Acquired hemophilia. 

A rare, spontaneous, and potentially deadly condition

- Only 1 to 1.5 per million people are affected yearly.
- Characterized by an inhibitor antibodies to FXVII that appears spontaneously.

Associated with severe and life-threatening bleeding

- Up to 2% mortality rate.

Often involving a delayed diagnosis

- 30% of patients go undiagnosed for more than 7 days.

Who “acquires” acquired hemophilia?

- Underlying conditions include autoimmune disorders, malignancies, dermatologic disorders, and pregnancy; however, in approximately 60% of patients, the cause is unknown.

Signs include:

- Isolated prolonged aPTT
- Petechiae and soft tissue hematomas
- Gastrointestinal, urological, retroperitoneal, or postpartum bleeding
- Prolonged bleeding following surgery

A delay could put your patients at risk

Prompt diagnosis of acquired hemophilia may impact care.

Stop the bleed with the only bypassing agent

FDA approved for acquired hemophilia

Important Safety Information (cont’d)

Adverse Reactions

- The most common and serious adverse reactions in clinical trials are thrombotic events.
- Thrombosis, adverse events following the administration of NovoSeven® RT in clinical trials occurred in 4% of patients with acquired hemophilia and 0.2% of bleeding episodes in patients with congenital hemophilia.

Please see additional important safety information, including Black Box Warning, throughout.

Important Safety Information

Indications and Usage

NovoSeven® RT (Coagulation Factor VIIa [Recombinant]), is a coagulation factor indicated for:

- Treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia
- Treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia

Please see accompanying Prescribing Information.

References:

2. Patients with acquired hemophilia A.

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Model is used for illustrative purposes only.
An acquired hemophilia case in which delayed diagnosis put a patient at risk

**The patient**

- A 60-year-old man with GI bleeding

**Initial presentation**

- Patient presented to the emergency department with GI bleeding and was transfused with 100,000 units of FVIII
- There was no history of bleeding in this patient

**Initial evaluation**

- A 1:1 aPTT mixing study after 2 hours of incubation at 37°C was not performed

**The delay**

- Mixing study results were misinterpreted as “correcting” and acquired hemophilia was inappropriately ruled out

**For hematologists/oncologists**

- A 1:1 aPTT mixing study performed only immediately at the time of testing is not sufficient to diagnose acquired hemophilia7
- As the laboratory reports the mixing study results in seconds, not as “corrected” or “not corrected,” physicians must appropriately evaluate the study results themselves1,6

**For pharmacists**

- Failure to properly diagnose acquired hemophilia in this case led to prolonged hospitalization and unsuccessful treatment with large doses of FVIII

**Management**

- Patient was followed for 6 to 12 months and was found to be in remission

**Important Safety Information (over)**

**Warnings and Precautions**

- Serious arterial and venous thrombotic events have been reported in clinical trials and postmarketing surveillance.

**Reimbursement**

- The ICD-9-CM code for acquired hemophilia is D68.31.10
- The ICD-10-CM code for acquired hemophilia is D68.31.11
- The appropriate code must be included on all claim forms for patients with acquired hemophilia treated with NovoSeven® RT

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**CASE STUDY**

**An international consensus recommends the use of NovoSeven® RT as first-line treatment**

**Using NovoSeven® RT first-line improved efficacy**

**95%**

**80%**

**First-line treatment**

**Salvage therapy**

**Recommended doses of NovoSeven® RT (1:1 Factor VIIa solution)**

| Treatment of acute bleeding episode | 75 mg/kg to 90 mg/kg immediately before surgery followed every 2 to 3 hours until hemostasis is achieved |
| Treatment of perioperative management (major or minor surgery) | 75 mg/kg to 90 mg/kg immediately before surgery followed every 2 to 3 hours until hemostasis is achieved |

**Theoretical adverse events within clinical data**

- 4% in patients with acquired hemophilia

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**Key takeaway**

- Acute bleeding in combination with an isolated prolongation of the aPTT should prompt an early consult with a hematologist7
- A 1:1 aPTT mixing study and the appropriate interpretation are critical to the proper diagnosis of acquired hemophilia—failure to properly diagnose acquired hemophilia in this case led to prolonged hospitalization and unsuccessful treatment with large doses of FVIII
- Failure to properly diagnose acquired hemophilia in this case led to prolonged hospitalization and unsuccessful treatment with large doses of FVIII

**For nonspecialist HCPs**

- Use of 100,000 units of FVIII over 10 days could have served as a red flag to consider the diagnosis of acquired hemophilia
- As the laboratory reports the mixing study results in seconds, not as “corrected” or “not corrected,” physicians must appropriately evaluate the study results themselves1,6

**For hematology/oncology specialists**

- Failure to properly diagnose acquired hemophilia in this case led to prolonged hospitalization and unsuccessful treatment with large doses of FVIII
- Earlier consult with a hematologist/oncologist or benign hematologist may support earlier diagnosis
- Acute bleeding in combination with an isolated prolongation of the aPTT should prompt an early consult with a hematologist7
- As the laboratory reports the mixing study results in seconds, not as “corrected” or “not corrected,” physicians must appropriately evaluate the study results themselves1,6

**For pharmacists**

- Failure to properly diagnose acquired hemophilia in this case led to prolonged hospitalization and unsuccessful treatment with large doses of FVIII
- Communication between the pharmacist and health care team is critical to the proper diagnosis of acquired hemophilia1,6
- Using NovoSeven® RT as first-line improved efficacy8,a,b

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