5. When should I get influenza vaccine?

You can get the vaccine as soon as it is available, usually in the fall, and for as long as illness is occurring in your community. Influenza can occur any time, but most influenza occurs from November through May. In most seasons, most infections occur in January and February.

Getting vaccinated in December, or even later, will still be beneficial in most years. Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need 2 doses to be protected. Ask your provider.

Influenza vaccine may be given at the same time as other vaccines.

6. What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses very rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine can cause mild symptoms in people who get it (see below).

Mild problems: Some children and adolescents 2–17 years of age have reported mild reactions, including:

• Runny nose, nasal congestion or cough
• Fever
• Headache and muscle aches
• Wheezing
• Abdominal pain or occasional vomiting or diarrhea

Some adults 18–49 years of age have reported:

• Runny nose or nasal congestion
• Sore throat
• Cough, chills, tiredness/weakness
• Headache

Severe problems:

• Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.
• If rare reactions occur with any product, they may not be identified until thousands, or millions, of people have used it. Millions of doses of LAIV have been distributed since it was licensed, and no serious problems have been identified. Like all vaccines, LAIV will continue to be monitored for unusual or severe problems.

7. What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes: Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

• Call a doctor, or get the person to a doctor right away.
• Tell the doctor what happened, the date and time it happened, and when the vaccination was given.
• Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS Web site at www.vaers.hhs.gov, or by calling 1–800–822–7967.

VAERS does not provide medical advice.

8. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1–800–338–2382, or visiting the VICP Web site at www.hrsa.gov/vaccinecompensation.

9. How can I learn more?

• Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
• Call your local or state health department.
• Contact the Centers for Disease Control and Prevention (CDC):
  —Call 1–800–232–4636 (1–800–CDC–INFO) or

Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Information Statement, Live, Attenuated Influenza Vaccine, (00/00/0000) (Proposed) 42 U.S.C. 300aa–26.


Tanja Popovic,
Deputy Associate Director for Science, Centers for Disease Control and Prevention.
period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

1. A concise description of the benefits of the vaccine,
2. A concise description of the risks associated with the vaccine,
3. A statement of the availability of the National Vaccine Injury Compensation Program, and
4. Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and trivalent influenza vaccines.

Instructions for use of the vaccine information materials and copies of the materials can be found on the CDC Web site at: http://www.cdc.gov/vaccines/pubs/VIS/. In addition, single-cameraready copies may be available from State health departments. A list of State health department contacts for obtaining copies of these materials is included in a December 17, 1999 Federal Register notice (64 FR 70914).

**Proposed Measles, Mumps, Rubella (MMR); Varicella; and Measles, Mumps, Rubella & Varicella (MMRV) Vaccine Information Materials**

On May 7, 2010 the Advisory Committee on Immunization Practices (ACIP) published recommendations on the use of combined Measles, Mumps, Rubella and Varicella (MMRV) vaccine. Because CDC/ACIP are now expressing a preference for use of MMRV vaccine (over MMR + V given separately) in some circumstances and the two separate vaccines in other circumstances, CDC is proposing publication of unique vaccine information materials for MMRV vaccine, which are included in this notice. In addition, CDC is proposing updated versions of the separate MMR and varicella vaccine information materials, containing information about MMRV vaccine.

**Development of Vaccine Information Materials**

The vaccine information materials referenced in this notice are being developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and health care provider groups.

In addition, we invite written comment on the proposed vaccine information materials that follow, entitled “Measles, Mumps, Rubella (MMR) Vaccine: What You Need to Know;” “Varicella Vaccine: What You Need to Know;” and “Measles, Mumps, Rubella and Varicella (MMRV) Vaccine: What You Need to Know.” Comments submitted will be considered in finalizing these materials. When the final materials are published in the Federal Register, the notice will include an effective date for their mandatory use.

We also propose to revise the June 9, 2010 Instructions for the Use of Vaccine Information Statements to include a reference to these vaccine information materials.

* * * * *

**Proposed MMR Vaccine Information Statement**

Measles, Mumps and Rubella (MMR) Vaccines: What You Need to Know 1. Why get vaccinated?

Measles, mumps, and rubella are serious diseases.

**Measles**
- Measles virus causes rash, cough, runny nose, eye irritation, and fever.
- It can lead to ear infection, pneumonia, seizures (jerking and staring), brain damage, and death.

**Mumps**
- Mumps virus causes fever, headache, and swollen glands.
- It can lead to deafness, meningitis (infection of the brain and spinal cord covering), painful swelling of the testicles or ovaries, and rarely sterility or death.

**Rubella (German Measles)**
- Rubella virus causes rash, mild fever, and arthritis (mostly in women).
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

You or your child could catch these diseases by being around someone who has them. They spread from person to person through the air.

Measles, mumps, and rubella (MMR) vaccine can prevent these diseases. Most children who get their MMR shots will not get these diseases. Many more children would get them if we stopped vaccinating.

2. Who should get MMR vaccine and when?

Children should get 2 doses of MMR vaccine:

—The first at 12–15 months of age
—And the second at 4–6 years of age.

These are the recommended ages. But children can get the second dose at any age, as long as it is at least 28 days after the first dose.

Some adults should also get MMR vaccine: Generally, anyone 18 years of age or older who was born after 1956 should get at least one dose of MMR vaccine, unless they can show that they have had either the vaccines or the diseases.

Ask your provider for more information.

MMR vaccine may be given at the same time as other vaccines.

**Note:** Children 12 years of age and younger can receive a “combination” vaccine called MMRV, which contains both MMR and varicella (chickenpox) vaccines. See the MMRV Vaccine Information Statement for more information.

3. Some People Should Not Get MMR Vaccine or Should Wait

- People should not get MMR vaccine who have ever had a life-threatening allergic reaction to gelatin, the antibiotic neomycin, or to a previous dose of MMR vaccine.
- People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting MMR vaccine.
- Pregnant women should wait to get MMR vaccine until after they have given birth. Women should avoid getting pregnant for 4 weeks after getting MMR vaccine.
- Some people should check with their doctor about whether they should get MMR vaccine, including anyone who:
  - Has HIV/AIDS, or another disease that affects the immune system.
  - Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer.
  - Has any kind of cancer.
What should I look for?

4. What are the risks from MMR vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of MMR vaccine causing serious harm, or death, is extremely small.

Getting MMR vaccine is much safer than getting any of these three diseases.

Most people who get MMR vaccine do not have any problems with it.

Mild Problems

- Fever (up to 1 person out of 6)
- Mild rash (about 1 person out of 20)
- Swelling of glands in the cheeks or neck (rare)
- Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)
- Seizure (jerk or staring) caused by fever (about 1 out of 3,000 doses)
- Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4)
- Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)
- Severe Problems (Very Rare)
  - Serious allergic reaction (less than 1 out of a million doses).
  - Several other severe problems have been known to occur after a child gets MMR vaccine. But this happens so rarely, experts cannot be sure whether they are caused by the vaccine or not. These include:
    - Deafness,
    - Long-term seizures, coma, or lowered consciousness,
    - Permanent brain damage.

Note: The first dose of MMRV vaccine has been associated with rash and higher rates of fever than MMR and varicella vaccines given separately. Rash has been reported in about 1 person in 20 and fever in about 1 person in 5.

If these problems occur, it is usually within 7–12 days after the shot. They occur less often after the second dose.

Moderate Problems

- Seizure (jerk or staring) caused by fever (about 1 out of 3,000 doses)
- Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4)
- Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)
- Severe Problems (Very Rare)
  - Serious allergic reaction (less than 1 out of a million doses).
  - Several other severe problems have been known to occur after a child gets MMR vaccine. But this happens so rarely, experts cannot be sure whether they are caused by the vaccine or not. These include:
    - Deafness,
    - Long-term seizures, coma, or lowered consciousness,
    - Permanent brain damage.

Note: The first dose of MMRV vaccine has been associated with rash and higher rates of fever than MMR and varicella vaccines given separately. Rash has been reported in about 1 person in 20 and fever in about 1 person in 5.

If these problems occur, it is usually within 7–12 days after the shot. They occur less often after the second dose.

Severe Problems (Very Rare)

- Serious allergic reaction (less than 1 out of a million doses).
- Several other severe problems have been known to occur after a child gets MMR vaccine. But this happens so rarely, experts cannot be sure whether they are caused by the vaccine or not. These include:
    - Deafness,
    - Long-term seizures, coma, or lowered consciousness,
    - Permanent brain damage.

Note: The first dose of MMRV vaccine has been associated with rash and higher rates of fever than MMR and varicella vaccines given separately. Rash has been reported in about 1 person in 20 and fever in about 1 person in 5.

If these problems occur, it is usually within 7–12 days after the shot. They occur less often after the second dose.

5. What if there is a severe or moderate reaction?

What should I look for?

Any unusual condition, such as a fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS Web site at http://www.vaers.hhs.gov, or by calling 1–800–822–7967.
- VAERS does not provide medical advice.

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine may file a claim with VICP by calling 1–800–338–2382 or visiting their Web site at http://www.hrsa.gov/vaccinecompensation.

7. How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1–800–232–4636 (1–800–CDC–INFO)
  - Visit CDC’s Web site at http://www.cdc.gov/vaccines
- Department of Health and Human Services Centers for Disease Control and Prevention
- Vaccine Information Statement

MMR Vaccine

[00/00/0000] (Proposed)

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Proposed Varicella (Chickenpox) Vaccine Information Statement

Chickenpox Vaccine: What You Need to Know

1. Why get vaccinated?

Chickenpox (also called varicella) is a common childhood disease. It is usually mild, but it can be serious, especially in young infants and adults.

- It causes a rash, itching, fever, and tiredness.
- It can lead to severe skin infection, scars, pneumonia, brain damage, or death.

- The chickenpox virus can be spread from person to person through the air, or by contact with fluid from chickenpox blisters.
- A person who has had chickenpox can get a painful rash called shingles years later.
- Before the vaccine, about 11,000 people were hospitalized for chickenpox each year in the United States.
- Before the vaccine, about 100 people died each year as a result of chickenpox in the United States.

Chickenpox vaccine can prevent chickenpox.

Most people who get chickenpox vaccine will not get chickenpox. But if someone who has been vaccinated does get chickenpox, it is usually very mild. They will have fewer blisters, are less likely to have a fever, and will recover faster.

2. Who should get chickenpox vaccine and when?

Routine

Children who have never had chickenpox should get 2 doses of chickenpox vaccine at these ages:

1st Dose: 12–15 months of age

2nd Dose: 4–6 years of age (may be given earlier, if at least 3 months after the 1st dose)

People 13 years of age and older (who have never had chickenpox or received chickenpox vaccine) should get two doses at least 28 days apart.

Catch-Up

Anyone who is not fully vaccinated, and never had chickenpox, should receive one or two doses of chickenpox vaccine. The timing of these doses depends on the person’s age. Ask your provider.

Chickenpox vaccine may be given at the same time as other vaccines.

Note: Children 12 years of age and younger can receive a “combination” vaccine called MMRV, which contains both MMR and varicella (chickenpox) vaccines. See the MMRV Vaccine Information Statement for more information.

3. Some People Should Not Get Chickenpox Vaccine or Should Wait

- People should not get chickenpox vaccine if they have ever had a life-threatening allergic reaction to a previous dose of chickenpox vaccine or to gelatin or the antibiotic neomycin.
- People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting chickenpox vaccine.
- Pregnant women should wait to get chickenpox vaccine until after they have
given birth. Women should not get pregnant for 1 month after getting chickenpox vaccine.

- Some people should check with their doctor about whether they should get chickenpox vaccine, including anyone who:
  - Has HIV/AIDS or another disease that affects the immune system
  - Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer
  - Has any kind of cancer
  - Is getting cancer treatment with radiation or drugs
- People who recently had a transfusion or were given other blood products should ask their doctor when they may get chickenpox vaccine.

Ask your provider for more information.

4. What are the risks from chickenpox vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of chickenpox vaccine causing serious harm, or death, is extremely small.

Getting chickenpox vaccine is much safer than getting chickenpox disease. Most people who get chickenpox vaccine do not have any problems with it. Reactions are usually more likely after the first dose than after the second.

Mild Problems

- Soreness or swelling where the shot was given (about 1 out of 5 children and up to 1 out of 3 adolescents and adults)
- Fever (1 person out of 10, or less)
- Mild rash, up to a month after vaccination (1 person out of 25). It is possible for these people to infect other members of their household, but this is extremely rare.

Moderate Problems

- Seizure (jerking or staring) caused by fever (very rare).

Severe Problems

- Pneumonia (very rare).
- Other serious problems, including severe brain reactions and low blood count, have been reported after chickenpox vaccination. These happen so rarely experts cannot tell whether they are caused by the vaccine or not. If they are, it is extremely rare.

Note: The first dose of MMRV vaccine has been associated with rash and higher rates of fever than MMR and varicella vaccines given separately. Rash has been reported in about 1 person in 20 and fever in about 1 person in 5.

Seizures caused by a fever are also reported more often after MMRV. These usually occur 5–12 days after the first dose.

5. What if there is a severe or moderate reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. You can file this report through the VAERS Web site at http://w.vaers.hhs.gov, or by calling 1–800–822–7967.

VAERS does not provide medical advice.

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine may file a claim with VICP by calling 1–800–338–2382 or visiting their Web site at http://www.hrsa.gov/vaccinecompensation.

7. How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1–800–232–4636 (1–800–CDC–INFO)
  - Visit CDC’s Web site at http://www.cdc.gov/vaccines

Department of Health and Human Services

Centers for Disease Control and Prevention

Vaccine Information Statement

Varicella Vaccine

(00/00/0000) (Proposed)

42 U.S.C. 300a–26

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Proposed MMRV Vaccine Information Statement

Measles, Mumps, Rubella & Varicella (MMRV) Vaccine: What You Need To Know

1. Measles, Mumps, Rubella, and Varicella

Measles, Mumps, Rubella, and Varicella (chickenpox) can be serious diseases:

- Measles
  - Causes rash, cough, runny nose, eye irritation, fever.
  - Can lead to ear infection, pneumonia, seizures (jerking and staring), brain damage, and death.
- Mumps
  - Causes fever, headache, swollen glands.
  - Can lead to deafness, meningitis (infection of the brain and spinal cord covering), infection of the pancreas, painful swelling of the testicles or ovaries, and rarely sterility or death.
- Rubella (German Measles)
  - Causes rash and mild fever; and can cause arthritis (mostly in women).
  - If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.
- Varicella (Chickenpox)
  - Causes rash, itching, fever, tiredness.
  - Can lead to severe skin infection, scars, pneumonia, brain amage, or death.
  - Can re-emerge years later as a painful rash called shingles.

These diseases can spread from person to person through the air. Varicella can also spread through contact with fluid from chickenpox blisters.

Before vaccines, these diseases were very widespread in the United States.

2. MMRV Vaccine

MMRV vaccine may be given to children from 1 through 12 years old to protect them from these four diseases. Two doses of MMRV vaccine are recommended:

- The first dose at 12 through 15 months of age
- The second dose at 4 through 6 years of age

These are recommended ages. But children may also get these vaccines as 2 separate shots: MMR (measles, mumps and rubella) and varicella.
1 Shot (MMRV) or 2 Shots (MMR & Varicella)?

- Both options give the same protection.
- Fewer injections with MMRV.
- MMRV has been associated with more fevers and fever-related seizures than MMR and varicella vaccines given separately (first dose only).

Unless you specifically request otherwise, CDC recommends separate MMR and varicella vaccines for the first dose and MMRV vaccine for the second dose.

Your health-care provider can give you more information, including the Vaccine Information Statements for MMR and Varicella vaccines.

- MMRV may be given at the same time as other vaccines.

3. Some Children Should Not Get MMRV Vaccine or Should Wait

Children should not get MMRV vaccine if they:

- Have ever had a life-threatening allergic reaction to a previous dose of MMRV vaccine, or to either MMR or varicella vaccine
- Have ever had a life-threatening allergic reaction to any component of the vaccine, including gelatin or the antibiotic neomycin. Tell the doctor if your child has any severe allergies.
- Have HIV/AIDS, or another disease that affects the immune system
- Are being treated with drugs that affect the immune system, such as high doses of steroids by mouth, for 2 weeks or longer
- Have any kind of cancer
- Are being treated for cancer with radiation or drugs
- Check with your doctor if the child:
  - Has a history of seizures, or has a parent, brother or sister with a history of seizures
  - Has a parent, brother or sister with a history of immune system problems
  - Has ever had a low platelet count, or another blood disorder
  - Recently had a transfusion or received other blood products
  - Might be pregnant

Children who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting MMRV vaccine.

Ask your provider for more information.

4. What are the risks from MMRV vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of MMRV vaccine causing serious harm, or death, is extremely small.

Getting MMRV vaccine is much safer than getting any of these four diseases.

Most children who get MMRV vaccine do not have any problems with it.

Mild Problems

- Fever (about 1 child out of 5)
- Mild rash (about 1 child out of 20)
- Swelling of glands in the cheeks or neck (rare)

If these problems occur, it is usually within 5–12 days after the first dose. They occur less often after the second dose.

Moderate Problems

- Seizure caused by fever (about 1 child in 1,250). These seizures usually occur 5–12 days after the first dose. They occur less often when MMR and varicella vaccines are given together as separate injections (about 1 child in 2,500), and rarely after a 2nd dose of MMRV.
- Temporary low platelet count, which can cause a bleeding disorder (about 1 child out of 40,000)

Severe Problems (Very Rare)

Several severe problems have been reported following MMR vaccine, and might also occur after MMRV. These include severe allergic reactions (fewer than 4 per million), and problems such as:

- Deafness
- Long-term seizures, coma, lowered consciousness
- Permanent brain damage

Because these problems occur so rarely, we can’t be sure whether they are caused by the vaccine or not.

5. What if there is a severe reaction?

What should I do?

- Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.
- What should I look for?

5. What if there is a severe reaction?

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.
- You can file this report through the VAERS Web site at http://www.vaers.hhs.gov, or by calling 1–800–822–7967.

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7. How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1–800–232–4636 (1–800–CDC–INFO)
- Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Information Statement, MMRV Vaccine, (00/00/0000) (Proposed)


Tanja Popovic,
Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2010–19785 Filed 8–10–10; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1923–DR; Docket ID FEMA–2010–0002]

Wyoming; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Wyoming (FEMA–1923–DR), dated July 14, 2010, and related determinations.

DATES: Effective Date: August 4, 2010.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Directorate,