

H1N1 PANDEMIC FLU VACCINATION:

Model Training for National Adaptation



Visit PREVENT at <http://h1n1vax.aed.org/>

This publication was prepared by AED and funded by USAID.
It does not necessarily represent the views of USAID or the US Government.

DRAFT January 2010



TABLE OF CONTENTS

Introduction to this manual.....	1
Content and activities for trainer's guide.....	5
Module 1: H1N1 pandemic flu and the H1N1 vaccine.....	7
Module 2: Handling and administering H1N1 influenza vaccine.....	15
Module 3: Handling and administering H1N1 influenza vaccine (alternative for vaccines the require adjuvant).....	23
Module 4: Interpersonal skills H1N1 vaccination acceptance.....	33
Handouts	
1. Frequently asked questions about the 2009 H1N1 influenza virus and the H1N1 vaccine.....	37
2. H1N1 Vaccination guide.....	53
3. Role-play observation checklist.....	55
4. Alternative role-play observation checklist (for use with vaccine manufactured by GSK).....	57
5. Scenario cards for practice in pairs.....	59
6. Training evaluation form.....	61

INTRODUCTION TO THIS MANUAL

Purpose of this training manual

This manual provides a model training for countries to adapt for training facility-level health workers to provide H1N1 pandemic flu vaccination to patients in priority groups. This manual should be reviewed and adapted at the national level by policymakers, program directors, and trainers prior to scheduling training for facility-level personnel.

The purposes of the training are to:

1. Educate health workers about H1N1 pandemic flu.
2. Ensure that vaccinators can properly handle H1N1 vaccine and administer it correctly and safely to all target groups.
3. Increase vaccination coverage for H1N1 vaccine by improving health workers' ability to communicate with patients from priority groups about H1N1 vaccination and pandemic flu in general.

Who should receive this training?

Health workers who give vaccinations, their supervisors, and facility managers should receive this training. Other health workers who may answer questions from patients about pandemic flu may also benefit from this training.

Objectives

By the end of this training, participants will be able to:

1. Cite key facts about pandemic flu infection and transmission, including prevention and symptoms.
2. Describe appropriate H1N1 vaccine storage and safe disposal of used needles and syringes.
3. Demonstrate correct vaccine administration techniques.
4. Communicate more effectively with patients about H1N1 influenza, H1N1 vaccination, and other ways of preventing H1N1 transmission.

Timeframe

The amount of time needed to present this training can vary from about 4 hours to 1 day, depending on the knowledge and practice needed by the health workers. For example, you may choose to allow more discussion time for participants to discuss H1N1 in your region, or you may decide that they should familiarize themselves with the new products, practice giving injections and role-play interactions with patients.

Preparation prior to training

- Review the entire manual before scheduling any training.
- Examine your country's H1N1 vaccination policies, type of vaccine that you are using and manufacturers' product information, vaccine arrival schedules, and service delivery strategies. Insert specific information into the training, where indicated. See the table on page 3 for steps to adaptation.
- Review the participant handouts and adapt them for your country, if necessary.
- Assemble all the training materials (list below).

Materials needed

- 1 set of handouts for each participant
- Vials of vaccine (and adjuvant if the vaccine requires adjuvant) or empty vaccine vials for demonstration and practice purposes
- Injection equipment (e.g., 0.5ml auto-disable syringe, 5 ml mixing syringes (if the vaccine requires adjuvant), safety boxes, cotton)
- Tally sheet
- Flip chart paper
- Markers
- Pens/pencils for participants

Checklist: Adapting this training in your country

This model training must be adapted within each country, as a variety of factors may differ according to national policy and availability of vaccine.

Action	Notes:
Collect the following information: <ul style="list-style-type: none"> • National policies related to priority groups for vaccination • Schedule for arrival of vaccine • Manufacturer’s product information for the vaccine(s) available to your facilities • National service delivery strategy for H1N1 vaccination • Country and local-level surveillance data for H1N1 influenza • Feedback from facilities and health workers about attitudes/beliefs around H1N1 vaccination and what skills vaccinators need to practice 	
Read this entire manual	
Follow “Adaptation Notes” in each section of this manual to add specific information where indicated	
Review information and skills needed by health workers, and assemble appropriate content and activities into a trainer’s guide	
Review all handouts and adapt to national policies, guidelines, and needs	
Translate trainer’s guide and handouts into local language(s), if appropriate	
Conduct a pilot training to ensure activities run as planned and health worker knowledge and skills improve	
Revise trainer’s guide and handouts, if necessary	
Conduct a training-of-trainers to introduce and disseminate the trainer’s guide	

Sample Agenda for a One-day Training

Time	Module
8:30 – 10:30	Module 1
10:30 – 10:50	Break
10:50 – 12 noon	Module 2 (or Module 3 adaptation), up to practicum activity
12 noon – 1 pm	Lunch break
1 pm – 1: 20 pm	Module 2/3: Vaccine administration practicum
1:20 – 2:30 pm	Module 4

ADAPTATION NOTE: The time periods allotted for each activity are estimates only. As you adapt the training for your country, pilot test the activities to assess the time needed for each.

Time	Module	Notes
Module 1: H1N1 pandemic flu and the H1N1 vaccine		
Welcome and introduction	20 minutes	
Key facts about the 2009 H1N1 influenza virus	15 minutes	
Activity: Group presentations of H1N1 virus facts	30 minutes	
Vaccination to prevent H1N1 influenza	40 minutes	
The important role of health workers	15 minutes	
Module 2: Handling and administering H1N1 influenza vaccine OR Module 3: Handling and administering H1N1 vaccine (alternative for vaccines that require adjuvant, such as GSK's product)		
Who should be offered the H1N1 vaccine? Discussion and Q&A	20 minutes	
How should you store and transport the vaccine? Discussion and Q&A: Vaccine handling and storage at facility	10 minutes	
How is the vaccine administered?	20 minutes	
Side effects	10 minutes	
Disposal of used syringes and needles	5 minutes	
Q&A	5 minutes	
Activity: Vaccine administration practicum	20 minutes	
Module 4: Interpersonal skills for improving H1N1 vaccination acceptance		
Communication to uncover the patient's concerns	15 minutes	
Activity: Practice in pairs	20 minutes	
Discussion and Q&A	20 minutes	
Closing session	15 minutes	

CONTENT AND ACTIVITIES FOR TRAINER'S GUIDE

The following 3 teaching modules comprise the training course.
They are:

Module 1: H1N1 pandemic influenza and the H1N1 influenza vaccine

Module 2: Handling and administering the H1N1 influenza vaccine

or

Module 3: Handling and administering the H1N1 influenza vaccine (alternative for vaccines that require adjuvant)

Module 4: Interpersonal skills for improving H1N1 vaccination acceptance.

Review all content and adapt using the Adaptation Notes.

MODULE 1: H1N1 PANDEMIC FLU AND THE H1N1 VACCINE

***Purpose:** This module provides introductory information about H1N1 pandemic flu and the vaccine. It also introduces the priority groups for vaccination, including health workers*

1. Welcome and introduction

ADAPTATION NOTES: Organize whatever opening activities are customary in your country.

- **At the beginning of the training session, introduce yourself.** Ask participants to introduce themselves and give information about their background and experience.
- **Acknowledge** varying levels of experience within the participant group and remind participants that everyone can benefit from the experiences and ideas of other group members.
- **Present the agenda, objectives, and explain** what participants will be able to do better after this training. Briefly relate the objectives to their work responsibilities.
- Ask participants to explain their expectations for the training session. They may mention important training needs that you had not anticipated, but which can easily be incorporated into the session.

2. Key facts about H1N1

ADAPTATION NOTES: You may wish to include national statistics in this section. If the following information is available to you, collect it and discuss it with the group.

- Local or national H1N1 incidence rates (if reported data are available and reliable)
- A map showing where H1N1 flu has been reported in your country.

- If no high-quality national figures are available, present information from your region.



- **Open the discussion by asking:**
 - What have you heard about H1N1 pandemic flu?
 - Have you seen patients with flu? What were the symptoms?
 - How can we prevent the spread of flu?
 - What persons do you think are more at risk of complications from flu?
 - How can health workers protect themselves from flu?
- List answers on a flip chart and discuss them with the group.
- Discuss any incorrect answers and provide correct information.
Use Handout 1, Frequently Asked Questions on the 2009 H1N1 Influenza Virus and H1N1 Influenza Vaccine to help you find correct information.

Activity: Group presentations of H1N1 facts

ADAPTATION NOTES: Review and adapt the handout before distribution. Provide participants with recommendations about where and how they can obtain up-to-date information (for example, the WHO H1N1 influenza website).

- **Divide participants into small groups.**
- Assign 1 question per group, from the list of questions on the following page.
- Ask each group to discuss and respond to their question using the handout as a guide.
- To save time, assign more questions per group.
- Allow 10 minutes for group discussion.
- Ask each group to present the key facts related to their question.



Small Group Questions:

1. How do people become infected with the H1N1 virus?
2. What are the symptoms of H1N1 flu?
3. What can I do to protect myself from catching H1N1 influenza?
4. Are some people more at risk?
5. Has the Ministry of Health identified any priority groups to receive the novel H1N1 influenza virus vaccine first? If not, which groups have been identified by the World Health Organization as priorities to receive the H1N1 influenza vaccine?

Thank the groups for their presentations. Close the discussion by sharing up-to-date influenza information about the outbreak in your country or region. Make sure to take the time to correct any misperceptions or misinformation that may arise during the small group discussions and presentations. The trainer should review the information provided in **Handout 1, Frequently Asked Questions on the 2009 H1N1 Influenza Virus and H1N1 Influenza Vaccine.**

Answer any additional questions from participants.

3. Vaccination to prevent H1N1 influenza

ADAPTATION NOTES: Check which vaccine product you are using in your country, meaning which product from which manufacturer. Read this section very carefully, and revise it for the specific type or types of vaccine products your health facilities will be receiving.

Introduce the vaccine by asking:

- What have you heard about the H1N1 vaccine?

Provide the basic information about the vaccine:

- There are several ways to prevent the transmission of H1N1 influenza. Some of the most important ways do not require any vaccine product at all. These include hand washing and sneezing into your arm or into a disposable tissue. H1N1 vaccination is important because it provides protection specifically against the H1N1 virus.
- This vaccine started being produced this year to prevent transmission of the particular virus causing the influenza pandemic that has been found in almost every country in the world.

How effective is the vaccine?

A single dose of H1N1 vaccine provides protection against H1N1 influenza, when given properly.

- This H1N1 vaccine has already been given to millions of people in countries around the world, including the United States and countries across Europe.
- Careful monitoring and scientific studies confirm that the vaccine is effective in preventing H1N1 influenza.

Is the H1N1 influenza vaccine safe?

- The H1N1 vaccine is safe. This vaccine uses the exact same manufacturing method as other influenza vaccines. Vaccines for influenza have been made for more than 20 years.
- The H1N1 vaccine is made using killed influenza virus. The virus is grown in chicken eggs, then removed and killed. This is used to create the “antigen,” which stimulates the body to have an immune response against the virus.
- Because H1N1 vaccine uses a killed virus, it is not possible for it to cause influenza, or any other diseases, itself.
- The World Health Organization (WHO) has extensively reviewed H1N1 vaccines from several manufacturers and has approved several of them¹ for use worldwide.
- Since October 2009, millions of people have been vaccinated with these vaccines in countries such as the U.S., United Kingdom, Australia, Canada, France, Germany and Switzerland.
- Careful monitoring has shown that most people who get the vaccine do not have serious side effects.
- The most common side effects that do occur are soreness or swelling at the injection site. (See Side Effects, page 20.)
- Like all other vaccines, in very rare cases, patients may get more severe reactions.

¹As of December 2009, WHO has pre-qualified H1N1 vaccines manufactured by CSL, GlaxoSmithKline, MedImmune, Novartis, and Sanofi.

Who should get the H1N1 vaccine?

ADAPTATION NOTES: Each country will need to adapt this section specifically to match its national policies on target groups for H1N1 vaccination. Also include the rationale for why only certain groups were selected for initial vaccination.

- WHO has recommended that H1N1 vaccine be given to those who are at highest risk of H1N1 influenza and its complications.

These include: health workers, pregnant women, and those people with certain chronic illnesses, such as asthma and diabetes.

The Strategic Advisory Group of Experts (SAGE) on Immunization recommended to the World Health Organization that health care workers – which include people who have close contact with potentially sick people at health care facilities, including support staff – should be the first priority for H1N1 vaccination.

- Because the global supply of the vaccine is limited, it is important to use the vaccine to protect the people most vulnerable to having complications related to H1N1 influenza.

What are some screening questions to ask people before they receive the vaccine?

Although most people will be able to receive the H1N1 influenza vaccine, there are some contraindications – or characteristics of people who should **NOT** be given the H1N1 vaccine. It is important to find out or ask people whether they have the following:

- An allergy to eggs or egg products.
- A previous adverse reaction to another influenza vaccine.
- Hypersensitivity to thimerosal, also known as thiomersal, which is a preservative used in multi-dose vaccines.
- The vaccine also should not be given to infants under 6 months of age. The vaccine would not be effective for them.

Why is there a limited supply of the vaccine?

Because the 2009 H1N1 influenza virus is a new virus, drug companies had not been making vaccine for this specific virus

subtype. Since the summer of 2009, drug companies have started making the vaccine. This production method takes time. It has taken until now to have enough vaccine to distribute around the world.

But there is still not enough vaccine to vaccinate everyone who may wish to have it. So the WHO recommends that the vaccine be given first to the people who are at highest risk of developing complications from H1N1 influenza.

4. The important role of health workers

Lead a discussion about both the participants' work responsibilities and their position as a priority group.

Begin with reviewing that health workers are also a priority group for vaccination. Ask participants why they think they are a priority for vaccination. List the reasons on a flip chart, such as:

- You will be better protected if patients ill with H1N1 influenza come to your facility
- By not getting ill from flu, you will be able to continue to work
- You will be able to care for your family, especially if your family members become ill.

Stress that the national vaccination policy is encouraging health workers to accept the vaccine but that it is not mandatory. Health workers are not required to accept it.

Explain that for the vaccinations to be effective in preventing deaths and severe illness from H1N1 influenza, the health workers have key responsibilities:

- Handle vaccine correctly
- Screen patients for eligibility in a target group
- Screen for contraindications
- Properly administer the vaccine to patients
- Correctly dispose of used needles and syringes

- Communicate with patients about the vaccine, common side effects and what actions they should take if they have a severe adverse reaction following vaccination.

Ask what other responsibilities at the facility will enable effective vaccination coverage, such as supervision, storage and other roles.

Explain that the rest of the training will review these key responsibilities and skills.

MODULE 2: HANDLING AND ADMINISTERING H1N1 INFLUENZA VACCINE

For use with the vaccine by Sanofi, CSL, and Novartis

Purpose: This module provides details about the H1N1 vaccine handling, storage and administration of vaccines manufactured by Sanofi, CSL and Novartis (vaccines without adjuvant). It also provides hands-on practice in steps for administration.

Introduce the topic of administering the H1N1 vaccine by asking:

- What have you heard about who should receive the H1N1 vaccine?
- Why should health workers get this vaccine? How will it benefit you in your work? What concerns do you have about it?

1. Who should be offered the H1N1 vaccine?

What are the priority groups to vaccinate?

ADAPTATION NOTES: Each country will need to adapt this section specifically to match its national policies on target groups for H1N1 vaccination. This may include indicating which specific adults and children with chronic conditions are to be immunized, and whether these and pregnant women should be vaccinated throughout the country or only those in certain areas. If the vaccine supply is limited, it may also be necessary to identify exactly which categories of health workers are to be immunized. Also include the rationale why only certain groups were selected.

We have already discussed the priority groups for H1N1 vaccination in broad terms. In our country, the priority groups are:

- **Health workers**, such as yourself, who provide care to ill patients
- **Pregnant women**, who are at risk of serious complications like pneumonia if they get the flu
- And other **adults and children with chronic conditions**. These patients are also more at risk of getting complications if they get the flu.

Most other people who get the flu recover on their own, without further complications.

What is the vaccination schedule?

All members of the target groups can be vaccinated as soon as possible after the vaccine is available.

Pregnant women can be vaccinated safely and effectively at any time during their pregnancy.

H1N1 vaccine may be given safely along with other vaccines during the same visit.

H1N1 vaccine should not be given to children before 6 months of age, because it will not be effective in them.

Can an extra dose of vaccine hurt a patient?

No, there is no danger if a patient receives an additional H1N1 vaccine dose by mistake.

2. How should you store and transport the vaccine?

ADAPTATION NOTES: The following instructions are for administering injectable, liquid vaccine in 10-dose vials, such as products manufactured by CSL, Novartis and Sanofi.

- If your country is using a liquid vaccine that requires adding adjuvant to it, see Module 3.
- Countries will need to provide clear instructions about use of opened, multi-dose vials of H1N1 vaccine. If the country has adopted the opened, multi-dose vial policy, then it may want to apply it to H1N1 vaccine, in accordance with the instructions on the manufacturers' package insert.
- Countries will need to provide clear guidance on what vaccinators and their supervisors should do if they suspect that a vial of H1N1 vaccine has been frozen.
- The H1N1 vaccine should be stored and transported at a temperature of **+2 to +8 degrees C**.
- Do not freeze the H1N1 vaccine. Freezing will damage the vaccine. If you suspect that vials have been frozen, do not use them. Check with your supervisor about what to do with them.
- Vials of H1N1 vaccine do not have Vaccine Vial Monitors (VVMs) on them. Therefore, it is important to take special care to maintain the vaccines at the correct temperature, and to check and record refrigerator temperatures twice a day.
- Let ice packs thaw prior to packing them in cold boxes with vaccines. This is to prevent the vaccines from freezing during transport.
- An opened vial of H1N1 vaccine should be maintained at +2 to +8 degrees C. The healthcare worker should mark the vial label with the date and time it was opened and discard it within **24 hours**. (See *Adaptation Note* on the previous page.)

3. Discussion: Vaccine handling and storage at our facility



Write the following questions on a flip chart.

1. Where would you store this vaccine in the refrigerator to assure that it does not freeze?
2. How will you handle this vaccine when going to outreach sessions?

3. How will you manage opened vials of H1N1 vaccine that contain leftover vaccine?

Ask participants to discuss the three questions with their partner. Give the pairs 10 minutes to discuss how they would handle and manage the vaccine at their facility.

Debrief: Ask several pairs to share best practices and ideas on how to handle the vaccine in their facilities.

4. How is the vaccine administered?

ADAPTATION NOTES: The following instructions are for administering injectable, liquid vaccine in 10-dose vials, such as products manufactured by CSL, Novartis and Sanofi.

- If your country is using a liquid vaccine that requires adding adjuvant to it, use **Module 3**.

- **Ask participants:** What are all the steps we generally follow when administering a vaccination?
- Allow participants to come up with a list of steps to follow when administering vaccines. Write their answers on flip chart paper.
- **Discuss** the importance of:
 - Ensuring that the vaccine is available.
 - Checking the vaccine label and expiration date.
 - Greeting the patient or caregiver.
 - Assessing the patient for eligibility and contraindications.
 - Explaining to the patient (and caregiver) about the vaccine and possible side effects.
 - Using sterile injection equipment.
 - Drawing the correct dose.
 - Giving the injection.

- Discarding equipment safely and correctly in the sharps container.

Distribute Handout 2: Vaccination guide.

Review the guide using the content below.

Preparing and giving the H1N1 vaccine

ADAPTATION NOTES: Use your country strategy to provide guidance on:

- The exact injection equipment to use
- Target groups to receive the H1N1 vaccination
- The site on the body that the vaccine should be given
- What to do with vaccine vials that are past their expiration date
- How to discard any unused vaccine remaining in vials.

SPECIAL NOTE: If a country is using Focetria ® H1N1 vaccine produced by Novartis, revise these instructions to indicate that each vial should be brought to room temperature before use, including any dose that has been drawn into a syringe. Room temperature usually ranges between 20 °C to 25 °C.

1. Check the expiration date of the vaccine vial. Do not use any vials that have passed the expiration date marked on its label. Inform your supervisor if you have H1N1 vaccine past the expiration date and ask what to do with it.
2. The vaccine appears as a suspension. Shake the vaccine vial gently before each use so that the vaccine is well mixed.
3. Remove the metal cap.
4. Use only a new, sterile auto-disable needle and syringe for each injection. Choose the correct size of auto-disable needle and syringe for intramuscular injections and insert it into the vial.
5. Draw up 0.5 ml of vaccine into the syringe.
6. For most children and adults, administer the H1N1 vaccine as an intramuscular injection in the deltoid (shoulder) region of the upper arm.

7. For small children receiving the H1N1 vaccine who do not have enough upper arm mass (usually infants and toddlers), administer the H1N1 vaccine as an intramuscular injection in the upper front (anterolateral) part of the thigh.
8. Dispose of the needle and syringe immediately into the safety box, without recapping them.

5. Side effects

Patients and caregivers are naturally concerned about vaccine side effects. Be available and willing to discuss side effects in a clear and informative manner.

Explain that participants will have a chance to practice their skills in talking with patients about common side effects and what to do about them.

What are the side effects of the H1N1 influenza vaccine?

- About 1 in 5 vaccine recipients will experience tenderness and swelling at the injection site.
- A small percentage of recipients may experience mild symptoms such as headache, body aches, nausea or low-grade fever. These symptoms may last 1 or 2 days.
- In rare instances, a patient may have an allergic reaction to flu vaccine. Signs of a severe allergic reaction include high fever, difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. These symptoms may appear a few minutes to a few hours after the injection. They should be treated in accordance with clinical guidelines for allergic reactions.
- The H1N1 vaccine cannot cause influenza.

How should you talk to people about side effects?

- Explain to patients and caregivers that some people may experience common side effects after vaccination, such as tenderness or swelling at the injection site or a headache and discomfort. The side effects are not serious and will not last more than a couple of days. This will help ease patients' minds about mild symptoms.

- Explain to patients and caregivers if a recipient becomes unusually ill for any reason in the hours or days following the vaccination, then the patient should return to the health facility as soon as possible to receive appropriate care.
- Ask the patient if they have any other questions about H1N1 vaccination.

6. Disposal of used syringes and needles

ADAPTATION NOTES: Policies for dealing with used needles, syringes, and other medical waste vary from country to country. Use your country waste management strategy to adapt the information in this section to reflect national guidelines and procedures. If possible, insert a photo or graphic of a safety box.

Explain that for H1N1 vaccination, waste disposal practices are the same as for other immunizations:

- Immediately after giving an injection, place the used needle and syringe in the safety box, without re-capping.
- When the box is $\frac{3}{4}$ full, seal the box and place it where the health facility waste handlers can take it for destruction according to facility procedures.

Discuss local or national medical waste procedures here such as:

- Locally available safety boxes
- Techniques for separating medical waste
- Keep a safety box within reach whenever you give injections.

7. Activity: Vaccine administration practicum

Adaptation Notes: Depending on the training needs and resources available, this activity can be adapted in 3 ways:

1. As written: participants administer the vaccine to each other to both practice and to take the opportunity to vaccinate health workers
2. As practice with alternative equipment: If you do not yet have the H1N1 supplies, use alternative vials without actually vaccinating.
3. As role-play only: this activity can be conducted without equipment, with participants simply role-playing the vaccination session.

Review the handouts to select the appropriate handout for the vaccine products available in your country.

Ask participants to get into pairs. Remind them of the importance of vaccination among health workers.

Give each participant a copy of **Handout 4: Role play observation checklist** and vaccination equipment.

Allow participants to review the checklist and ask any questions about the steps.

Ask pairs to take turns role playing a complete patient vaccination visit, from greeting to completion. Ask the “vaccinator” to follow all the steps listed, as well as use interpersonal skills to explain the purpose and benefit of the vaccine.

Ask the participant being vaccinated to check off the steps on the checklist and provide feedback to the “vaccinator.”

When the first role play is completed, have participants switch roles.

Allow time for pairs to share feedback about the experience with each other. Ask if there are any technical questions about the equipment or supplies.

Afterwards, discuss with the participants:

- What was different about administering this vaccine, compared with others you usually provide?
- What is similar?
- What might be some concerns by patients to this vaccine?
- What benefits can you tell them, as someone who already has received the vaccine?

Thank participants for their practice and feedback.

MODULE 3: HANDLING AND ADMINISTERING H1N1 INFLUENZA VACCINE

For use with vaccines that require health care workers to add adjuvant to them before giving the vaccine, such as the vaccine by GlaxoSmithKline.

Purpose: This module provides details about the H1N1 vaccine handling, storage and administration of the vaccines manufactured by GlaxoSmithKline. It also provides hands-on practice in steps for administration.



The following instructions are for administering injectable, liquid H1N1 vaccine manufactured by GlaxoSmithKline (GSK). This vaccine comes in 2 separate vials. Just before vaccination, the vaccinator must mix the contents of the two vials. One vial contains 10 doses of an adjuvant, which is an agent that increases the body's immune response to the H1N1 antigen. The second, larger vial contains the H1N1 antigen.

Introduce the topic of administering the H1N1 vaccine by asking:

- What have you heard about who should receive the H1N1 vaccine?
- Why should health workers get this vaccine? How will it benefit you in your work? What concerns do you have about it?

1. Who should be offered the H1N1 vaccine?

What are the priority groups to vaccinate?

ADAPTATION NOTES: Each country will need to adapt this section specifically to match its national policies on target groups for H1N1 vaccination. This may include indicating which specific adults and children with chronic conditions are to be immunized, and whether these and pregnant women should be vaccinated throughout the country or only those in certain areas. If the vaccine supply is limited, it may also be necessary to identify exactly which categories of health workers are to be immunized. Also include the rationale why only certain groups were selected.

We have already discussed the priority groups for H1N1 vaccination in broad terms. In our country, the priority groups are:

- **Health workers**, such as yourself, who provide care to ill patients
- **Pregnant women**, who are at risk of serious complications like pneumonia if they get the flu
- And other **adults and children with chronic conditions**. These patients are also more at risk of getting complications if they get the flu.

Most other people who get the flu recover on their own, without further complications.

What is the vaccination schedule?

All members of the target groups can be vaccinated as soon as possible after the vaccine is available.

Pregnant women can be vaccinated safely and effectively at any time during their pregnancy.

H1N1 vaccine may be given safely along with other vaccines during the same visit.

H1N1 vaccine should not be given to children before 6 months of age, because it will not be effective in them.

Can an extra dose of vaccine hurt a patient?

No, there is no danger if a patient receives an additional H1N1 vaccine dose by mistake.

2. How should you store and transport the vaccine?

ADAPTATION NOTES:

- Using your country policy, provide clear guidance on what vaccinators and their supervisors should do if they suspect that a vial of H1N1 antigen or adjuvant has been frozen.
 - Provide guidance on how long it takes for a vial to reach room temperature, to help health workers plan injection sessions.
-
- Both the GSK antigen and the adjuvant must be stored **between +2°C and +8°C**.
 - Keep it cold but **Do Not Freeze** the H1N1 antigen or adjuvant. Freezing will damage these products. If you suspect that any vials have been frozen, do not use them. Check with your supervisor about what to do.
 - Vials of this vaccine do not have Vaccine Vial Monitors (VVMs) on them. Therefore, it is important to take special care to maintain them at the correct temperature.

- Bring the H1N1 antigen and the adjuvant to room temperature (it usually takes 1 or 2 hours) before mixing and administering the vaccine to patients. Mark the vial label with the date and time it was opened.
- Once the adjuvant and antigen are mixed, the vaccine must be used as soon as possible.
- If the mixed vaccine will be stored briefly before use, return the vial of vaccine to cold conditions, that is, +2 to +8 degrees C.
- All mixed vaccine must be discarded within 24 hours after the antigen and adjuvant are mixed.

3. Discussion: Vaccine handling and storage at our facility

Write the following questions on a flip chart.



- Where would you store this vaccine in the refrigerator to assure that it does not freeze?
- How will you handle this vaccine when going to outreach sessions?
- How will you manage opened vials of H1N1 vaccine that contain leftover vaccine?

Ask participants to discuss the three questions with their partner. Give the pairs 10 minutes to discuss how they would handle and manage the vaccine at their facility.

Debrief: Ask several pairs to share best practices and ideas on how to handle the vaccine in their facilities.

4. How is the vaccine administered?

- **Ask participants:** What are all the steps we generally follow when administering a vaccination?
- Allow participants to come up with a list of steps to follow when administering vaccines. Write their answers on flip chart paper.

- Discuss the importance of:
 - Ensuring that the vaccine is available.
 - Checking the vaccine label and expiration date.
 - Greeting the patient or caregiver.
 - Assessing the patient for eligibility and contraindications.
 - Explaining to the patient (and caregiver) about the vaccine and possible side effects.
 - Using sterile injection equipment.
 - Drawing the correct dose.
 - Giving the injection.
 - Discarding equipment safely and correctly in the sharps container.

Distribute Handout 2: Vaccination guide.

Review the guide using the content below.

Preparing and administering the GSK H1N1 influenza vaccine

ADAPTATION NOTES: Use your country strategy to provide guidance on:

- The exact injection equipment to use
- Target groups to receive the H1N1 vaccine
- How long the vials of adjuvant and antigen should be set out to reach “room temperature” (usually 1 to 2 hours in most climates)
- What to do with vials that are past their expiration date
- Which injection site to use in young children and if there is a cut-off age or other criterion (e.g., arm mass) for switching from injecting in the thigh as opposed to the arm
- Whether and how to record and report doses administered

Ask participants how they reconstitute vaccines – or in other words, how vaccines that are freeze-dried are mixed with liquids before they

are administered. Explain that the GSK H1N1 influenza vaccine must be mixed in a way that is similar to reconstituting lyophilized (freeze dried) vaccines.

Steps to follow:

1. Read the label and expiration date on the vaccine vial. If the expiration date has passed or the label has fallen off, discard the vial. Make sure the vial is not cracked or damaged.
2. Make sure you have and use the correct adjuvant supplied by the manufacturer for this vaccine. Check that the expiration date has not passed. If it has or if the label has fallen off, discard the vial. Make sure the vial is not cracked.
3. Bring both the adjuvant and the antigen to room temperature. This takes 1 to 2 hours in most climates.
4. Mix the vaccine. Using a sterile syringe and mixing needle, draw up the entire contents of the vial of adjuvant. Insert the needle into the H1N1 antigen (vaccine) vial and expel all of the contents of the syringe.
5. Discard the mixing needle and syringe into the safety box and the used adjuvant vial into the garbage.
6. Shake the vaccine vial gently, but thoroughly.
7. Always use a new, sterile auto-disable needle and syringe for each injection. Choose the correct size auto-disable needle and syringe for intramuscular injections.
8. Draw up 0.5 ml of vaccine into the syringe.
9. For most people, administer the H1N1 influenza vaccine as an intramuscular injection in the deltoid (shoulder) region of the upper arm.
10. For small children who do not have enough upper arm mass (usually infants and toddlers), administer the H1N1 influenza vaccine as an intramuscular injection in the upper front (antero lateral) part of the thigh.
11. Dispose of the needle and syringe immediately into the safety box, without recapping.

Group discussion:

Ask participants to get into small groups of 3-4 participants.

Write the following on a flip chart:

- Identify 3 steps that are similar to handling other vaccines
- Identify at least 3 steps that are different from handling other vaccines
- Describe any concerns they may have to handling or administering this vaccine
- Propose solutions to those problems

Allow groups to discuss these for 10 minutes.

Ask participants to list the steps that are different than other vaccines.

Ask several groups to share concerns and solutions they identified.
Thank participants for their discussion.

5. Side effects

Patients and caregivers are naturally concerned about vaccine side effects. Be available and willing to discuss side effects in a clear and informative manner.

Explain that participants will have a chance to practice their skills in talking with patients about common side effects and what to do about them.

What are the side effects of the H1N1 influenza vaccine?

- About 1 in 5 vaccine recipients will experience tenderness and swelling at the injection site.
- A small percentage of recipients may experience mild symptoms such as headache, body aches, nausea or low-grade fever. These symptoms may last 1 or 2 days.
- In rare instances, a patient may have an allergic reaction to flu vaccine. Signs of a severe allergic reaction include high fever, difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. These symptoms may

appear a few minutes to a few hours after the injection. They should be treated in accordance with clinical guidelines for allergic reactions.

- The H1N1 vaccine cannot cause influenza.

How should you talk to people about side effects?

- Explain to patients and caregivers that some people may experience common side effects after vaccination, such as tenderness or swelling at the injection site or a headache and discomfort. The side effects are not serious and will not last more than a couple of days. This will help ease patients' minds about mild symptoms.
- Explain to patients and caregivers if a recipient becomes unusually ill for any reason in the hours or days following the vaccination, then the patient should return to the health facility as soon as possible to receive appropriate care.
- Ask the patient if they have any other questions about H1N1 vaccination.

6. Disposal of used syringes and needles

ADAPTATION NOTES: Policies for dealing with used needles, syringes, and other medical waste vary from country to country. Use your country waste management strategy to adapt the information in this section to reflect national guidelines and procedures. If possible, insert a photo or graphic of a safety box.

Explain that for H1N1 vaccination, waste disposal practices are the same as for other immunizations:

- Immediately after giving an injection, place the used needle and syringe in the safety box, without re-capping.
- When the box is $\frac{3}{4}$ full, seal the box and place it where the health facility waste handlers can take it for destruction according to facility procedures.

Discuss local or national medical waste procedures here such as:

- Locally available safety boxes
- Techniques for separating medical waste
- Keep a safety box within reach whenever you give injections.

7. Activity: Vaccine administration practicum

ADAPTATION NOTES: Depending on the training needs and resources available, this activity can be adapted in 3 ways:

1. As written: participants administer the vaccine to each other to both practice and to take the opportunity to vaccinate health workers
2. As practice with alternative equipment: If you do not yet have the H1N1 supplies, use alternative vials without actually vaccinating.
3. As role-play only: this activity can be conducted without equipment, with participants simply role-playing the vaccination session.

Review the handouts to select the appropriate handout for the vaccine products available in your country.

Ask participants to get into pairs. Remind them of the importance of vaccination among health workers.

Give each participant a copy of **Handout 4: Role play observation checklist** and vaccination equipment.

Allow participants to review the checklist and ask any questions about the steps.

Ask pairs to take turns role playing a complete patient vaccination visit, from greeting to completion. Ask the “vaccinator” to follow all the steps listed, as well as use interpersonal skills to explain the purpose and benefit of the vaccine.

Ask the participant being vaccinated to check off the steps on the checklist and provide feedback to the “vaccinator.”

When the first role play is completed, have participants switch roles.

Allow time for pairs to share feedback about the experience with each other. Ask if there are any technical questions about the equipment or supplies.

Afterwards, discuss with the participants:

- What was different about administering this vaccine, compared with others you usually provide?
- What is similar?
- What might be some concerns by patients to this vaccine?
- What benefits can you tell them, as someone who already has received the vaccine?

Thank participants for their practice and feedback.

MODULE 4: INTERPERSONAL SKILLS FOR IMPROVING H1N1 VACCINATION ACCEPTANCE

Purpose: This module outlines key communication skills and gives health workers time to practice using role play scenarios

Introduce this session: Next we will review some of the concerns patients may have about the vaccine, and discuss how to best use interpersonal skills to answer patient questions and address their concerns.

Communication to uncover the patient's concerns (10 minutes)

Remind the group that only patients from the specific target groups will be eligible for the H1N1 influenza vaccine.

Make the following points:

- Patients from target groups may not have heard about the vaccine before, and may feel unsure about getting it. Others may not think they need the vaccine, if H1N1 has not yet been common in their area.
- Similarly, some patients may have heard about the vaccine, but may not realize that they are not eligible to receive the vaccine at this time.
- For persons who request the vaccine, but are not eligible, be sure to reassure them that their risk for complications are low, and offer education about preventing influenza through hygiene and social distancing measures, such as keeping sick family members in a separate area away from others.

Explain that health workers must respond to all questions and concerns from people receiving the vaccine. This may mean taking

extra time to explain the vaccine and why it is important, and allaying fears and other concerns by noting that H1N1 vaccination is NOT mandatory, and that people will not be required to take it if they do not want it.

Write **“active listening”** and **“assertive statements”** on a flip chart.

Define these two communication tips and how they can help to reassure people who are getting vaccinated.

Active listening:

Pay attention to what the person being vaccinated is saying. Probe if you are unsure what the patient is feeling or what his/her concerns are about the vaccine. Repeat back feelings that you are hearing to make sure you understand.

For example, ***“It sounds like you don’t believe that this vaccine will keep you from getting sick.”***

Listen to ensure that you understand how the person feels and what he understands about the vaccine.

Assertive statements:

Sometimes people are not clear about what health care providers want them to do. Health workers often need to repeat instructions and rephrase them in a way that is relevant to the person being vaccinated. There are three parts to an assertive statement:

1. Be specific about what you recommend. For example:
“We recommend that you get this vaccine today.”
2. Acknowledge the person’s feelings. For example: ***“I know that you are worried that this vaccine won’t keep you from getting sick.”***
3. Restate the behavior and desired outcome, from the patient’s point of view. For example: ***“If you get this vaccine today, you are less likely to get sick from influenza and end up with more serious illness, like an infection in your lungs.”***

Explain that these communication tips may seem simple, but they take practice. Reinforce that by stating concerns back to the person being vaccinated, the health provider acknowledges these concerns, and makes it more likely that the person will agree to receive the vaccine.

Activity: Practice in pairs (20 minutes)

Ask participants to get into pairs. Explain that each will take a turn being the health worker and the person getting vaccinated so they can practice the communication tips. **Distribute**

Handout 5: Practice in pairs scenario cards to each participant.

Give instructions for this exercise:

- You each have a card that describes a scenario from the perspective of the person being vaccinated.
- You will each take a turn playing each role: the health care worker (vaccinator) and the person being vaccinated.
- As the person being vaccinated, tell the health worker the information suggested on the card.
- As the health worker (vaccinator), ask questions to uncover concerns and provide responses to encourage acceptance of the vaccine.
- You will have 3 minutes only.
- We will discuss the experience afterwards.

After 3 minutes, call time and have participants switch roles. When they switch roles, give them different cards with which to practice.

After 3 minutes, call time. Thank participants for their participation in the practice.

Ask each pair to give feedback to the group on what worked well and what was difficult.

Debrief with group:

- How does the limited amount of time affect your counseling?
- What makes it difficult to provide responses to people receiving the vaccine?
- What makes it easier to provide responses to people receiving the vaccine?
- Who else can assist you in counseling?

Briefly acknowledge that there will be people who will still refuse the vaccine, as well as people who are not in priority groups who will request to receive the vaccine.

Vaccinators should still use their best judgment to ensure that the H1N1 influenza vaccine is distributed fairly and effectively.

Closing session

Ask participants if they have any final questions about H1N1 influenza, the H1N1 influenza vaccine, the priority groups, or counseling tactics.

Distribute **Handout 6: Evaluation form**.

Ask participants to complete the form and hand it in before leaving.

Thank participants for their time.

HANDOUT 1: Frequently Asked Questions about the 2009 H1N1 Influenza Virus and the H1N1 Vaccine

1. What is the novel H1N1 influenza virus?

The current pandemic influenza is an influenza A (H1N1) virus that has never before circulated among humans.

2. How do people become infected with the virus?

The virus is spread from person-to-person. It is transmitted as easily as the normal seasonal flu and can be passed to other people by exposure to infected droplets expelled by coughing or sneezing that can be inhaled, or that can contaminate hands or surfaces.

3. What are the symptoms of novel H1N1 influenza virus?

Symptoms of H1N1 are similar to those of regular, seasonal flu: fever higher than 38° C, headache or body aches, chills, fatigue, sneezing or runny/stuffy nose, and diarrhea and vomiting (this symptom is more common in children).

4. Most people experience mild illness from the novel H1N1 influenza virus and recover at home. When should someone seek medical care?

A person should seek medical care if they experience difficulty breathing, chest pain, shaking that cannot be controlled, lips or skin turning blue, severe vomiting or diarrhea, not waking up, or confusion such as not recognizing family members. For parents with a young child who is ill, seek medical care if a child has fast or labored breathing, continuing fever or convulsions (seizures).

Always bring a sick infant younger than 2 months and refuses to feed to the health care facility. If you live in an area where malaria is common, you should always go to the health care facility if you have a fever.

5. How do I know if I have novel H1N1 influenza?

You will not be able to tell the difference between seasonal flu and the novel H1N1 influenza virus without medical help. Typical symptoms to watch for are similar to seasonal viruses and include fever, cough, headache, body aches, sore throat and runny nose. Only your medical practitioner and local health authority through tests can confirm a case of H1N1.

However, people should avoid going to the health care facility unless they have serious health problems or complications because otherwise health facilities may become overwhelmed by people seeking tests. In most cases, the novel H1N1 virus symptoms will go away on their own within 2 weeks.

6. Why are we so worried about this flu when thousands die every year from seasonal influenza epidemics and other outbreaks?

Seasonal influenza occurs every year and the viruses change each year, but many people have some immunity to the circulating virus which helps limit infections. Some countries also use seasonal influenza vaccines to reduce illness and deaths.

There are three aspects of this virus that are causing the worry among health professionals.

1. Novel H1N1 influenza appears to be more contagious than seasonal influenza, and has been spreading fast particularly among young people (from ages 10 to 35). The severity of the disease ranges from very mild symptoms to severe illnesses that can result in death.
2. Pharmaceutical interventions such as vaccines will not be available for wide distribution.
3. There is the potential for community services and functions – such as transportation, markets and health care – to become disrupted due to high numbers of people becoming ill and staying home from work.

7. What can I do to protect myself from catching the novel H1N1 virus?

The main route of transmission of the novel H1N1 virus seems to be similar to seasonal influenza, via droplets that are expelled by speaking, sneezing, or coughing. You can prevent getting infected

by avoiding close contact with people who show influenza-like symptoms (try to maintain a distance of about 2 meters – or three large steps away – if possible) and taking the following measures:

- **Washing your hands with soap and water often**
- **Regularly cleaning objects** that sick people use – like phones, eating utensils, and door knobs.
- **Covering your mouth and nose** with a cloth or tissue when you sneeze or cough. If you do not have a cloth or tissue, you can cough or sneeze into your arm.
- **Avoiding public places** where many people gather, such as markets, church or mosque, workplaces, and schools.

8. Should I wear a mask?

If you are caring for a sick person, you can wear a mask or cover your nose and mouth and the patient's nose and mouth with a cloth when you are in close contact with the ill person. Remember to dispose of it immediately after using it, and wash your hands thoroughly with soap and water afterwards.

9. What good respiratory etiquette practices can help prevent the spread of novel H1N1 influenza virus?

In addition to always covering your mouth and nose with a cloth or tissue when you sneeze or cough, you can wear a mask, scarf, or other piece of clean cloth over your mouth and nose to protect others from getting the novel H1N1 influenza virus, and protect you from other illnesses. If you wear a disposable mask over your nose and mouth, throw it away in a trash bin immediately after use. If you wear a cloth over your nose and mouth, wash it with soap and warm water immediately after use. You should also avoid spitting in public.

10. Are there any special recommendations for pregnant women?

Yes. This is because there seems to be a higher risk of serious complications in women who are pregnant and infected with the novel H1N1 influenza virus, especially in the second and third trimesters. Therefore, pregnant women should avoid situations where they could be exposed to the novel H1N1 influenza virus, such as large social gatherings.

Pregnant women who work in health care facilities should try to avoid patients with known or suspected novel H1N1 virus infection, and if possible, ask to be assigned tasks that do not involve being near people with the novel H1N1 influenza virus. If pregnant health care workers cannot avoid patients with the novel H1N1 influenza virus, they should always cover their nose and mouth with a mask. In areas where novel H1N1 influenza virus is widespread, pregnant women should pay attention to symptoms of influenza-like illness and tell their health care provider if they suspect they might have the novel H1N1 influenza virus.

11. Are some people more at risk of illness and death from the H1N1 influenza virus?

Yes, in addition to pregnant women, there are some people who seem to be at greater risk for illness and death from the novel H1N1 influenza virus, such as older people and young children. People who already have a health problem – such as tuberculosis or other lung diseases, HIV/AIDS, diabetes, heart problems, and kidney disease – are at higher risk of major health problems related to novel H1N1 influenza virus.

As with pregnant women, people with HIV and other serious illnesses should avoid situations where they could be exposed to the novel H1N1 influenza virus. If they need to go out in public, they should cover their mouth and nose with a mask or cloth. If they are currently taking medications for a pre-existing illness, they should continue to take them and follow their doctor's orders. For example, if you have HIV or AIDS and are taking medicines to prevent infections continue with your prescribed treatment and follow the advice of your health care provider to keep your immune system healthy.

USE OF VACCINES AGAINST H1N1 INFLUENZA

Is an effective vaccine against the 2009 H1N1 pandemic virus already available?

Yes, several vaccines have been developed to help prevent the H1N1 virus. The vaccines are available in limited supply for those people at high risk of being infected with H1N1 virus or having complications from it. This includes health care workers such as doctors and nurses; pregnant women; and people with certain chronic health problems.

Because the vaccine can take up to two weeks to become effective after you receive the vaccination, it is important to take other actions to prevent getting the flu. These include washing your hands regularly with soap and water, regularly cleaning commonly used surfaces, covering your nose and mouth with a tissue or your arm when you cough or sneeze, and staying at least 2 meters away from other people.

If I get the H1N1 vaccine, am I guaranteed to not get the virus?

No vaccine provides a 100 percent guarantee of effectiveness. Moreover, because influenza vaccines only become effective about 14 days after vaccination, people infected one to three days after vaccination may still get the H1N1 virus. People may also get influenza caused by a different strain of influenza virus for which the vaccine does not provide protection, or they may have an illness caused by other common viruses that are not influenza. In all of these instances, a person may believe that the vaccine failed to protect them or that vaccine had caused the disease, but this is not the case.

How many doses of the vaccine will people need?

According to the WHO Strategic Advisory Group of Experts (SAGE) on immunization, individuals should receive one dose of the vaccine.

How is the vaccine given?

Most of the vaccines that are being used in developing countries contain inactivated (or killed) viruses. These vaccines are given by injection into the upper arm for most people. In infants and younger children the thigh is the preferred site for the vaccine shot.

Why do some pandemic influenza vaccines contain adjuvant and others do not? Are vaccines with adjuvants safe?

Adjuvants are substances that enhance the immune response in vaccines and can make them more effective. They have been used for many years in some vaccines, and vaccine manufacturers decide whether a product is made with or without an adjuvant. Some pandemic vaccines contain an adjuvant to reduce the amount of virus antigen to be used (an antigen is a substance capable of stimulating an immune response). Adjuvants used with pandemic influenza vaccines have already been used in other vaccines (e.g., seasonal influenza, hepatitis B) and have a safe track record.

Can the pandemic influenza vaccine be administered simultaneously with other vaccines?

The inactive version of the influenza vaccine can be given at the same time as other injectable, non-influenza vaccines, but the vaccines should be administered at different injection sites.

VACCINE SAFETY

Is the H1N1 vaccine safe?

The H1N1 vaccine is safe and has been approved by health authorities, including the US Food and Drug Administration and the World Health Organization, because it meets very strict standards of quality and safety.

The H1N1 vaccine was made the same way and at the same factories as regular seasonal influenza vaccine, which is a safe vaccine used every year in many countries. There is a long and successful history of vaccine safety and effectiveness using this manufacturing technology. Side effects seen so far are similar to those observed with seasonal influenza vaccines, which include mild soreness or redness at the injection site.

What kind of testing is being done to ensure safety?

Because the pandemic virus is new, both non-clinical and clinical testing is being done to gain essential information on immune response and safety. The results of studies reported to date suggest the vaccines are as safe as seasonal influenza vaccines. However, even very large clinical studies will not be able to identify possible rare events that can become evident when pandemic vaccines are administered to many millions of people. WHO has urged all countries administering pandemic vaccines to conduct intensive monitoring for safety and report serious adverse events.

Who approves pandemic vaccines for use?

National authorities for medicines approve (or license) pandemic influenza vaccines for use. These authorities carefully examine the known and suspected risks and benefits of any vaccine prior to its licensing. Expedited regulatory processes in some countries have helped to license the new vaccine in a timely manner. However, the testing and manufacturing processes for the new vaccines are similar to seasonal influenza vaccines to ensure quality and safety.

Is the vaccine safe for pregnant women?

To date, studies do not show harmful effects from the pandemic influenza vaccine with respect to pregnancy, fertility, or a developing embryo or fetus, birthing or post-natal development. In view of the elevated risk for severe illness for pregnant women infected by the new influenza, in clinical studies, pregnant women are a group that should be vaccinated against infection, as supplies allow.

Recent studies show that infected pregnant women have a 10 times higher chance to require hospitalization in intensive care units than infected persons in the general population, and 7% to 10% of hospitalized cases are women in their second or third trimester of pregnancy. The benefits of vaccination far outweigh the risks. Additional studies on pregnant women following vaccination are continuing.

Is the vaccine safe for children?

The most frequent vaccine reactions in children following influenza vaccination are similar to those seen after other childhood immunizations (such as soreness at the injection site, or fever). A child's health care provider or vaccinator can advise on the most appropriate methods for relief of the symptoms. If there are concerns about a child's safety from a reaction, consult a health care provider as soon as possible. Please note that a child may suffer from a condition not related to immunization, which coincidentally developed after vaccination.

Will pandemic vaccines contain thiomersal, which some believe is a risk to health?

Thiomersal (also spelled thimerosal) is a commonly used vaccine preservative to prevent vaccine contamination by bacteria during use. Inactivated vaccines will contain thiomersal if they are supplied in multi-dose vials. Some products can have "traces" of thiomersal when the chemical is used during the production process as an antibacterial agent, which is later removed during the purification process.

Thiomersal does not contain methyl mercury, which is a naturally-occurring compound and whose toxic effects on humans have been well studied. Thiomersal contains a different form of mercury (i.e., ethyl mercury, which does not accumulate, is metabolized and removed from the body much faster than methyl mercury).

The safety of thiomersal has been rigorously reviewed by scientific groups. There is no evidence of toxicity in infants, children or adults, including pregnant women, exposed to thiomersal in vaccines.

VACCINE SIDE EFFECTS AND ADVERSE EVENTS

Are there any side effects from the vaccine?

Experience so far indicates that the H1N1 vaccine will have the same effects as most other influenza vaccines given every year. These effects usually last one or two days and include: mild soreness, swelling, or redness at the injection site. There has been no evidence of harm or serious side effects in the vaccine clinical tests that were conducted.

How often side effects occur can depend on the type of vaccine, how it is administered, and the age of the vaccine recipient.

Have clinical studies identified all the possible side effects?

Again, even very large clinical studies will not be able to identify possible rare events that can become evident when pandemic vaccines are administered to many millions of people. These can only be assessed when a vaccine is in widespread use. Clinical trials often provide safety information for the general population. Additional monitoring of some special groups of vaccine recipients is necessary to gather specific safety information. Additional and comprehensive monitoring efforts of the pandemic influenza vaccine are being planned as they are being used by more and more people around the world.

WHO has advised all countries administering pandemic vaccines to conduct intensive monitoring for safety, and report adverse events.

Have there been any reports of serious reactions, or adverse events, to pandemic vaccines?

As of late October 2009, there is no indication that unusual adverse events are being observed after vaccination, according to clinical trials and adverse event monitoring during deployment of vaccines in early introducer countries. The need for continued vigilance and regular evaluation by health authorities is ongoing.

How should serious reactions to the vaccines be reported?

Reports of serious adverse events, and those raising concerns, should always be submitted to national authorities. So far, reports of potential adverse events following vaccination have been successfully reported to authorities.

What happens when an adverse event is reported?

At the national level, individual reports are scrutinized for completeness and possible errors. In some instances, reports need to be validated and additional details must be checked. Reports are analyzed for findings that are expected or appear more frequently than expected. If an analysis indicates a potential problem, further studies and evaluation are conducted and all relevant national and international authorities are informed. Decisions for appropriate measures are then made to ensure continuing safe use of the vaccine.

Is it possible that the safety of the vaccine will change over time, as more people get vaccinated?

The safety of the vaccine is not expected to change. Governments and WHO, however, will continue to monitor the safety and effectiveness of the H1N1 vaccine carefully. Comprehensive monitoring efforts are being planned for H1N1 vaccines to continue to monitor their safety as their use becomes more widespread.

Is there anyone who should NOT get the vaccine?

Although the 2009 H1N1 vaccine is safe for almost everyone, there are a few people who should not get the 2009 H1N1 vaccine. This includes:

- People who have had life-threatening allergic reactions to previous influenza vaccines
- People who have experienced any other severe reaction to an influenza vaccination.
- People who developed Guillain-Barré syndrome within 6 weeks of getting an influenza vaccine
- Children under 6 months of age (the vaccine is not approved for this age group)

- People with allergies to eggs

In addition, people who have a moderate-to-severe illness with a fever should wait until they recover to get vaccinated.

AVAILABILITY OF VACCINE AND PRIORITY GROUPS

Will the vaccine be available in my country?

WHO in coordination with governments and ministries of health has identified 100 countries that will receive the 2009 H1N1 vaccine. The distribution of an approximately 200 million doses of vaccines began in November 2009 and will continue into June 2010.

If there are limited supplies of vaccine, who will have priority for getting vaccinated?

WHO has recommended that health workers be given high priority for early vaccination because they are most in contact with sick patients who might have the H1N1 virus. Countries may decide on other priority groups based on their particular situation and WHO guidelines. Some countries, for example, have identified pregnant women and others who are at high-risk of suffering complications from H1N1 as priority groups.

Why are pregnant women considered at high risk?

There is a higher risk of serious complications in women who are pregnant and infected with the 2009 H1N1 influenza virus, especially in the second and third trimesters. That is why it is important for pregnant women to get the 2009 H1N1 vaccine to protect themselves and their baby. Women can safely receive the vaccine at any stage of their pregnancy. SAGE recommends that any licensed vaccine can be used in pregnant women provided no specific contraindication has been identified by the regulatory authority.

What other people are considered high-risk?

People with long-term sicknesses such as asthma or diabetes, or who have diseases such as malaria and HIV that weaken their immune system, are considered high risk. Your government will decide what risk groups should receive the 2009 H1N1 vaccine.

Will there be enough pandemic influenza vaccine for everyone?

Production of the pandemic influenza vaccines continue but in some areas demand for vaccination is greater than the supply. This gap will narrow as more vaccines become available over time.

Who will receive priority for vaccination?

WHO continues to recommend that health workers be given first priority for early vaccination to protect themselves and their patients, and help keep health systems functioning as the pandemic evolves.

Why is it important for health care workers to get vaccinated?

WHO has recommended that health care workers be among the first to receive the vaccine to protect them from infection, and to ensure the healthcare system is able to continue to function and provide care during the pandemic.

What if I cannot get the H1N1 vaccine?

Most people will not have access to the vaccine. However, there are simple actions you and your family can take that will help prevent the spread of the H1N1 virus. These include washing your hands regularly with soap and water, staying at home if you are sick, and covering your mouth and nose with a tissue when you cough or sneeze, and sneeze or cough into the crook of your arm if you do not have a tissue.

Will developing countries have access to pandemic influenza vaccines? What is WHO doing to help?

The WHO Director-General has called for international solidarity to provide fair and equitable access to pandemic influenza vaccines for all countries. So far, WHO has helped secure significant donations of vaccines from countries and partners (about 200 million doses) for 95 low- and middle-income countries. Deployment of the first supplies of vaccines to these countries is expected to take place from December 2009 to February 2010.

NON-PHARMACEUTICAL INTERVENTIONS

What are non-pharmaceutical interventions?

Non-pharmaceutical interventions (NPI) are actions that individuals and communities can take to reduce contact and consequently person-to-person transmission of influenza to contain and delay the spread of pandemic influenza and reduce the number of cases of morbidity and mortality.

Non-pharmaceutical interventions refer to measures such as:

- Maintaining good personal hygiene,
- Good respiratory etiquette,
- Isolation and home care of the sick, and
- Social distancing.

What good respiratory etiquette practices can help prevent the spread of pandemic influenza?

In addition to always covering your mouth and nose with a cloth or tissue when you sneeze or cough, you can wear a mask, scarf, or other piece of clean cloth over your mouth and nose to protect others from getting the 2009 H1N1 influenza virus, and protect you from other illnesses. If you wear a disposable mask over your nose and mouth, throw it away in a trash bin immediately after use. If you wear a cloth over your nose and mouth, wash it with soap and warm water immediately after use. You should also avoid spitting in public.

What are the benefits of isolating the sick person from others?

The primary benefit from keeping sick people and people who have been exposed to the 2009 H1N1 influenza isolated from others is to slow or stop the spread of the disease.

HOME-BASED CARE OF THOSE WITH PANDEMIC INFLUENZA

What should I do if I think I have the illness?

If you are showing symptoms of the flu, stay at home, rest, and drink plenty of fluids. Do not go to work or school, and avoid public gatherings if you can, so you can avoid spreading the virus to others. Even at home, you should rest in a separate room, away from others in the household.

Also remember to cover your nose and mouth with a tissue or cloth when coughing and sneezing, and wash your hands immediately after with soap and water. If you do not have a tissue close by when you cough or sneeze, cover your mouth as much as possible with the crook of your arm.

How do you care for those who have pandemic influenza?

As soon as symptoms develop, you should make sure that the sick person stays at home and rests. Keep them separate from others in the household – in a separate room or in a space that is at least two meters (three large steps) away from others.

Try to limit visitors to the sick person. It is best to have only one person in the family take care of the sick person to prevent others in the household from getting sick. The person chosen as the caregiver should ideally be healthy and not have medical conditions that would put him or her at risk for severe influenza disease. Pregnant women also should avoid caring for those who are sick with the 2009 H1N1 influenza virus.

How do you protect yourself and your household if you are caring for a person with pandemic influenza?

If you are caring for a person with influenza, take care of your own health first. If you become sick, you will be of little use to those who need you. Wear a mask or cloth over your mouth and nose whenever you are within an arm's length of them. After contact with a sick person or anything the sick person touches, wash your hands with soap and water.

Place tissues used by the sick person in a bag and throw them away with other household waste. Consider placing a bag at the bedside for this purpose.

Should I go to work if I have the flu but am feeling OK?

No. Whether you have H1N1 or a seasonal influenza, you should stay home and away from work through the duration of your symptoms. This can help to protect your work colleagues and others.

Should I take an antiviral now just in case I catch the new virus?

No. You should only take an antiviral, such as oseltamivir or zanamivir, if your health care provider advises you to do so.

What about breastfeeding? Should I stop if I am ill?

No, not unless your health care provider advises it. Breastfeeding provides the best overall nutrition for babies and increases their defense factors to fight illness.

Can I travel?

If you are feeling unwell or have symptoms of influenza, you should avoid travel, if possible. If you are travelling to an area with outbreaks of the 2009 H1N1 pandemic influenza, take precautions such as always covering your mouth and nose with a tissue or cloth when coughing or sneezing, washing your hands frequently with soap and water, and keeping at least a two-meter distance (or three large steps) from other people.

Wherever you travel, it will be important to observe and follow the rules from the local health authorities. You should also expect additional health screening procedures at airports.

Is it safe to eat pork and pork products?

Yes. The 2009 H1N1 virus has not been shown to be spread to people through eating properly handled and prepared pork (pig meat) or other products made from pigs. The H1N1 virus is killed by cooking temperatures of 160°F/70°C.

Should I worry if there are outbreaks of avian influenza in my area?

If you live in an area with avian influenza outbreaks and you have been in contact with poultry and have flu symptoms, you should visit your health care facility to find out if you have the H5N1 virus. When

you go to your health facility, tell the doctor or health provider that you have been working or living with poultry and now have flu symptoms.

If there are widespread outbreaks, will governments close down their borders or prevent people from entering their countries without screening?

According to the revised International Health Regulations (2005), countries are asked to follow directions from the World Health Organization and not impose any travel restrictions or bans unless notified by WHO. Decisions about screening people upon entry to a country are made by the individual countries.

USE OF ANTIVIRAL DRUGS AGAINST H1N1 INFLUENZA

Which antiviral drugs can be used to treat 2009 H1N1 pandemic influenza?

Antiviral drugs may reduce the symptoms and duration of H1N1 influenza illness, just as they do for seasonal influenza. There are two antiviral drugs that have been found to reduce the symptoms of the 2009 H1N1 pandemic influenza virus, and to reduce the time people are sick. They are oseltamivir and zanamivir.

When should antivirals be used?

Worldwide, most people infected with the 2009 H1N1 pandemic influenza virus continue to experience typical influenza symptoms and recover within a week, even without any form of medical treatment. Healthy people with uncomplicated illness do not need to be treated with antivirals. In most cases, do not worry if you cannot obtain an antiviral medicine. Most people that have been sick with the flu have recovered without antiviral treatment.

HANDOUT 2: H1N1 Vaccination Guide

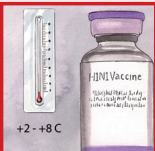
H1N1 Vaccine

VACCINATION GUIDE





Novartis CSL Sanofi US GlaxoSmithKline


Steps in vaccinating using Novartis, CSL, Sanofi US H1N1 pandemic flu vaccines

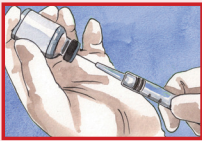
1  **Maintain vaccine at temperature** between +2 and +8°C.
Do not freeze.
(Note: this vaccine does not have a vaccine vial monitor on it.)

Most manufacturers are stating that open vials can be kept for 24 hours under cold chain storage conditions, +2 to +8°C. There are differences however, please follow the instructions from the manufacturer.


2  **Ask the person to be vaccinated for eligibility and contraindications.**
The vaccine should not be given to those who are allergic to egg or who have had an allergic reaction to influenza vaccine in the past. Pregnant women can be vaccinated at any time during their pregnancy.

3  **Advise the person what they are receiving and why.** Tell the person that they are receiving H1N1 influenza vaccine and that it will protect them from a form of influenza that can cause serious respiratory (breathing) problems.

4  The vial should be shaken prior to each administration.

5  **Prepare to vaccinate.**
Use a syringe with the same needle length and gauge as is used for other intramuscular vaccinations.

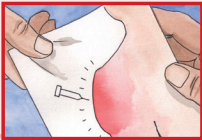
Use the vaccine within 24 hours and do not store above 25°C.

6  **Administer the vaccine.** Administer the administration following the national guidelines on age and body site.

7  **WHO recommends one dose for anyone receiving the vaccine.**

Directly dispose of syringe into a safety box and without re-capping the needle. This is to be done immediately after vaccinating.

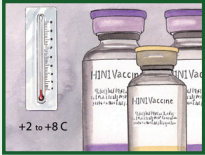
The injection site is the upper arm. If national policy permits vaccination of infants, the site of administration in children XX months to less than nine months old is the outer aspect of the upper thigh.

8  **Counsel the person about common side effects and adverse events.**
Common side effects are redness, swelling, and/or pain at the injection site for 1-2 days. If there is any serious health issues, such as difficulty breathing, return to the health facility for care as soon as possible.


9  **Ask the person if they have any questions.**


Type of vaccine	Inactivated viral	Special precautions	Need to verify....
Number of doses	One dose	Dosage	0,5 mL
Schedule	Can be given at any time	Injection site	Upper arm for adults; outer aspect of the upper thigh children under 9 months
Booster	No	Injection type	Intramuscular
Contraindications	Allergy to chicken or egg products	Storage	+2 to +8°C; do not freeze
Common side effects	Soreness, redness, swelling at injection site		

Steps in vaccinating using GlaxoSmithKline H1N1 pandemic flu vaccine

- 


1 **Maintain vaccine at temperature** between +2 and +8°C.
Do not freeze.
(Note: this vaccine does not have a vaccine vial monitor on it.)

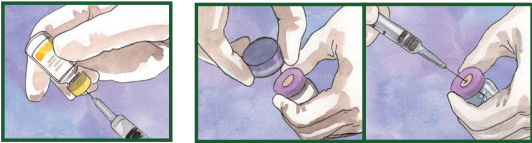
Most manufacturers are stating that open vials can be kept for 24 hours under cold chain storage conditions, +2 to +8°C. There are differences however, please follow the instructions from the manufacturer.
- 

2 **Screen the person to be vaccinated for eligibility and contraindications.**
The vaccine should not be given to those who are allergic to egg or who have had an allergic reaction to influenza vaccine in the past. Pregnant women can be vaccinated at any time during their pregnancy.
- 


3 **Advise the person what they are receiving and why.**
Tell the person that they are receiving H1N1 influenza vaccine and that it will protect them from a form of influenza that can cause serious respiratory (breathing) problems.

Instructions for mixing and administration of the GlaxoSmithKline H1N1 pandemic flu vaccine

- 

4 Before mixing the two components, the mixture and liquid vaccine should be allowed to reach room temperature, shaken and inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, discard the vaccine.
- 

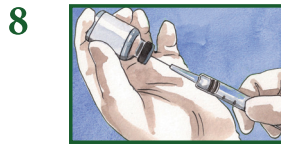
5 The vaccine is mixed by withdrawing the contents of the vial containing the mixture by means of a syringe and by adding it to the vial containing the liquid vaccine.

After mixing the 2 vials it is equal to 10 doses of the vaccine.
- 

6 After the addition of the mixture to the liquid vaccine, the mixture should be well shaken. The mixed vaccine is a whitish mixture. In the event of other variation being observed, discard the vaccine.



7 The vial should be shaken prior to each administration.



8 Use a syringe with the same needle length and gauge as is used for other intramuscular vaccinations.

After mixing, use the vaccine within 24 hours and do not store above 25°C.



9 **Administer the vaccine.** Administer the administration following the national guidelines on age and body site.



WHO recommends one dose for anyone receiving the vaccine.

The injection site is the upper arm. If national policy permits vaccination of infants, the site of administration in children XX months to less than nine months old is the outer aspect of the upper thigh.



10 **Directly dispose of syringe into a safety box** and without re-capping the needle. This is to be done immediately after vaccinating.



11 **Counsel the person about common side effects and adverse events.** Common side effects are redness, swelling, and/or pain at the injection site for 1-2 days. If there is any serious health issues, such as difficulty breathing, return to the health facility for care as soon as possible.



12 **Ask the person if they have any questions.**

Type of vaccine	Inactivated viral	Special precautions	Need to verify....
Number of doses	One dose	Dosage	0.5 mL
Schedule	Can be given at any time	Injection site	Upper arm for adults; outer aspect of the upper thigh children under 9 months
Booster	No	Injection type	Intramuscular
Contraindications	Allergy to chicken or egg products	Storage	+2 to +8°C; do not freeze
Common side effects	Soreness, redness, swelling at injection site		

The H1N1 flu vaccine is **effective** and **safe**. It is made like other flu vaccines that have been used for years. Millions of people in countries around the world have received the H1N1 vaccine since October 2009. Only a single shot is needed. People who get it may have a sore arm for 1 or 2 days. But there have been no dangerous side effects.



People with some illnesses can get very sick they get pandemic flu.



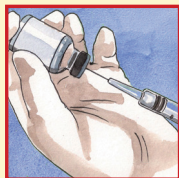
Ministry of Health recommends the new H1N1 flu vaccine for health care workers, pregnant women and people who have long-term illnesses such as HIV/AIDS, cancer, diabetes or having trouble breathing.



Pregnant women can be vaccinated any time during their pregnancy.



The vaccine is effective and safe and has been used for millions of peoples.



It is produced the same way other flu vaccines are produced.



Tell your people that their arm may feel sore for 1 or 2 days and it may appear red or swollen. That is normal.

Families of vulnerable people and others that do not get the vaccine can protect themselves by **practicing good hygiene** and staying apart from people who are sick.



CLEAN
Wash your hands with soap and water before preparing food or after you cough or sneeze.



COVER
Cough or Sneeze into the crook of your elbow.



DISTANCE
Keep a safe distance from sick people

HANDOUT 3: Role-play Observation Checklist

ADAPTATION NOTE: This checklist is for use of 10-dose vials of injectable liquid vaccine manufactured by CSL, Novartis, or Sanofi.

	Vaccinator's Action	Observed	
		Yes	No
1	Wash hands before a vaccination session.		
2	Check that the H1N1 vaccine is available and not past expiration date. [If using Focetria® vaccine produced by Novartis, remove a vial from refrigerator and allow it to come to room temperature (approximately one hour).]		
3	Greet the person getting vaccinated. Introduce H1N1 and the reason for vaccinating.		
4	Assess the person for eligibility and contraindications.		
5	Explain the possible side effects and signs of allergic reaction.		
6	Shake the vaccine vial gently, but thoroughly.		
7	Select a sterile auto-disable syringe with the appropriate size sterile needle for an intramuscular injection.		
8	Draw 0.5 ml of the vaccine into the syringe.		
9	Inject the entire dose by intramuscular injection into the deltoid region (near the shoulder) of the upper arm.		
10	If vaccinating a young child that does not have enough upper arm mass (usually infants and toddlers), position the caregiver with the child sideways on their lap, and ask the caregiver to hold the child's legs. Inject the entire dose by intramuscular injection into the upper front (anterolateral) aspect of the child's thigh.		
11	Immediately dispose of the used needle and syringe in safety box without re-capping.		
12	Remind the person of possible side effects, and tell them to come back to the clinic if there are any problems following vaccination.		

Comments and feedback for vaccinator:

HANDOUT 4: Alternative: Role-play Observation Checklist for GSK Vaccine

ADAPTATION NOTE: This checklist is for use with 10-dose vials of liquid vaccine manufactured by Glaxo SmithKline, which requires adding adjuvant.

	Vaccinator's Action	Observed	
		Yes	No
1	Wash hands before a vaccination session.		
2	Remove a vial of the GSK antigen and a vial of the GSK adjuvant from the refrigerator and let them come to room temperature (approximately one hour). Greet the person getting vaccinated. Introduce H1N1 and the reason for vaccinating.		
3	Assess the person for eligibility and contraindications.		
4	Explain the possible side effects and signs of allergic reaction.		
5	Check the label of the adjuvant ("emulsion") vial and make sure it is the correct product to use with GSK antigen (vaccine).		
6	Take a sterile mixing syringe and draw the entire contents of the adjuvant vial into the syringe.		
7	Insert the mixing syringe into the vial of antigen (vaccine) and expel all of its contents into the vial.		
8	Discard mixing syringe and needle in safety box. Discard the used adjuvant vial in the garbage.		
9	Shake the vaccine vial gently, but thoroughly.		
10	Select a sterile auto-disable syringe with the appropriate size sterile needle for an intramuscular injection.		
11	Draw 0.5 ml of the vaccine into the syringe.		
12	Inject the entire dose by intramuscular injection into the deltoid (shoulder) region of the patient's upper arm.		
13	If vaccinating a young child that does not have enough upper arm mass (usually infants and toddlers), position the caregiver with the child sideways on their lap, and ask the caregiver to hold the child's legs. Inject the entire dose by intramuscular injection into the upper front (anterolateral) part of the child's thigh.		
14	Immediately dispose of the used needle and syringe in safety box without re-capping.		
15	Remind the person of possible side effects, and tell them to come back to the clinic if there are any problems following vaccination.		

Comments and feedback for vaccinator:

HANDOUT 5: Scenario cards for practice in pairs

ADAPTATION NOTE: Use the feedback about H1N1 in your country to create cards that reflect common situations. Write short descriptions on cards from a patient perspective; one per participant.

<p>Scenario</p>	<p>Scenario</p>
<p>You are an older woman bringing your five-year old grandson in for treatment of diarrhea. He also has asthma. You have not heard about this new vaccine, and are not sure why he needs it, since he does not have influenza.</p>	<p>You are pregnant with your third child and you have come to the clinic for vitamins for your pregnancy. You feel fine, and do not know why you need an influenza vaccine.</p>
<p>Scenario</p>	<p>Scenario</p>
<p>You are a local businessman who has heard about the new vaccine. You have made a visit to the clinic to receive it, because you are concerned that if you get ill, you will have to close your restaurant. You are otherwise a healthy man with no chronic illnesses.</p>	<p>You are the main caregiver in your family. Last week, you took care of two sick children with influenza, and you are worried that you may become ill, too. You have come to the clinic to ask that you get the vaccine, so that you will not get sick. You are otherwise a healthy woman, with no chronic illnesses.</p>

HANDOUT 6: Training Evaluation Form

ADAPTATION NOTE: Adapt this form to gather information to help your trainers improve the training.

H1N1 Pandemic Influenza Vaccination Training

If you need more space to write your responses, please use the back of the paper.

1a. Please evaluate how well the training was able to meet its **four objectives**.

Objective	Very well 5	Well 4	Somewhat Well 3	Not to Well 2	Not at all 1
To help you understand key facts about H1N1 infection and prevention					
To help you correctly handle and store the H1N1 vaccine					
To help administer the H1N1 vaccine correctly and safely dispose of needles and syringes					
To help you communicate more effectively with priority groups to be vaccinated					

1b. If you rated any objective **3 or less**, please tell us why:

2. If there are any aspects of H1N1 vaccination that you are not sure about, please describe them.

3a. Please evaluate each of the following **aspects of the training** by putting a check in the appropriate column.

Aspect	Very well 5	Well 4	Somewhat Well 3	Not to Well 2	Not at all 1
Achieved my personal expectations					
Content is relevant to my job					
Training method was effective					
Training was well organized					
Materials and handouts were useful					
Trainers and resource persons were knowledgeable					
Training room was conducive to learning					

3b. If you rated any aspect 3 or less, please tell us why:

Any other comments?

