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Drugs

Information on Adverse Event Reports and Heparin

- The chart below shows numbers of deaths reported after heparin administration that occurred and were submitted to FDA from January 1, 2007 through May 31, 2008.
 - The reports are sorted according to the date of the medical event in the report, indicated in the first column. This date may be different than the date of death.
 - The second column indicates the number of deaths reported after heparin administration, regardless of cause.
 - The third column indicates the number of death reports that included one or more allergic symptom(s) or symptoms of hypotension (low blood pressure). These are the events that prompted a series of heparin recalls.
 - There have been 246 reports of death reported to FDA since January 1, 2007; 238 were *reported* to FDA on or after January 1, 2008.
 - Of the 149 reports that included one or more allergic symptom(s) or symptoms of hypotension and death, 146 were *reported* to FDA on or after January 1, 2008.
 - The fact that allergic symptoms or hypotension was reported does not mean that these were the cause of death in all cases.
 - FDA received reports of 97 patients who died without mention of allergy or hypotension. These patients died of a variety of causes.
 - In the majority of reports with a death outcome, there was not enough clinical information to assess the relationship between death and the use of heparin.
 - The recent internet posting from the Center for Devices and Radiological Health (CDRH) ([Questions and Answers on Heparin, Medical Devices and In-vitro Diagnostic Assays](#)¹) states that CDRH has received reports of 11 deaths associate with heparin-containing devices. The CDRH reporting system is separate from the Adverse Event Reporting System (AERS) used to capture the reports counted below. It is possible that reports of one death were sent to both systems, and could potentially be counted twice.

**Number of Deaths of Patients Receiving Heparin Reported to FDA,
January 1, 2007 through May 31, 2008**

Month the Medical Event(s) Occurred	Number of Reported Deaths*	Reported Deaths with One or More Allergic/Hypotensive Symptom(s)
Jan-07	6	3
Feb-07	2	1
Mar-07	5	2
Apr-07	7	4
May-07	3	1
Jun-07	5	2
Jul-07	6	3
Aug-07	4	4
Sep-07	3	2
Oct-07	10	5
Nov-07	12	11
Dec-07	34	23
Jan-08	50	32
Feb-08	49	29
Mar-08	14	10
Apr-08	7	4
May-08	5	3
Unknown date	24	10

Total 246 149

*The reports in this table concern heparin produced by any manufacturer.

- For comparison purposes, FDA reviewed the reports it received for all deaths of patients in whom heparin was listed as a potentially suspect drug in 2006.
 - A total of 55 deaths were reported from January 1, 2006 to December 31, 2006 - an average of four or five per month.
 - Across these 55 reports of death, there were a variety of underlying medical conditions.
 - Three of the reports listed allergic reactions or hypotension (low blood pressure) as a medical event, similar events to the cases that prompted the heparin recall in 2008.

**Number of Deaths of Patients Receiving Heparin Reported to FDA,
January 1, 2006 through December 31, 2006**

Year the Medical Event(s) Occurred	Number of Reported Deaths*	Reports with One or More Allergic/Hypotensive Symptom(s)
2006	55	3

* The reports in this table concern heparin produced by any manufacturer.

- FDA continues to receive reports of adverse events occurring after heparin administration.
 - FDA will analyze these and all other reports of adverse events after heparin administration.
 - FDA will update the data on this website on a periodic basis.
- Patients, consumers, physicians, nurses, pharmacists, and others can report adverse events either directly to the FDA via the MedWatch program either online, by regular mail or by fax (using the contact information at the bottom of this page), or to the drug product's manufacturer.
 - FDA receives approximately 400,000 reports of adverse events per year.
 - The majority of these (over 90%) come from manufacturers.
- The public can send reports of adverse events to FDA or the manufacturer any time after the event occurs.
 - In some cases, the report is sent to FDA or the manufacturer several months or more after the event has occurred.
 - After there is a lot of media attention to a particular adverse event, often more reports of similar adverse events are submitted.
- The fact that someone reports an adverse event does not necessarily mean that a specific drug caused the medical event or death.
 - Reports have to be analyzed to see if there is a plausible causal association between the drug and the medical event.
 - It is often not possible to tell in an individual case if there is a causal relationship between the drug and the medical event or death.
 - Many patients have other serious conditions that could have caused the reported problem.

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• **Report a Serious Problem**

- 1-800-332-1088
- 1-800-FDA-0178 Fax

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Regular Mail: Use postage-paid [FDA Form 3500](#)³

Mail to: MedWatch 5600 Fishers Lane
Rockville, MD 20857

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