be individually identified before presentation for treatment.

The PGDs are the directive to be used by the suitably trained Pharmacist / Nurse in offering flu immunisation.

References:

Public Health England. Immunisation against infectious disease: the green book. Chapter 19: Influenza, August 2012. Available online https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147958/Green-Book-Chapter-19-v4_71.pdf (accessed June 2013)

NOVARTIS VACCINES AND DIAGNOSTICS

FURTHER READING AND RESOURCES

Please note Novartis Vaccines and Diagnostics Limited have no control over these websites and therefore accept no responsibility for their content.

- Public Health England, Immunisation against infectious disease: green book - https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book
- The Resuscitation Council - http://www.resus.org.uk
- National Institute for Health and Care Excellence (NICE) - http://www.nice.org.uk
- NICE - Medicines and prescribing support - http://www.nice.org.uk/mpc/
- Medicines and Healthcare products Regulatory Agency (MHRA) - http://www.mhra.gov.uk
- General Pharmaceutical Council - http://www.pharmacyregulation.org/
- The Royal Pharmaceutical Society - http://www.rpharms.com/home/home.asp
- Pharmaceutical Services Negotiating Committee - http://www.psnc.org.uk
- Anaphylaxis Campaign - http://www.anaphylaxis.org.uk
- Flu vaccinations: top tips to boost your service this season – Chemist & Druggist 2010 - http://www.chemistanddruggist.co.uk/feature-content/-/article_display_list/4394854/4394850
- Vaccine Administration in Pharmacies – A Scottish Success Story Pharmaceutical Journal (Volume 277) 29 July 2006
- Pharmacy Flu Jabs Popular with Patients – Pharmacy Magazine, October 2009
- Royal College of Nursing – Sharps Safety, November 2011 http://www.rcn.org.uk/__data/assets/pdf_file/0008/418490/004135.pdf
- Royal College of Nursing – Health care service standards in caring for neonates, children and young people, April 2011 - http://www.rcn.org.uk/__data/assets/pdf_file/0010/378091/003823.pdf
- Royal College of Nursing – Essential practice for infection prevention and control, January 2012 - http://www.rcn.org.uk/__data/assets/pdf_file/0008/427832/004166.pdf
- General Pharmaceutical Council – Guidance on consent, February 2012 - http://www.pharmacyregulation.org/sites/default/files/GPHC%20Guidance%20on%20consent.pdf
- NSPCC - http://www.nspcc.org.uk
- Centre for Pharmacy Postgraduate Education (CPPE) - http://www.cppe.ac.uk
- BUPA on flu jabs, 19 March 2012 - http://www.webwire.com/ViewPressRel.asp?aId=154204

Other sources of advice

Further information or advice on the professional or legal obligations of the pharmacy profession can be obtained by contacting the General Pharmaceutical Council 020 3365 3400 or e-mail info@pharmacyregulation.org

NOVARTIS VACCINES AND DIAGNOSTICS

PRODUCT PRESCRIBING INFORMATION

FLUVIRIN® ABBREVIATED PRESCRIBING INFORMATION

Fluvirin® suspension for injection in pre-filled syringe Influenza Vaccine (Surface Antigen, Inactivated) Ph.Eur. **Presentation:** Each 0.5ml of Fluvirin® contains 15 micrograms of each of three influenza virus antigens prepared from the strains of influenza virus that comply with the WHO recommendations (northern hemisphere) and EU decision for the current season. **Indications:** Prophylaxis of influenza, especially in those who run an increased risk of associated complications. **Dosage and Administration:** Intramuscular or deep subcutaneous injection. Adults and children from 4 years: single dose 0.5ml. For children who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks. **Contra-indications:** Hypersensitivity to the active substances, to any of the excipients and to eggs or chicken proteins. The vaccine may contain residues of the following substances: betapropiolactone, nonoxynol 9, neomycin, polymixin, formaldehyde or thiomersal. Immunisation shall be postponed in patients with febrile illness or acute infection. **Warnings and Precautions:** Appropriate medical treatment and supervision should be readily available in case of a rare anaphylactic event following the administration of the vaccine. Do not inject intravascularly. Endogenous or iatrogenic immunosuppression may affect the success of vaccination. Thiomersal has been used in the manufacture of this medicinal product and residues of it are present in the final product. The maximum thiomersal content in Fluvirin® is 0.002mg (0.0004% w/v). **Interactions:** If it is given at the same time as other vaccines, immunisation must be carried out on separate limbs. It should be noted that the adverse reactions may be intensified. Immunosuppressive treatment may diminish immune response. After influenza vaccination false positive result in ELISA tests for HIV1-, Hepatitis C-, HTLV1-antibodies have been observed. **Pregnancy and Lactation:** Data are limited. Use of vaccine may be considered from second trimester of pregnancy. For women with medical conditions that increase their risk of complications from influenza, administration of vaccine is recommended irrespective of the stage of pregnancy. May be used during lactation. **Effects on ability to drive and use machines:** The vaccine is unlikely to produce an effect on the ability to drive and use machines. **Side Effects:** Common reactions from clinical trials are redness, swelling, pain, ecchymosis, induration, fever, malaise, shivering, fatigue, headache, sweating, myalgia, arthralgia. These reactions usually disappear within 1-2 days without treatment. **Adverse events from postmarketing surveillance:** Generalised skin reactions including pruritus, urticaria or non-specific rash were reported. Transient lymphadenopathy, neuralgia, paraesthesia, febrile convulsions, transient thrombocytopenia have been observed. Allergic reactions, in rare cases leading to shock, and angioedema have been reported. Vasculitis with transient renal involvement and neurological disorders such as encephalomyelitis, neuritis, Guillain-Barré syndrome have been reported. **Overdose:** Overdosage is unlikely to have any untoward effect. **Legal Category:** POM. **Package Quantities:** Packs of 1 or 10 pre-filled syringes. **Marketing Authorisation Number:** UK: PL 18532/0038. **Basic NHS Cost:** £5.55 per dose, £55.50 per 10 pack. **Marketing Authorisation Holder:** Novartis Vaccines and Diagnostics Limited, Gaskill Road, Speke, Liverpool, L24 9GR, UK.

For full prescribing information and details of other side effects see Summary of Product Characteristics

Full prescribing information is available on request from:
Novartis Vaccines and Diagnostics Limited,
Customer Service Department, Site 4, Renaissance Way,
Boulevard Industry Park, Speke, L24 9JW.
Telephone: 08457 451500

Date of prescribing information: August 2012 UK/FLUV/12-0001(1)

® Registered trade mark of Novartis Vaccines and Diagnostics Limited, UK

AGRIPPAL® ABBREVIATED PRESCRIBING INFORMATION

Agrippal® suspension for injection in pre-filled syringe Influenza Vaccine (surface antigen, inactivated) **Presentation:** Each 0.5ml of Agrippal® contains 15 micrograms of each of three purified influenza virus antigens prepared from the strains of influenza virus that comply with the WHO recommendations (northern hemisphere) and EU decision for the current season. **Indications:** Prophylaxis of influenza, especially in those who run an increased risk of associated complications. **Dosage and Administration:** Intramuscular or deep subcutaneous injection. Adults and children from 36 months: Single dose 0.5ml; children from 6 months to 35 months, clinical data are limited: single doses of 0.25ml or 0.5ml have been used. For children who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks. **Contra-indications:** Hypersensitivity to the active substances, to any of the excipients, or to eggs, chicken proteins, kanamycin and neomycin sulphate, formaldehyde, cetyltrimethylammonium bromide (CTAB) or polysorbate 80. Immunisation shall be postponed in patients with febrile illness or acute infection. **Warnings and Precautions:** Appropriate medical treatment and supervision should be readily available in case of a rare anaphylactic event following the administration of the vaccine. Do not inject intravascularly. Endogenous or iatrogenic immunosuppression may affect the success of vaccination. **Interactions:** If it is given at the same time as other vaccines, immunisation must be carried out on separate limbs. It should be noted that the adverse reactions may be intensified. Immunosuppressive treatment may diminish immune response. After influenza vaccination false positive result in ELISA tests for HIV1-, Hepatitis C-, HTLV1-antibodies have been observed. The transient false positive reactions could be due to the IgM response to the vaccine. **Pregnancy and Lactation:** Data are limited. Use of vaccine may be considered from second trimester of pregnancy. Pregnant women with an increased risk of complications from influenza should receive influenza vaccination irrespective of the stage of pregnancy. May be used during lactation. **Effects on ability to drive and use machines:** The vaccine is unlikely to produce an effect on the ability to drive and use machines. **Side Effects:** The most common reactions are redness, swelling, pain, ecchymosis, induration, fever, malaise, shivering, fatigue, headache, sweating, myalgia, arthralgia. Uncommon reactions include pruritus, urticaria or non-specific rash. The following events are observed rarely: neuralgia, paraesthesia, convulsions, and transient thrombocytopenia. Allergic reactions, in rare cases leading to shock, have been reported. Vasculitis with transient renal involvement and neurological disorders such as encephalomyelitis, neuritis, and Guillain-Barré syndrome have been reported very rarely. **Overdose:** Overdosage is unlikely to have any untoward effect. **Legal Category:** POM. **Package Quantities:** Packs of 1 or 10 pre-filled syringes. **Marketing Authorisation Number:** UK: PL 13767/0004. **Basic NHS Cost:** £5.85 per 0.5ml pre-filled syringe, £58.50 per 10 pack. **Marketing Authorisation Holder:** Novartis Vaccines and Diagnostics S.r.l., Via Fiorentina 1, Siena, Italy.

For full prescribing information and details of other side effects see Summary of Product Characteristics

Full prescribing information is available on request from:
Novartis Vaccines and Diagnostics Limited,
Customer Service Department, Site 4, Renaissance Way,
Boulevard Industry Park, Speke, L24 9JW.
Telephone: 08457 451500

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Novartis Vaccines and Diagnostics Limited on 08457 451 500

NOVARTIS VACCINES AND DIAGNOSTICS

PRODUCT PRESCRIBING INFORMATION

OPTAFLU® ▼ ABBREVIATED PRESCRIBING INFORMATION

Optaflu® suspension for injection in pre-filled syringe influenza vaccine (surface antigen, inactivated, prepared in cell cultures). **Presentation:** Each 0.5ml of Optaflu® contains 15 micrograms of each of the three purified influenza virus antigens prepared from the strains of influenza virus antigens that comply with the WHO recommendations (northern hemisphere) and EU decision for the current season. **Indications:** Prophylaxis of influenza for adults, especially in those who run an increased risk of associated complications. **Dosage and Administration:** A single 0.5ml dose should be administered by intramuscular injection into the deltoid muscle. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. Immunisation shall be postponed in patients with febrile illness or acute infection. **Warnings and Precautions:** Appropriate medical treatment and supervision should be readily available in case of a rare anaphylactic event following the administration of the vaccine. Do not inject intravascularly. Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient. **Pregnancy and Lactation:** Safety during pregnancy and breast-feeding has not been established. General data do not indicate adverse foetal and maternal outcomes attributable to the vaccine. For pregnant women with medical conditions that increase their risk of complications from influenza, vaccine is recommended irrespective of stage of pregnancy. Optaflu® can be used during lactation. **Effects on ability to drive and use machines:** Optaflu® is unlikely to produce an effect on the ability to drive and use machines. **Adverse Events:** Data from Post-Marketing surveillance are limited. During clinical trials the following side effects were observed: Very common: Headache, erythema, pain, malaise and fatigue. Common: Sweating, myalgia, arthralgia, swelling, ecchymosis, induration, fever, shivering and gastrointestinal disorders such as abdominal pain, diarrhoea or dyspepsia. Uncommon: Generalised skin reactions including pruritis, urticaria or non-specific rash. Rare: Local lymphadenopathy and fever greater than 39°C. Very rare: Transient thrombocytopenia, neurological disorders such as encephalomyelitis, neuritis and Guillain-Barré syndrome, vasculitis, possibly associated with transient renal involvement, allergic reactions rarely leading to shock. In the elderly, frequencies were similar, except for headache and pain which were classified as 'common'. **Overdose:** Overdosage is unlikely to have any untoward effect. **Legal Category:** POM. **Package Quantities:** Pack sizes of 1, 10 or 20 (2 x 10) pre-filled syringes (type 1 glass) with or without needle. **Marketing Authorisation Number:** EU/1/07/394/001 – EU/1/07/394/009 **Basic NHS Cost:** £6.59 per 0.5ml pre-filled syringe. £65.90 per 10 pack. **Marketing Authorisation Holder:** Novartis Vaccines and Diagnostics GmbH & Co.KG, Emil-von-Behring-Strasse 76, D-35041 Marburg, Germany.**For full prescribing information and details of other side effects see Summary of Product Characteristics.**

For full prescribing information and details of other side effects see Summary of Product Characteristics

Full prescribing information is available on request from:
Novartis Vaccines and Diagnostics Limited,
Customer Service Department, Site 4, Renaissance Way,
Boulevard Industry Park, Speke, L24 9JW.
Telephone: 08457 451500

Date of prescribing information: August 2012 UK/OPT/12-0001

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Adverse events should also be reported to Novartis Vaccines and Diagnostics Limited on 08457 451 500

NOVARTIS
VACCINES AND
DIAGNOSTICS

June 2013

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UK/FLU/13-0001(2) June 2013.

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