

衛生福利部疾病管制署

輪狀病毒疫苗

衛福部 疾病管制署
中區傳染病防治醫療網
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美國輪狀病毒醫療負擔

- 每年感染人數300萬人
- 每年>40萬輪狀病毒門診人次
- 每年20萬輪狀病毒急診人次
- 每年5.5-7萬輪狀病毒住院人次
- 每年20-60輪狀病毒死亡人數

Source: MMWR 2006;55 (RR-12)

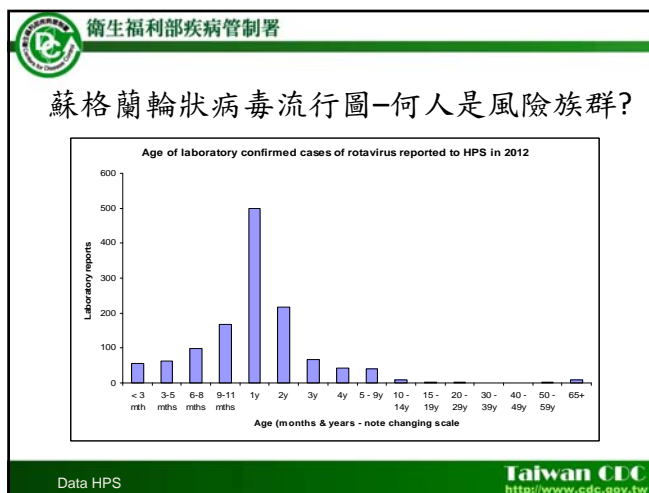
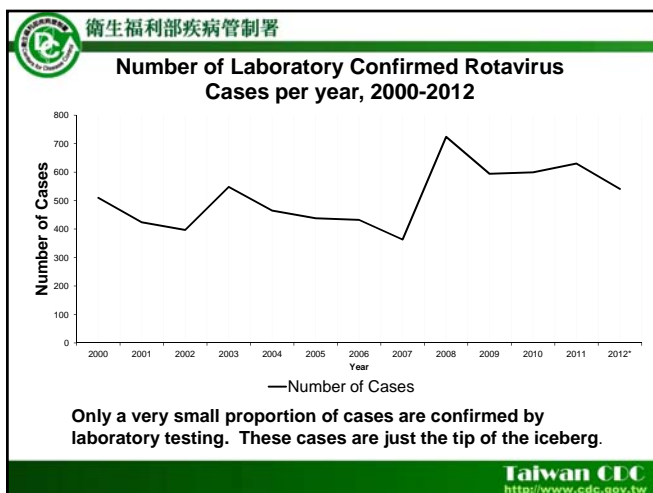
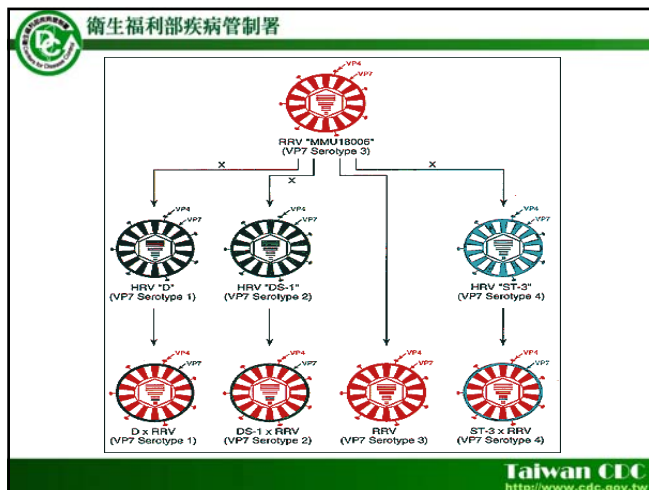
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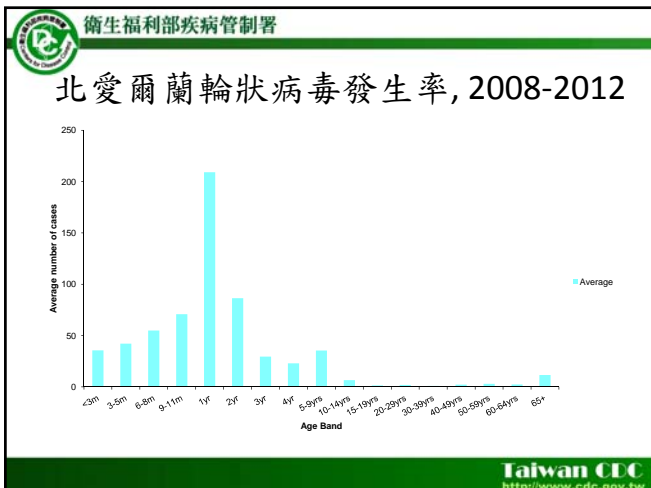
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早期輪狀病毒疫苗

- 為活的四架猴-人重配株疫苗，商品名Rotashield
- 1998年8月上市
- 1999年10月因有腸套疊風險而下市
- 腸套疊發生在施打疫苗後3-20天
- 發生率15病例/150萬施打劑量
- 新的疫苗來自牛的輪狀病毒

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Is there a vaccine against rotavirus?

- Currently there are 2 rotavirus vaccines:
 - RotaTeq™ (MSD)
 - Rotarix™ (gsk)
- Main characteristics
 - Both are highly effective and safe
 - Both protect against severe forms of rotavirus disease
 - Both do not protect against diarrhea caused by other agents than rotavirus

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Why vaccinate against rotavirus?

Effectiveness of the vaccine

- Very effective at protecting against the most common strains of rotavirus.
- Very effective in protecting against severe rotavirus infection requiring hospitalisation.

	1 st Year of Life Rotarix N = 2572 Placebo N = 1302	2 nd Year of Life Rotarix N = 2554 Placebo N = 1294
Vaccine efficacy (%) against rotavirus gastro-enteritis requiring medical attention [95% CI]		
Circulating rotavirus strains	91.8 [84; 96.3]	76.2 [63.0; 85.0]
Vaccine efficacy (%) against hospitalisation due to rotavirus gastro-enteritis [95% CI]		
Circulating rotavirus strains	100 [81.8; 100]	92.2 [65.6; 99.1]

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Rotavirus Vaccine and Intussusception

	接受疫苗接種者	接受安慰劑接種者
疫苗接種42天內	6個案	5個案
疫苗接種1年內	13個案	15個案

Source: *New Eng J Med* 2006;354:23-33

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RotaTeq Intussusception Reports Received by VAERS*

- 117 confirmed reports
 - 38 cases 1-21 days after vaccination
 - 23 cases 1-7 days after vaccination
 - about one third of 38 cases occurred following the first dose
- 6 million vaccine doses distributed

*March 2006 through mid-June 2007

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Expected and Reported Cases of Intussusception After RotaTeq

Age Group	Number Expected*	Number Reported
6-14	30	14
15-23	36	14
24-35	33	10
Total	99	38


*Among children 6-35 weeks of age, within 21 days of a dose based on VSD data

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What is rotavirus vaccine presentation?

- Rotavirus vaccine is a ready-to-use, oral vaccine in a liquid formulation
 - Specially designed tube for direct oral administration
- 1 tube = 1 dose
- 1 tube has 2 mL liquid



A squeezable plastic tube

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How safe is the vaccine?

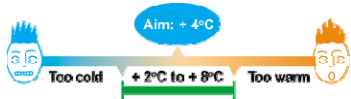
- Rotavirus vaccines are safe and do not cause any serious adverse events
- Irritability and loss of appetite are very common side effects of rotavirus vaccine
- Rotavirus vaccine may be given with other vaccines in the infant Expanded Program on Immunization (EPI) schedule without interfering with their effectiveness

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At which temperature must the vaccine be stored?

- Rotavirus vaccines should be stored between +2° C to +8° C



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Where do you store the vaccine?

- The rotavirus vaccine should be stored in a refrigerator

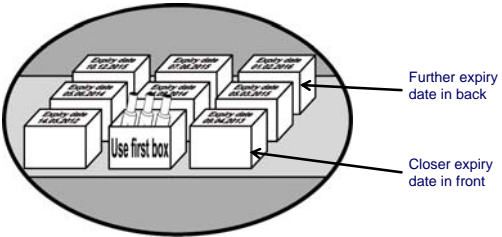


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Which vaccine should be stored in front?

- Vaccines with early expiration dates should be kept in front to be used first



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Handling RotaTeq™ with No VVM

- In the absence of a VVM, it is impossible to know if
 - vaccines have been exposed to high temperatures (above 8 degrees) and
 - for how long and
 - how many times
- It is extremely important that cold chain conditions are strictly maintained and closely monitored from vaccine receipt to vaccine administration.
- Temperatures should be recorded twice daily on a monitoring chart and corrective action taken immediately if there is a cold chain failure.

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Handling RotaTeq™ with No VVM: Outreach

- Careful micro-planning is needed so that the appropriate numbers of rotavirus tubes are placed in the vaccine carrier; this will minimize unnecessary wastage at the end of the session.
- Discard unopened vaccine RotaTeq tubes at the end of outreach or mobile sessions if there is no assurance that the cold chain was maintained.

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Handling RotaTeq™ with No VVM: Outreach

- To avoid wastage, careful planning for outreach and mobile sessions is needed:
 - Keep a due list that has names of all children needing Rotavirus vaccine
 - Put the RotaTeq vaccine in the vaccine carrier based on the number of children expected to get the vaccine
- Keep vaccine carrier in a cool place away from Sun
- Keep the RotaTeq vaccine inside the vaccine carrier until you are ready to give the vaccine

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Key messages



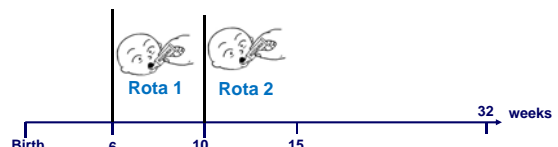
- Rotavirus vaccine is an oral vaccine has a liquid formulation
- Vaccine comes in a squeezable plastic tube
- RotaTeq vaccine comes without a VVM and therefore proper planning and handling is essential
- Store vaccines between +2° C to +8° C
- Vaccines with early expiration dates should be kept in front of the refrigerator to be used first
- Regularly monitor the temperature of the refrigerator
- Do not open the refrigerator door often

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What is the rotavirus vaccine schedule?: I

- Rotavirus vaccine is given in a 2-dose schedule at 6 and 10 weeks of age
- Rotavirus vaccine can be given at the same time as first and second dose of DTP-HepB-Hib (i.e. Penta1 & Penta2)
- Maintain an interval of **4 weeks** between doses



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What is the rotavirus vaccine schedule?: II

- First dose of vaccine should be given before **15 weeks**
- Second dose has to be given before **32 weeks**
- 16 weeks is too late for 1st dose and 33 weeks is too late for 2nd dose

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Absolute contraindications

- Hypersensitivity after previous administration of rotavirus vaccines
- Previous history of intussusception
- Administration of Rotarix™ should be postponed in subjects suffering from diarrhea or vomiting and in need of rehydration therapy

- Mild illness such as an upper respiratory tract infection or mild diarrhea is **not** a contraindication

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Key messages

- On-time vaccination is very important for rotavirus vaccine
- First dose of rotavirus should be given at 6 weeks of age
- Second dose should be given at 10 weeks of age
- Rotavirus vaccine can be given with other vaccines like pentavalent vaccine.

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How to check the quality of the vaccine?: I

- Before administering the vaccine, you need to check the Vaccine Vial Monitor (VVM) on the tube cap

- Stage 1: Vaccine OK
- Stage 2: Vaccine OK but use first
- Stage 1: Do not use the vaccine
- Stage 1: Do not use the vaccine

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How to check the quality of the vaccine?: II

- Before administering the vaccine, always check the expiration date on the tube cap

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How to prepare for vaccination? : I

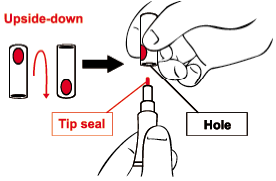
- Pull off the cap from the tube
- Clear the fluid from the upper part of the tube by tapping the tube

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How to prepare for vaccination? : II

- Turn the cap upside-down and place the cap vertically onto the tip seal
- Insert the tip seal into the small hole in the top of the cap

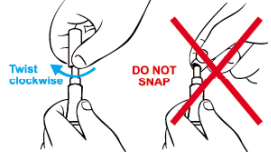


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How to prepare for vaccination? : III

- Twist the cap in the direction of the arrow (clockwise) to remove the tip seal
- Do not snap off tip seal as may fall inside the tube

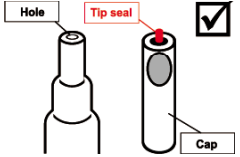


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How to prepare for vaccination? : IV

- Ensure that a hole clearly appears at the top of the tube
- Ensure that the detached tip seal is inside the top of the cap



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Can rotavirus vaccine be given at the same time as other childhood vaccines?


- Rotavirus vaccine can be administered with any of the following routine childhood vaccines without interfering with their effectiveness:
 - Diphtheria–tetanus–pertussis vaccine (DTP)
 - *Haemophilus influenzae* type b vaccine (Hib)
 - Inactivated polio vaccine (IPV)
 - Hepatitis B vaccine
 - Pneumococcal vaccine
 - Oral polio vaccine (OPV)
- Give the rotavirus vaccine **first**, then administer other childhood vaccines

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How to position the child for rotavirus vaccination?

- The child should be seated in a semi reclining position to take the vaccine orally




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How to position the vaccine?

- Open the child's mouth by gently pressing the cheeks together
- Angle the tube towards the inner cheek





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How to administer the vaccine?

- Administer the vaccine by pressing the tube
 - Squeeze the tube **slowly**
- Make sure the child is swallowing the vaccine
 - Hold the cheeks together and stroke him/her under the chin to help with swallowing





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What to do if the infant spits out part of the vaccine?


- A dose of rotavirus vaccine is larger than a dose of oral polio vaccine (Rotarix™ = 1.5 mL, Polio = 3 drops)
- To prevent spitting
 - Place the tip of the tube towards the inside of the child's cheek
 - Slowly** administer the vaccine in small portions
- A replacement dose is not needed if an incomplete dose is administered for any reason
 - E.g. infant spits or regurgitates the vaccine

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How many vials to take for outreach?

- Rotavirus vaccine can be given at the same time as pentavalent vaccine
- For outreach take the same amount of pentavalent single dose vials as rotavirus vaccine tubes
- Unused and sealed rotavirus tubes brought back from outreach should be immediately kept in the refrigerator for use in the next session



30 single doses



30 single doses

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Key messages

- Check and interpret vaccine vial monitor and check expiration date on the tube cap before giving the vaccine
- When opening the rotavirus vaccine tube, twist the tube cap clockwise to remove the tip seal
- Give the rotavirus vaccine and OPV first, then administer other injectable vaccines
- The rotavirus vaccine dose quantity is larger than that of oral polio vaccine (Rotarix™ 1.5 mL) and infants may not take the full dose all at once
 - To prevent spitting, slowly administer the vaccine in small amounts and properly place the tip of the tube towards the inside of the child's cheek
 - If the infant spits out some or all of the vaccine, the dose does not need to be given again during that visit



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輪狀病毒疫苗施打建議

- 3劑疫苗分別在出生2, 4, 6月施打
- 最早可自出生6周即可施打第一劑
- 第一劑可在出生6-12週時投予
- 第一劑不建議在出生12週後投予
- 二劑疫苗投予區間不得小於4週
- 所有三劑疫苗必須在出生32週前施打完畢
- 32週以後不建議再給疫苗

Source: MMWR 2006;55 (RR-12)

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