

News Release

Public Health - Dayton & Montgomery County
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For Immediate Release

Some of those vaccinated at the December 17 H1N1 Clinic at Cross Pointe Center should be revaccinated

Public Health - Dayton & Montgomery County announced today that some of those vaccinated at the H1N1 Clinic on December 17 at Showcase Cinema at Cross Pointe Center in Centerville should be revaccinated. Health officials have reason to believe that some of the injectable vaccine (shots) used from the beginning of the clinic up until about 5:30 p.m. may have been frozen prior to use at the clinic. This involves 2,154 individuals.

Anyone who was vaccinated after 5:30 p.m. on December 17 at Showcase Cinema is properly protected. Additionally, those who received nasal spray and children from 6-35 months are properly protected, **regardless of the time they came through the clinic**, because they received a different kind of vaccine.

Dr. Thomas Herchline, Medical Director for Public Health, stressed, "This is not a safety-related issue with the vaccine, but has to do with the effectiveness of the vaccine if it has been stored outside the acceptable temperature range of 35-46 ° F." He cautioned, "We believe those who received shots from the start of the clinic up until 5:30 p.m. may not be fully protected by the shot they received." He explained, "When we discovered that there might be a problem with this particular batch of vaccine we were using, we immediately changed to another." He also noted that this issue is unique to this clinic and is not related to any other H1N1 clinic held by Public Health, including all school clinics.

Everyone who was vaccinated with the questionable vaccine has been contacted by phone by Public Health. Individuals will also receive a letter with additional details. The letter will encourage those affected to get revaccinated at their earliest convenience. It is very important that everyone understand that the situation is not a safety-related issue. There was no problem with the manufacturing of the vaccine. However, if the questionable vaccine was held at any time outside of the proper storage temperatures, it may not be fully protective. The only way to be sure you are protected, if you received this vaccine, is to be revaccinated.

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Montgomery County Health Commissioner Jim Gross, said, "We have vaccinated nearly 100,000 citizens so far, and are very dedicated to providing the best public health services for all of our citizens." "We sincerely apologize for the inconvenience this will cause some of those who were vaccinated on December 17," he continued. "We are in the process of investigating where and how the vaccine was frozen," Gross explained. "We do know the problem did not develop while the vaccine was under the control of Public Health - Dayton & Montgomery County," he stressed. "We have very stringent temperature control procedures, and we have temperature-sensitive warning devices on all our refrigerated storage units," he assured.

Additional information about this situation and upcoming H1N1 clinics can be found at phdmc.org or by calling the flu information line at 224-8796.

Questions and Answers about the need for some individuals to be revaccinated against H1N1

Can you tell us what happened?

Some of those vaccinated at the H1N1 clinic on December 17 at Showcase Cinema at Cross Pointe in Centerville received flu shots with vaccine that was frozen prior to use at the clinic. This is not a safety-related issue but has to do with the effectiveness of the vaccine if it has been stored outside the acceptable holding range of 35-46 ° F. If you received a flu shot at this clinic prior to 5:30 p.m., you should be revaccinated to make sure you are protected. Those who received flu mist and children from 6-35 months, do not need to be revaccinated regardless of the time they came through the clinic, because they received a different type of vaccine.

How many people were affected?

2154 vaccines were given prior to 5:30 p.m.

How are those who were affected being helped?

We are attempting to contact all the affected individuals both by phone and by letter to notify them that this is not a safety-related issue, but we recommend they be revaccinated to make sure they are adequately protected.

Is the situation under control?

Yes, we have isolated all of the remaining vaccine from the questionable batch and it will not be used.

Is there any immediate danger if I was vaccinated?

No, this is not a safety-related issue but has to do with the effectiveness of the vaccine. If you were among those affected, we recommend that you be revaccinated.

Is there a certain amount of time I need to wait before I am vaccinated again?

No, you can receive another vaccination at any time.

Do children under age 10 need to wait to be revaccinated if this was their 1st shot?

No, this first dose is invalid. You can repeat the first dose as soon as possible. You will still need an additional booster dose after 28 days, after the new valid vaccination.

Do children under age 10 need to wait to be revaccinated if this was their 2nd shot?

No. You should get revaccinated as soon as possible.

What is being done in response to what happened?

We are still investigating how the vaccine could have become frozen. We are confident that all of our vaccine storage and temperature control systems at Public Health - Dayton & Montgomery County were, and are functioning properly.

What can we expect next?

We are planning another clinic at Showcase Cinema at Cross Pointe in Centerville on Tuesday December 29 from 2 p.m. till 6 p.m., in order that those affected can be revaccinated.

What are you advising people to do?

People should get revaccinated as soon as possible. We encourage everyone to check phdmc.org and local media for additional information about H1N1. They can also continue to call the flu information line at 224-8796 with questions.

What are you doing now?

We are following the directives of the Ohio Department of Health, and planning to revaccinate all of those affected at upcoming clinics as soon as possible.

Why did this happen?

We believe that sometime prior to Public Health - Dayton & Montgomery County receiving this lot of vaccine, the temperature control standards to maintain the vaccine between 35-46 °F were not followed.

How did you discover the problem?

During the clinic, nurses while drawing up the vaccine for use in the clinic, discovered that some vaccine located in the center of the batch of 3000 units, was frozen. Therefore, all of the vaccine in that batch was considered unacceptable.

How do we know this won't happen again?

Since our quality assurance procedures detected this problem, we have implemented additional precautionary procedures to insure this does not happen again. We will be doing additional visual inspection of random samples of shipments when received. We intend to limit transfer of vaccine from some sources. Additionally, we are purchasing equipment for enhanced on-site temperature monitoring and expanding some quality control procedures.

Who is to blame?

We have quality standards for maintaining, packing, and transporting vaccine to the delivery site. Since we followed all of our normal procedures and all of our systems were working properly, we believe the vaccine was frozen prior to being delivered to us.

Could this have been avoided?

We are not sure exactly where the problem occurred but we are still investigating.

When did your response to this begin?

We took corrective action as soon as the problem was detected, about 5:30 p.m., on December 17. We immediately stopped using the questionable batch and started using a new batch of vaccine.

Has this ever happened before?

We are not aware of this problem ever happening at any of our other clinics.

What would you like to say to those that have been affected?

We are very dedicated to providing the best public health services for all of our citizens, and we sincerely apologize for the inconvenience this will cause those who have already taken the proper steps to protect themselves by getting vaccinated against the H1N1 virus.

Why didn't we hear about this until Monday December 21?

We determined immediately that this is not a safety-related issue, and we have been further investigating to determine the extent of the situation. We also wanted to arrange another clinic at the same location as quickly as possible to assist with the revaccinations. Establishing a new clinic for December 29 and preparing to inform all those affected by phone and letter has taken some time.