Module 6:
Other Considerations

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Module 6 : Other Considerations

- After completion of this module, learners will have a better understanding of:
  - Common PEP administration errors including:
    - No RIG administered when indicated.
    - RIG not infiltrated at the exposure site.
    - Vaccine and RIG given at same anatomical location.
    - RIG given to previously immunized individual.
    - Timing deviations.
  - Appropriate actions when a deviation in ACIP-recommended rabies PEP occurs.
  - How to address situations where rabies PEP was initiated overseas.

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Case 5:
A Cat Bite on the Face
Presentation

Chief Complaint:

Day 3 Vaccine Dose Needed

- A man, aged 42, was bitten on the face by a stray cat three days ago. The day of the incident, he visited an ED where rabies PEP was initiated. The doctors were hesitant to infiltrate RIG into the wounds on his face, so the full dose of RIG was given in his right deltoid. He received the first dose of rabies vaccine in his left deltoid.
- He arrives at your ED to get his day three vaccine. You note a deviation in RIG administration (RIG not being infiltrated into wounds). The cat is still missing.

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Case 5:
A Cat on the Face
Examination

Chief Complaint:
Day 3 Vaccine Dose Needed

- **Physical Findings:**

  Puncture wounds to the left mandible and scratch marks on the right and left sides of his neck.

- **Patient's Rabies Vaccination History:**

  Not previously vaccinated.

What's The Problem?

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The Problem

Deviations from the Centers for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP) guidelines occur when the administration of rabies postexposure prophylaxis (PEP) does not follow the recommended route of administration or schedule.

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Why Are ACIP Guidelines Deviations a Concern?

- Most serious consequence
  - PEP failure (death)
- Most common consequences
  - Excess medical costs, including extra hospital fees
  - Corrective doses of biologics
  - Serological testing
  - Indirect costs (time off work, travel, etc.)

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Common Rabies PEP Administration Errors

- No RIG administered
- RIG not infiltrated at the wound or exposure site
- Vaccine and RIG given in the same anatomical location
- RIG given to a previously immunized individual
- Timing deviations

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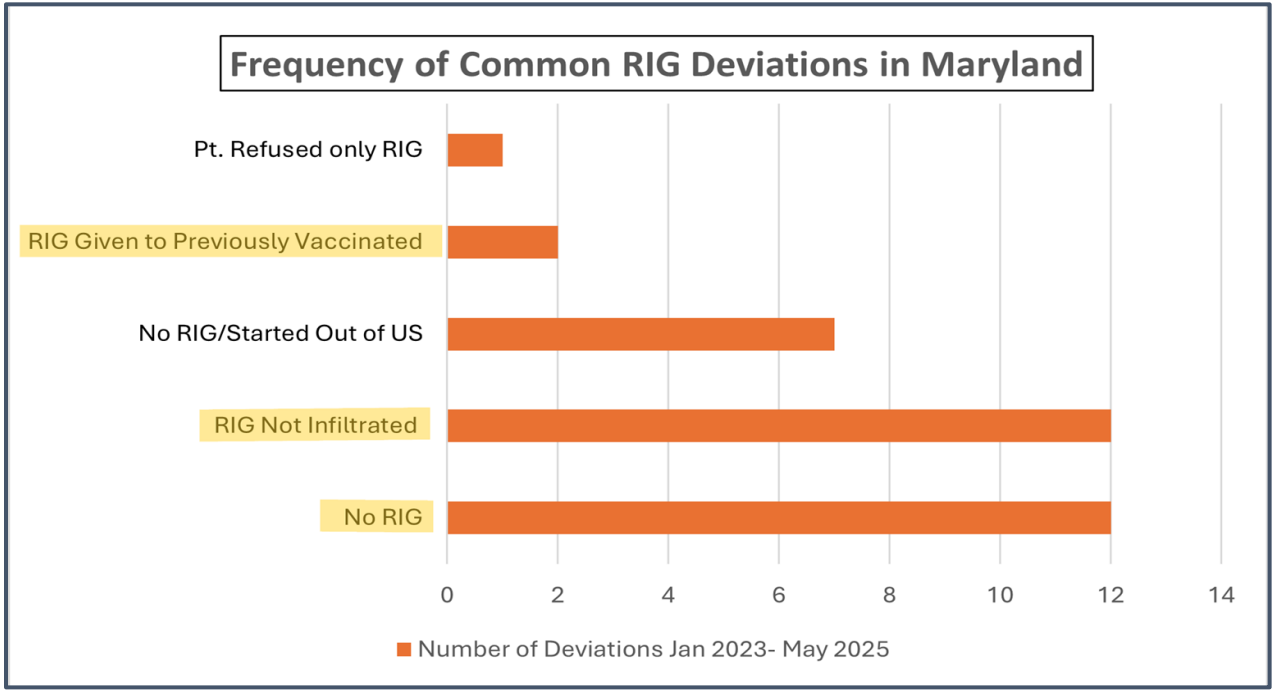
Most Frequent HRIG Deviations



Highlighted

Deviations are PREVENTABLE at the hospital level!

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Top Reasons For RIG Deviations

Top Reasons For Not Giving RIG	Top Reasons Cited for Not Infiltrating RIG into Wound
• Provider felt it had been too long since the exposure • No visible mark (ex., healed wound or bat exposure)	• Severity of wound • Location of the wound (ex., head or neck) • Wound already starting to heal

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RIG Not Administered on Day 0

Deviation:

- Administration of RIG was not done at the time rabies PEP was initiated.

Corrective Action:

- RIG may be administered up and including the seventh day after the first vaccine dose.
- RIG is not indicated beyond this point because an antibody response to the cell culture vaccine is presumed to have occured.

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RIG Not Infiltrated at Wound or Exposure Site

Deviation:

- Patient was administered a full dose of RIG without having the wound(s) or exposure site(s) infiltrated appropriately.

Corrective Action:

- Administration of additional RIG (as much as is anatomically feasible) into and around the wound(s) within seven days after the first dose of vaccine may be indicated, especially for exposure to animals that are confirmed to be rabid or are a high-suspect for rabies.
- Total RIG volume from initial and repeat doses should not exceed twice the recommended dose or the immune response may be blunted.

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RIG Not Infiltrated Corrective Action

Corrective Action (cont):

- Re-administration of RIG should include only the volume sufficient to infiltrate into and around the wound(s) **(even if completely healed)** up to a maximum volume of a full repeat dose.
    - A clinical study has supported that up to twice the calculated dose of RIG can be administered to a patient without significantly compromising the immune response.
- If the wound has healed, or there is no obvious wound at the anatomic site of exposure, **RIG should still be administered at the site where the contact or wound occurred.**

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RIG Not Infiltrated: Corrective Action Cont.

Corrective Action (cont):

- Even if only a small amount of RIG can be infiltrated, an attempt should be made to instill RIG at the site of a rabies exposure.
- This includes PEP provided due to **bat-skin contact** in the absence of a visible wound, but where there is concern because of the possibility of a bat bite, and the site of bat contact is known.
- The only exceptions are mucous membrane exposures and bat exposures in which there is no information about the site of exposure.
    - The entire dose of RIG must be administered IM at an anatomic site distant from the site of rabies vaccination.

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RIG Given to Previously Immunized Individual

Corrective Actions:

- Contraindicated because it may interfere with the anamnestic/immune response to the rabies vaccine.
- If RIG is erroneously given, the patient should receive an extra dose of vaccine on or after day seven.
    - This recommendation is not part of the national ACIP guidelines, but has been suggested by the CDC as a precautionary measure. Please contact your state or local health department for additional guidance regarding corrective actions.

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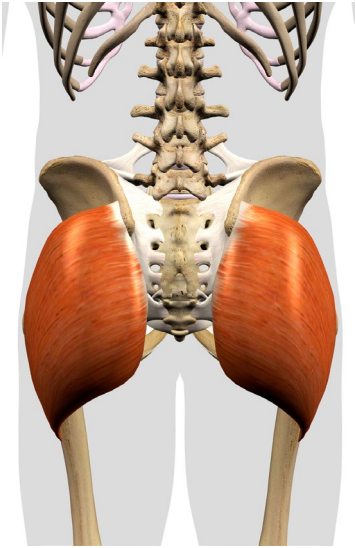
Vaccine Given in the Gluteal Area



Deviation:

- Rabies vaccine administered in the gluteal area.

Corrective Action:

- Rabies vaccine dose should be treated as if it were not given and another rabies dose should be administered. The subsequent doses should be shifted to maintain the same (0, 3, 7, 14) intervals between doses.

The administration of rabies vaccine in the gluteal area has been attributed to PEP failure and death!

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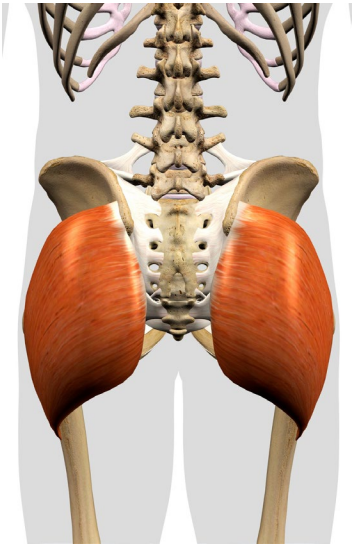
RIG Given in the Gluteal Area

Although RIG administration in the gluteal area is not contraindicated, due to concerns about absorption and sciatic nerve damage, the gluteal area is the site of **LAST RESORT** for RIG administration and should only be used if it is the site of exposure or there are no other available options.

No corrective action is needed.



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Vaccine and RIG Given in the Same Muscle

Deviation:

- Rabies vaccine administered in the same muscle/anatomical site as RIG*.

* Subsequent doses of vaccine in the 5-dose series can be administered in the same anatomic location where the HRIG dose was administered, if this is the preferable site for vaccine administration.

Corrective Action:

- Rabies vaccine and RIG dose should be treated as if it were not given and another rabies dose and RIG (if within the window) should be administered. The subsequent doses should be shifted to maintain the same (0, 3, 7, 14) intervals between doses.

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Vaccine and RIG Same Muscle: Corrective Action

Corrective Action (cont):

- If within the first two days following RIG administration, the vaccine dose should be given as soon as possible in an appropriate body site, and that dose will now be considered “day 0”.
- If subsequent vaccine doses have already been given, the “day 3” dose should be treated as “day 0” and the schedule adjusted accordingly to keep the same spacing in between vaccine doses.

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Vaccine Timing Deviations

Corrective Action:

- A deviation of a single day from the recommended schedule should be managed by maintaining vaccine doses as per the original schedule, keeping the intervals between doses the same, if possible.

- If deviations of greater than a single day from the original schedule are necessary or unavoidable, all subsequent doses should be administered on a new schedule adjusted for the time delay.
- Significant (greater than seven days) deviation from the schedule, antibody titers should be verified on a serum sample collected 1-2 weeks after the final vaccine dose.

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Vaccine Timing Deviations: Schedule Generator

CDC Rabies Post-Exposure Prophylaxis Schedule Generator can be used to help determine dose spacing based on dates entered by the user.

https://www.cdc.gov/rabies/hcp/clinical-care/pep-calculator.html

Note: *This is a decision-support tool only. It does not replace clinical judgment or public health consultation. Any deviations or errors require consultation with public health authorities.*

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Handling Schedule Delays

Interval preservation

Resume the schedule by maintaining the specific required intervals between all remaining doses.

Original Schedule Target	Scenario: Missed Day 3 Maintenance Dose	Actual Administration	Resulting Schedule Shift
Dose 2: Day 3 Dose 3: Day 7	~~Day 3~~	Dose 2: Day 5 (Delayed)	Next Dose Adjustment: Dose 3: Day 9 (4 days later)

1-Day Deviations

If the delay is only 24 hours, maintain original intervals if possible.

>1-Day Deviations

Adjust the entire remaining schedule to account for the specific time delay.

Significant Deviations (>7 Days)

Verify antibody titers 1–2 weeks after the final dose is administered.

Key Points: PEP Deviations

- RIG should be administered to all persons getting rabies PEP, unless the person has previously been vaccinated.
- RIG **must** be infiltrated around the wound/exposure site.
- RIG and vaccine should **never** be administered in the same anatomical loca
- Vaccine should **never** be administered in the gluteus.
- Gluteus can be used for RIG administration, but should be done only as a **last resort** after all other anatomic sites (e.g., opposite deltoid, thigh) have been considered.
- Call Local/State Health Department for assistance/guidance, postvaccination serological testing may be recommended to verify immune response.

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Case 5:
A Cat on the Face
Risk Assessment

Risk Assessment:

- It is reasonable to suspect that the cat involved in this scenario could be rabid. The cat is still missing, and therefore, there is no new information to support the decision to discontinue PEP.
- The patient sustained face and neck wounds, elevating the urgency of treatment following exposure due to the proximity of the exposure sites to the central nervous system. If the cat is rabid, failure to infiltrate wounds with RIG may result in rabies PEP failure and death.

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Case 5:
A Cat on the Face
PEP Determination

PEP Determination:

- Infiltrate as much RIG as anatomically feasible into and around the wounds up to a maximum volume of a full repeat dose.
- Administer the additional doses of the vaccine per the ACIP schedule.
- Consult the local or state health department to determine if postvaccination serological testing is advisable.

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Care Received Outside of The United States

- If a patient received rabies PEP outside the United States, the regimen may have included medications not approved for use in the United States. Therefore, additional therapy/corrective actions might be necessary.
- Considerations include:
  - Was it a WHO recognized schedule?
  - Was it a reliable vaccine product (check for fraud alerts on CDC website and make sure it is a modern cell-culture vaccine product)?
  - Was the vaccine administered via the appropriate route?
  - Was the vaccine properly stored (ALL rabies vaccines require cool-storage and should never be sitting at room temp)?

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Care Outside of The United States: Next Steps

- **If there are any doubts as to the storage, quality, or method of administration of the vaccine, consult your health department to discuss additional steps.**
- Serological testing may be needed to confirm adequate response 14-28 days after completion of PEP. An RFITT result of ***0.5 IU/mL or higher*** is considered an adequate immune antibody response.

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Knowledge Check Module 6

TRUE OR FALSE?

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Knowledge Check Question 1

TRUE OR FALSE?

RIG should always be infiltrated into the site of exposure (if known), even if there is no obvious bite or scratch mark or if it is on a painful area like the hand or face.

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Knowledge Check Question 1 Answer

If you answered <u>TRUE</u>, you were correct.

RIG is an essential step in the PEP process for persons not previously vaccinated against the rabies virus. RIG provides passive antibodies that neutralize the rabies virus before it enters the peripheral nerves and provides protection before vaccine-induced immunity appears.

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Module 6 Conclusion

Exit and continue to the next module

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