Sharps injuries with Lovenox and generic enoxaparin prefilled safety syringes: A 12-year retrospective cross-sectional analytical study

BY TERRY GRIMMOND, FASM, BAgrSc, GrDpAdED, TR; MARYANN GRUDEN, MSN, RN, FNP, COHN-S/CM; BOBBI JO HURST, MBA, BSN, RN, COHN-S; AND LYDIA F. CRUTCHFIELD, MA, BSN, RN, CLC

Abstract

Purpose: Investigate the incidence and mechanisms of sharps injuries (SI) to staff using Lovenox and generic enoxaparin prefilled syringes.
Methods: Four national adverse event databases were examined over a 12-year period for incidence and brands involved with injury events to staff using enoxaparin prefilled syringes.
Results: The search revealed 581 adverse events (including 20 sharps injuries) associated with device malfunction in 8 of 16 brands, with one brand mentioned significantly more frequently than others. No national alert had been issued.
Conclusions: Use of certain brands of enoxaparin prefilled syringes poses a small but serious risk of injury to staff. Conducting root cause analyses on all SI is essential, as is the need for regularly evaluating safer devices, reporting all device incidents, enabling simpler reporting of adverse events, and establishing more effective intervention by FDA and manufacturers.

Keywords: enoxaparin, Lovenox, malfunction, needle stick, prefilled safety syringes, safety mechanism

Enoxaparin sodium, first marketed under the brand name Lovenox in prefilled safety syringes in 1993 by Rhone-Poulenc Rorer (now Sanofi), is a low-molecular-weight heparin commonly used in the prevention and management of deep vein thrombosis.[1-3] Between 2010 and 2019, Sandoz, Amphastar, Zydus, Apotex, and Nanjing King-Friend/Meitheal gained FDA approval to market generic versions of Lovenox under the name enoxaparin sodium in prefilled safety syringes.[4] Currently, 2 brands of Lovenox and 14 brands of enoxaparin prefilled devices are marketed in the US.[5]

In August 2020, in response to a Listserv inquiry by a member of the Association of Occupational Health Professionals in Healthcare (AOHP), 14 AOHP members reported that staff had sustained sharps injuries (SI) while administering Lovenox in prefilled safety-engineered syringes (Sanofi US, Bridgewater, N.J.). Members mentioned malfunctions with, or difficulty engaging, the safety mechanism postinjection. When the AOHP Executive Board initiated a national survey of members to examine the issue further, 86% (90/105) of respondents reported SI with the device, and confirmed safety mechanism issues.[6] Of concern was that the majority of respondents confirmed a risk of SI with the device, but neither the manufacturer nor the FDA had issued an alert. Furthermore, responses indicated the malfunction issue may not be confined to Lovenox and may also involve generic enoxaparin devices.

Therefore, this study aimed to examine national databases of medical device adverse event reports (MDRs) for reported near-misses, malfunctions, and injuries involving the safety mechanisms of Lovenox and generic enoxaparin brands of prefilled syringes. Along with market share, these reports were used to estimate the risk of an incident by manufacturer. Estimated risk was compared between manufacturers with the goal of allowing device users to make informed decisions about choice of device.

METHODS

A search was conducted within the FDA's three MDRs databases to determine the frequency and period of adverse events with Lovenox/enoxaparin devices: Manufacturer and User Facility Device Experience (MAUDE), FDA Adverse Event Reporting System (FAERS), and Medical Product Safety Network (MedSun).[7-9] Reports submitted between 2010 and 2021 were examined because only the 10 most recent years of MDRs are accessible via MAUDE, and 2010 captured the final year of Lovenox being the sole enoxaparin source on the US market. FAERS event summaries were available for each of the 11 study years from the FAERS website, but they omitted

details of injury type and malfunction mechanism. Although available by request to FDA under the Freedom of Information Act (FOIA), details of each product event were not sought as the FDA advises an 18- to 24-month process time. In addition to the FDA MDRs, a request was made to the Emergency Care Research Institute (ECRI) and the Institute for Safe Medication Practices (ISMP) Patient Safety Organization for name-removed copies of Lovenox/enoxaparin MDRs submitted to them over the study period (see *Enoxaparin device adverse event search criteria*).[10]

For the MAUDE, MedSun, and ECRI/ISMP MDRs databases, device malfunctions were classified into:

- Syringe fell apart upon plunger activation.
- Needle/shield forcefully ejected when safety mechanism activated.
- Syringe failed to activate when activation force was placed on plunger.
- Safety mechanism activated prematurely before injection was completed.
- Excessive force was required to activate safety mechanism.

Incidents were also classified by whether SI or other injury occurred, the year, and supplier. Safety devices were categorized as semi-automatic (needing an extra step in the procedure to activate the safety mechanism) or automatic (not needing an extra step to activate the safety mechanism) based on details supplied in each supplier's Instructions for Use.[5,11]

The MDRs per million units sold were estimated in aggregate and by the manufacturer, where possible. The literature and company annual reports were examined to determine each company's Lovenox/enoxaparin sales revenue to ascertain market share in 2020. To calculate the number of syringes sold by suppliers in 2020, the average unit cost to hospitals of Lovenox/enoxaparin syringes was sought, and device numbers were calculated by dividing product sales revenue by product unit cost.

Where applicable, results were statistically analyzed using a two-tailed test for comparison of rates with significance set at $P \leq .05$, *P*-values below .001 were expressed as $P < .001$, and risk ratios (RR) and 95% confidence intervals (CI) were calculated.[12]

The Institutional Review Board did not need to approve this study as all data were publicly available and did not constitute human subjects research. Furthermore, the study did not involve any patient, patient name, data, or specimen.

RESULTS

Over the 12-year study period, the four databases revealed 581 Lovenox/enoxaparin MDRs. "Injury" was mentioned in 397, with 8 brands named (see *Enoxaparin device adverse reports by supplier and database 2010–2021*). Of the 16 marketed brands, 14 used semi-automatic safety syringes, and 2 used automatic (Amphastar and BluePoint) (see *Lovenox/enoxaparin device adverse reports by malfunction for MAUDE, MedSun, and ECRI/ISMP databases 2010 – 2021*). The earliest MDRs were submitted in March 2010 (see *Annual occurrence of Lovenox/enoxaparin device adverse reports by database 2010 –2021*).

MAUDE, MedSun, and ECRI/ISMP databases

Excluding report duplications, MAUDE, MedSun, and ECRI/ISMP databases revealed 60 MDRs associated with 20 SI. All MDRs were submitted by healthcare personnel (HCP) with the manufacturer informed in 15. In the 20 SI, 19 were needle sticks (17 to HCP, 2 to patient/consumer) and 1 was a laceration to the HCP (from a broken safety-shield).

FAERS database

In the study period, 22,214 MDRs citing Lovenox/enoxaparin devices were submitted, of which 12,115 reported Lovenox/enoxaparin as the sole medication. After applying exclusion criteria, 521 MDRs remained, of which 465 (89.3%) were reported by manufacturers and 56 (10.7%) had reporter unstated. Of the 521 MDRs, 377 (72.4%) reported "Injury associated with device". The original reporters of FAERS MDRs were HCP in 403 (77.4%) and consumers in 114 (21.9%), with reporter unstated in 4. No significant difference was found between HCP (299 [74.2%] of 403) and consumer (74 [64.9%] of 114) reporting ($P = .51$, RR 1.14, CI 0.99-1.32).

MDRs incidence by brand

In 2020, the only year where brand and national revenues were available, 115 Lovenox/enoxaparin MDRs were submitted to the four databases and involved the following syringe suppliers: Sanofi-Aventis/Winthrop (89), Meitheal (2), Teva (1), Apotex (1), Fresenius Kabi (1) (all semi-automatic safety devices), and Amphastar (2) (automatic safety device, with 19 having manufacturer unstated). The year 2020 showed the highest annual number of MDRs in the study period.

Enoxaparin device adverse event search criteria

Database	Inclusions	Exclusions*
FDA MAUDE	Adverse events with product name "Lovenox" or "enoxaparin"	• Events not involving prefilled safety syringes, such as enoxaparin Carpuject
FDA FAERS	Adverse events with product name "Lovenox" or "enoxaparin" and with any of the following descriptors: • "Injury Associated with Device" • "Device Breakage" • "Device Malfunction" • "Device Safety Feature Issue" • "Device Failure" • "Device Defective" • "Device Difficult to Use" • "Device Mechanical Issue" • "Product Design Issue"	• Events occurring outside US or country unspecified • Events listing additional suspect products other than enoxaparin • Single, nonspecific adverse event descriptors, such as "Device operational issue," "Device quality issue" • Events/injuries occurring to patients/consumers and which appeared unrelated to safety mechanism malfunction, such as "rash," "nausea," "hypotension" • Duplicated reports within FAERS or with MAUDE or MedSun (detected by date, record number, and/or event description)
FDA MedSun	Adverse events with product name "Lovenox" or "enoxaparin"	• Events not involving prefilled safety syringes, such as enoxaparin Carpuject • Duplicated reports within MedSun or with FAERS or MAUDE (detected by date, record number, and/or event description)
ECRI/ISMP Supplied reports	Adverse events with product name "Lovenox" or "enoxaparin" + Sharps injury and/or Device malfunction	• Duplicated reports with FDA databases (detected by date and/or event description)

*Excluded from all databases were enoxaparin device "activation in packaging" events, an earlier prefilled device issue unrelated to the issue in the current study.

Market share

In 2020, Lovenox/enoxaparin supplier sales revenues were found only for Sanofi Lovenox and Amphastar enoxaparin (US $36.5 million and US $48.7 million, respectively), with total sales revenue for all Lovenox/enoxaparin brands being US $600 million.[13-15]

MDRs incidence per million devices

Per-unit prices of Sanofi Lovenox and enoxaparin to hospitals were not available because of confidential agreements and the variability of spend-dependent, hospital-specific pricing. The lowest discounted/wholesale US price per 40 mg in 0.4 mL syringe for Sanofi Lovenox and generic enoxaparin syringes was $9.94 and $3.81, respectively.[16,17] Using these prices and the above 2020 annual revenues, the syringes sold in 2020 by Sanofi and Amphastar were estimated to be 3.7 million and 12.8 million, respectively, giving an MDRs per million syringes sold of 24.2 and 0.16, respectively ($P <$ .001; RR 164.7; CI 38.1-628.5). For 2020, when the 89 Sanofi Lovenox MDRs were compared with the 26 MDRs from all enoxaparin suppliers, the MDRs per million syringes were 24.2 and 0.18, respectively ($P <$ .0001; RR 137.8; CI 89.0-213.24). This calculation conservatively assumed that the 19 "manufacturer unstated" MDRs were suppliers other than Sanofi, and all generic enoxaparin syringes were priced at $3.81, with market revenue of $565.7M.

Discussion

The four MDRs databases revealed a safety mechanism malfunction with several Lovenox/enoxaparin devices and confirmed earlier reports of the issue.[6,18] Of the eight brands cited in the MDRs, Sanofi citations were significantly higher than other brands (see *Type of device malfunction event by supplier* (MAUDE, MedSun, ECRI/ISMP databases)). The MDRs concerning Lovenox/enoxaparin increased in the later years available for analysis (*Annual occurrence of Lovenox/enoxaparin device adverse reports by database 2010–2021*); however, reports may be considerably less than their true incidence.[6] Total Lovenox/enoxaparin MDRs in 2020 were less than one per million devices sold; however, two-thirds of the MDRs cited "injury associated with the device" and all injuries in MAUDE, MedSun, and ECRI/ISMP MDRs were SI, with many "near-misses" having potential for SI.[7,9,10] To minimize SI, malfunctioning

Enoxaparin device adverse reports by supplier and database 2010–2021

Supplier	MAUDE (No. SI)	FAERS*	MedSun (No. SI)	ECRI-ISMP (No. SI)	Total (%)	Device-related injuries (% of injury reports)
Sanofi/Aventis & Winthrop (SA)	18 (8)	396	5 (2)	20 (4)	439 (75.6)	302 (76.1)
Sandoz Novartis (SA)	1 (1)	26	1	0	28 (4.8)	21 (5.3)
Fresenius Kabi (SA)	1	0	0	11 (1)	12 (2.1)	1 (0.3)
Amphastar (A)	0	17	0	0	17 (2.9)	14 (3.5)
Teva (SA)	1 (1)	14	0	0	15 (2.6)	10 (2.5)
Meitheal (SA)	0	11	0	0	11 (1.9)	5 (1.3)
Apotex (SA)	0	1	0	0	1 (0.2)	1 (0.3)
Unknown	0 (2)	56	0	2 (1)	58 (10.0)	43 (10.8)
Total	21 (12)	521	6 (2)	33 (6)	581(100)**	397 (100)**

A—automatic safety mechanism; SA—semi-automatic safety mechanism

*FAERS online reports do not state whether injury was a "sharps" injury.

**Total may not equal 100% due to decimal-point rounding.

safety devices must be eliminated as a cause.[19]

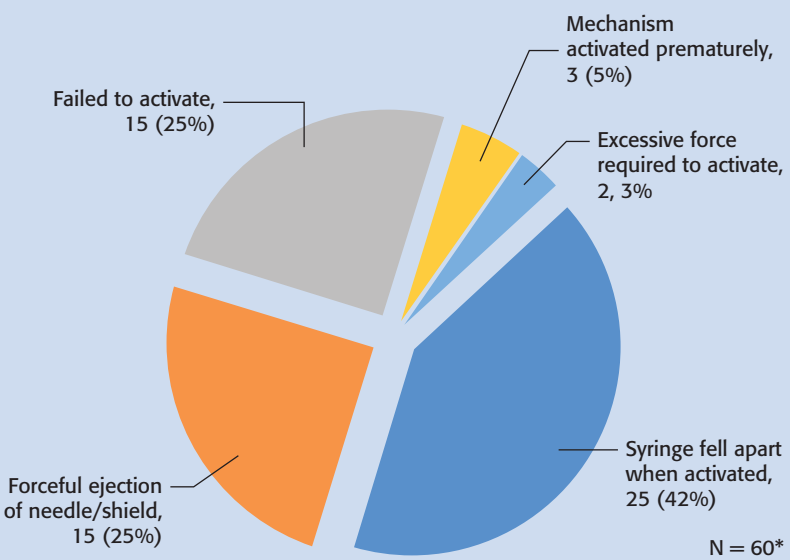
Safety mechanism malfunction

Maude, MedSun, and ECRI/ISMP MDRs were all associated with malfunction of the devices' safety mechanism and appear related to plunger force, the activation of the spring-mechanism, and the integrity of assembly. The FAERS reports, although nonnarrative, support this finding, with injury and device breakage/malfunction occurring in each of the seven brands cited, whether semi-automatic or automatic (see *FAERS MDR by adverse event type and supplier*). In 2019, Cohen reviewed 42 enoxaparin detailed FAERS MDRs (obtained under FOIA from FDA), of which 50% involved SI, and all described safety mechanisms being difficult to activate, breaking apart, failing to activate, or prematurely activating.[18] One SI occurred after being used for a patient with HIV infection, and three involved needles embedded into the patient's abdomen, with one needing an X-ray to detect it.[18]

No details of third-party safety syringes or their manufacturer were available publicly, nor in FDA submissions or approvals. Thus, it was impossible to determine if safety-syringes came from one third-party manufacturer or many. The significantly higher incidence of MDRs with Sanofi devices indicates that the device may be

Lovenox/enoxaparin device adverse reports by malfunction for MAUDE, MedSun, and ECRI/ISMP databases 2010–2021

*FAERS online reports do not state type of device malfunction and are excluded.



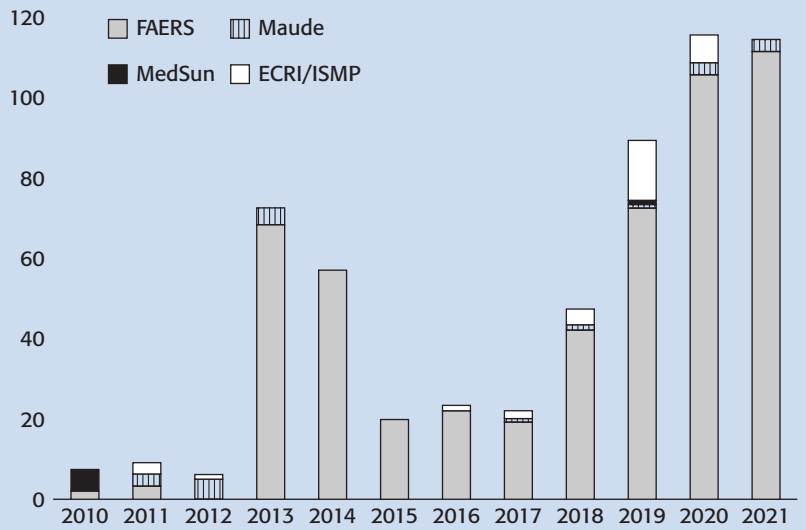
from a different safety syringe manufacturer, although visually similar to all other semi-automatic devices. Of interest is that Amphastar automatic safety devices were unnamed in SI events but mentioned in 15 FAERS "injury associated with device" events (injury type unstated); however, it was impossible to confirm that Amphastar and BluePoint automatic safety devices had zero SI.

Absence of alert

From as early as 2004, the supplier product inserts for the 14 semi-automatic Lovenox/enoxaparin syringes state that the device should be oriented "away from you and others," then activated, indicating that the risk of malfunction and injury has been known for years.[5]

It is disturbing that SI with Lovenox/enoxaparin devices have been occurring through safety mechanism malfunction for more than a decade; the malfunctions are known to manufacturers; 3 years have elapsed since Cohen brought the issue to FDA attention; and 2 years have elapsed since the AOHP survey results were forwarded to Sanofi and FDA; yet no alert has been issued.[18] When an alert is issued on a device malfunction, user facilities immediately know there is a problem with a device. With no alert, the event may be erroneously classed as "user error."[20] A product alert puts correct attention on the malfunctioning device and pressure on manufacturers to remedy the issue.

Annual occurrence of Lovenox/enoxaparin device adverse reports by database 2010–2021



Note. ECRI/ISMP adverse reports for 2021 were not available at time of study completion.
N = 581

Reporting device malfunctions

Device malfunctions must be reported to the manufacturer and the FDA so investigation and remedial action can be taken. Although the FDA reporting

Type of device malfunction event by supplier (MAUDE, MedSun, ECRI/ISMP databases)

Supplier*	Syringe fell apart when activated	Needle/shield forcefully ejected on activation	Safety mechanism failed to activate	Mechanism activated prematurely	Excessive force required to activate	Total	% of MDR
Sanofi-Aventis/ Winthrop	16	11	11	2	1	41	68.3%
Sandoz/Novartis			1	1		2	3.3%
Fresenius Kabi	5	4	2		1	12	20.0%
Teva	1					1	1.7%
Unstated	3		1			4	6.7%
	25	15	15	3	2	60	100.0%

*The prefilled syringes of these brands are all semi-automatic safety devices.
Note. FAERS online reports do not state type of device malfunction and are excluded from table.

systems for HCP injuries/near-misses/device malfunction are not user-friendly and are more targeted to patients, it is vital that the FDA learns of all adverse events with devices. Time-pressured occupational HCPs need a simple, efficient, quick reporting method in which they have the confidence of remedial action.

Reporting to FDA MAUDE

Under the Safe Medical Devices Act (SMDA), manufacturers and user facilities must submit MDRs within 10 days to FDA MAUDE if an adverse event results in death.[7] When the event classifies as an FDA "serious injury," user facilities must report the event to the manufacturer.[7] Of note is clause 5.13 of the 1996 Medical Device Reporting Guide, which states that a "patient" also includes an HCP if they suffer a device-related death or serious injury.[21] However, FDA defines "serious injury" as life-threatening, resulting in permanent impairment, or necessitating medical or surgical intervention to preclude permanent impairment.[22]

All SI are serious; however, they rarely meet the FDA's "serious injury" criteria, and therefore MAUDE is seldom used by user facilities to report SI or device malfunction. Manufacturers, if informed of the event, may voluntarily submit the report to the FDA via the Voluntary Malfunction Summary Reporting (VMSR) program, and these reports are incorporated into the publicly accessible MAUDE database.[23]

Reporting to FDA MedWatch

The 1992 amendment to the SMDA requires FDA to collect reports on any significant device adverse events from any party.[21] The FDA voluntary MedWatch reporting system was created to allow the public, including user facilities, to voluntarily report device malfunctions that do not result in death or FDA "serious injury," including the voluntary reporting of SI.[21,24,25] The MedWatch reports are used to build the FDA FAERS database monitored by FDA clinical reviewers and acted upon if a potential safety concern is identified. However, five major drawbacks to MedWatch/FAERS database are of concern:

1. It is primarily for adverse events affecting patients.
2. Categorization of outcomes is centered around death and the FDA's classification of "serious injury".
3. The FAERS online database does not describe the type of injury, to whom the injury occurred, or the device malfunctions (detailed MDRs need to be requested from FDA under FOIA).
4. Medwatch is not a fast or user-friendly tool—a must for user facilities.
5. MedWatch/FAERS has been ineffective in invoking remedial action or national alerts for the longstanding Lovenox/enoxaparin issue. Whether this is an FDA staffing issue or an incident report threshold issue, it must be addressed by the FDA.

Reporting to FDA MedSun

The FDA MedSun reporting system is designed specifically for

FAERS MDR by adverse event type and supplier

Supplier	Injury associated with device (%)		Device: Breakage, safety feature issue, failure, malfunction, or defective (%)		Device: Difficult, mechanical issue, or product design (%)	
Sanofi-Aventis/Winthrop (SA)	288	(76.4)	94	(76.4)	14	(66.7)
Sandoz/Novartis (SA)	20	(5.3)	5	(4.1)	1	(4.8)
Amphastar (A)	14	(3.7)	1	(0.8)	2	(9.5)
Meitheal (SA)	5	(1.3)	6	(4.9)	0	(0)
TEVA (SA)	9	(2.4)	3	(2.4)	2	(9.5)
Apotex (SA)	1	(0.3)	0	(0.0)	0	(0)
Manufacturer not stated	40	(10.6)	14	(11.4)	2	(9.5)
N = 521	377	(100.0)	123	(100.0)	21	(100.0)

A—auto safety device; SA—semi-auto safety device

Note: FAERS online reports do not state whether injury was a "sharps" injury, nor details of the device malfunction.

user facilities and uses MedWatch forms.[9] Its goal is to solve medical device problems, including those that result in "close-calls," potential for harm, and other safety concerns for both patients and HCP.[9] Unfortunately, very few HCP know of the system because it was not available when the current 1996 FDA "Medical Device Reporting for User Facilities" was published, and it is not mentioned in the FDA's "How to Report Medical Device Problems" web page.[21,26] MedSun's internal portal system has an easy user interface, with each report being individually reviewed by an FDA analyst who has a dialogue with the user facility. However, it is a "closed" reporting system in that only partner facilities can participate; facilities need to be vetted by the FDA for their suitability to become a partner; and there is a waitlist for new enrollees. Despite these limitations, the MedSun concept is excellent and is an example of reporting improvements that would allow the FDA to scrutinize the safety profiles of specific medical devices more accurately.[27] However, the FDA's vetting system should be removed to allow all healthcare facilities access to MedSun.

Reporting to the manufacturer

Submitting adverse event reports to manufacturers of medical devices is easier than FDA reporting because many manufacturers have simple forms on their websites. In the absence of a specific form, details of the malfunction, injury, or "near-miss" should be forwarded to the manufacturer, including a detailed description of the incident and date, details of the product and lot number, and if possible, the actual device involved or a photo of the device. Most manufacturers will endeavor to resolve issues, and this study revealed many manufacturers regularly forward user reports to the FDA via VMSR or MedWatch.

Reporting to ECRI/ISMP

Device issues can now be easily reported via the ECRI/ISMP website.[28] ECRI/ISMP has regular meetings with relevant FDA centers to raise device issues and may follow up with a publication in their Medication Safety Alerts. All reports are kept strictly confidential, the service is free, and a redacted database of reports can be requested.

Clinical practice implications

In the US, more than 300,000 HCP sustain SI annually.[29] The incidence is not decreasing, injuries may transmit more than 60 pathogens, and they can cause high anxiety and emotional trauma in injured HCP.[30-33] With zero SI as our aim, it is important to prevent every SI by conducting education and competency-based training of staff on all safety devices they will use—at orientation, during regular intervals thereafter, whenever new devices are introduced, and whenever an SI occurs with a device.[29,34,35] When injury or sharps device malfunction occurs, conducting a root cause analysis with the injured HCP is important to identify and mitigate factors that led to the injury, in particular, to discuss how they used the device and whether it may have malfunctioned.[35,36] Injured users too readily blame themselves and cite "user error," as frequently occurred in the AOHP Lovenox survey.[6,20] Device users must be aware, as demonstrated in this study, that not all safety devices are safe.[19,20] This "error or malfunction" anomaly is not uncommon, and with root cause analyses, user blame can be avoided and systems issues evaluated.[20,35]

When a trend of device-associated SI is detected, user facilities are reminded that OSHA mandates safer devices be evaluated at least annually.[37] Facilities are encouraged to evaluate devices with automatic safety mechanisms as they have a significantly lower risk of user SI than manual or semi-automatic devices.[11,19] Finally, this study recommends facilities report adverse device events to the manufacturer and to ECRI/ISMP (and to FDA MedSun if the FDA ceases vetting facilities for partnership).[28]

With zero SI as our aim, the FDA as a medical device regulator, and OSHA mandating the evaluation of safer devices, it is unacceptable for HCP injuries due to malfunctioning Lovenox/enoxaparin devices to continue.

Strengths and limitations

Strengths of the study are the number of adverse event databases accessed, the detailed description of adverse events and device malfunction in MAUDE, MedSun, and ECRI/ISMP databases, and the information on approved suppliers and their Instructions for Users available through FDA and the National Medical Library.

Limitations of the study are the fact that many adverse incidents with Lovenox/enoxaparin syringes are likely not reported; the inability, as stated by FDA, to use MAUDE, FAERS, and MedSun databases for incident trends; the

absence of detailed information on injuries or device malfunctions in the FDA FAERS online database; the large, nondetailed FAERS database contributing 90% of MDRs in the study; the possibility that generic enoxaparin devices were misnamed "Lovenox"; the absence of information on third party syringe manufacturers; the absence of market share and hospital pricing for all suppliers; the use of lowest wholesale price for Lovenox and Amphastar products; and the inability to determine if MDRs for many suppliers was due to safer devices, or low market share.

Recommendations

User facilities should conduct root cause analyses on device injuries and malfunctions and if a trend is noticed, evaluate safer devices (preferably automated); user facilities should report all adverse sharps device events to the manufacturer and ECRI/ISMP; the FDA or manufacturer should issue a device alert on Lovenox/enoxaparin prefilled syringes; suppliers of malfunctioning devices must work with their device manufacturer to correct the malfunctions or seek safer devices for their product; FDA MDRs submission procedures should be streamlined for easy reporting by user facilities; FDA FAERS online data should include details of injury and device malfunction; the FDA threshold for issuing device alerts should be examined; and further studies should be conducted to compare safety-mechanism reliability of Lovenox/enoxaparin devices, particularly among the numerous FAERS MDRs where online details were a limitation in this study.

Conclusions

Following an initial alert by an occupational health manager at a US hospital, this study used FDA and ECRI/ISMP MDRs databases to investigate the incidence and mechanisms of SI among HCP administering Lovenox/enoxaparin prefilled syringes. Examination of MDRs confirmed device malfunction had been occurring for at least 10 years, was associated with SI to HCP, had not decreased with time, and, although occurring in several brands, one brand had a significantly higher incidence unrelated to market share. The results highlight the importance of conducting root cause analyses on all SI, evaluating safer sharps devices regularly, and reporting all device incidents. This study also highlights the absence of a product alert and calls for simpler adverse event reporting and more effective intervention by the FDA and manufacturers. ■

REFERENCES

1. U.S. Food and Drug Administration. Rhone-Paulenc Rorer, Lovenox approval letter, 1993. www.accessdata.fda.gov/drugsatfda_docs/appletter/pre96/20-164ltr.pdf. Accessed October 3, 2022.

2. Blake H. A history of Sanofi. PharmaPhorum, February 25, 2013. https://pharmaphorum.com/articles/a_history_of-_sanofi/. Accessed October 3, 2022.

3. Enoxaparin. DrugBank Online. https://go.drugbank.com/drugs/DB01225. Accessed October 3, 2022.

4. U.S. Food and Drug Administration. FDA approved drug products ('Orange Book'). www.fda.gov/media/71474/download. Accessed October 3, 2022.

5. Enoxaparin. DailyMed, National Library of Medicine, Bethesda, MD. https://dailymed.nlm.nih.gov/dailymed/search.cfm?query=Enoxaparin. Accessed October 3, 2022.

6. Gruden M, Grimmond T, Hurst BJ, Crutchfield L. Results of AOHP Lovenox Prefilled Syringe Survey – August 2020. Lovenox Prefilled Syringe Project – Part 1. Report to the AOHP Executive Board. *J Assoc Occup Health Prof*. 2020;40(3):34-38.

7. U.S. Food and Drug Administration. About Manufacturer and User Facility Device Experience (MAUDE), May 2022. www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/about-manufacturer-and-user-facility-device-experience-maude. Accessed October 3, 2022.

8. U.S. Food and Drug Administration. FDA Adverse Events Reporting System (FAERS) Public dashboard. www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard. Accessed October 3, 2022.

9. U.S. Food and Drug Administration. MedSun - Medical Product Safety Network. www.fda.gov/medical-devices/medical-device-safety/medsun-medical-product-safety-network. Accessed October 3, 2022.

10. ECRI and the Institute for Safe Medication Practices Patient Safety Organization. www.ecri.org/solutions/patient-safety-organization. Accessed October 3, 2022.

11. Tosini W, Ciotti C, Goyer F, et al. Needlestick injury rates according to different types of safety-engineered devices: results of a French multicenter study. *Infect Control Hosp Epidemiol*. 2010;31(4):402-407.

12. MedCalc Software Ltd Belgium. www.medcalc.org. Accessed October 3, 2022.

13. Sanofi Q4 2020 Press Release. February 5, 2021. www.sanofi.com/en/media-room/press-releases/2021/2021-02-05-07-30-00. Accessed October 3, 2022.

14. United States Securities and Exchange Commission. Form 10-K Amphastar Pharmaceuticals, Inc. www.annualreports.com/Click/20327. Accessed October 3, 2022.

15. Meitheal Pharmaceuticals announces launch of enoxaparin sodium injection, USP in the United States. May 28, 2020. www.businesswire.com/news/home/20200528005081/en/Meitheal-Pharmaceuticals-Announces-Launch-of-Enoxaparin-Sodium-Injection-USP-in-the-United-States. Accessed October 3, 2022.

16. Enoxaparin Prices, Coupons and Patient Assistance Programs. Drugs.com. www.drugs.com/price-guide/enoxaparin. Accessed October 3, 2022.

17. Lovenox Prices, Coupons and Patient Assistance Programs. Drugs.com. www.drugs.com/price-guide/lovenox. Accessed October 3, 2022.

18. Cohen M. Alarming malfunctions can lead to needle sticks. Medication Errors. *Nursing*. 2019;49(6):72. https://journals.lww.com/nursing/Citation/2019/06000/Medication_Errors.19.aspx. Accessed October 3, 2022.

19. Black L. Chinks in the armor: percutaneous injuries from hollow bore safety-engineered sharps devices. *Am J Infect Control*. 2013;41(5):427-432. doi:10.1016/j.ajic.2012.05.025.

20. Hyman W. Human factors analysis of needle safety devices. *J Clin Eng*. 2002;27:280-286.

21. U.S. Food and Drug Administration. FDA guidance: medical device reporting for user facilities. 1996. www.fda.gov/media/73972/download. Accessed October 3, 2022.

22. Medical Device Reporting Part 803.3. CFR – Code of Federal Regulations Title 21. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803&gshowFR=1#:~:text=(w)%20Serious%20injury%20means%20an,damage%20to%20a%20body%20structure. Accessed October 3, 2022.

23. U.S. Food and Drug Administration. Voluntary Malfunction Summary Reporting Program. Medical Device Reporting (MDR): how to report medical device problems. www.fda.gov/medical-devices/

medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems#malfunction. Accessed October 3, 2022.

24. U.S. Food and Drug Administration. Medwatch - FDA Safety Information and Adverse Event Reporting Program. www.accessdata.fda.gov/scripts/medwatch/. Accessed October 3, 2022.

25. U.S. Food and Drug Administration. Needlesticks. Medical device reporting guidance for user facilities, manufacturers, and importers. www.fda.gov/media/71528/download. Accessed October 3, 2022.

26. U.S. Food and Drug Administration. Medical device reporting: how to report medical device problems. www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems. Accessed October 3, 2022.

27. Sandberg JM, Gray I, Pearlman A, Terlecki RP. An evaluation of the Manufacturer and User Facility Device Experience database that inspired the United States Food and Drug Administration's Reclassification of transvaginal mesh. *Investig Clin Urol.* 2018;59(2):126-132.

28. ECRI. Report a device problem. www.ecri.org/pages/ReportADeviceProblem.aspx. Accessed October 3, 2022.

29. Grimmond T, Good L. Exposure Survey of Trends in Occupational Practice (EXPO-S.T.O.P.) 2015: a national survey of sharps injuries and mucocutaneous blood exposures among health care workers in US hospitals. *Am J Infect Control*. 2017;45(11):1218-1223. doi:10.1016/j.ajic.2017.05.023.

30. International Safety Center. EPINet Sharps Injury and Blood and Body Fluid Data Reports 2020. https://internationalsafetycenter.org/wp-content/uploads/2021/08/Official-2020-US-Needle-Summary.pdf. Accessed October 3, 2022.

31. Grimmond T, Good L. EXPO-S.T.O.P. 2018 – an overview of blood exposure incidence in 281 US hospitals. *J Assoc Occup Health Prof.* 2020;40(2):25-28.

32. Tarantola A, Abiteboul D, Rachline A. Infection risks following accidental exposure to blood or body fluids in health care workers: a review of pathogens transmitted in published cases. *Am J Infect Control.* 2006;34(6):367-375. doi:10.1016/j.ajic.2004.11.011. www.ajicjournal.org/article/S0196-6553(05)00435-9/pdf. Accessed October 3, 2022.

33. Cooke CE, Stephens JM. Clinical, economic, and humanistic burden of needlestick injuries in healthcare workers. *Med Devices Evid Res*. 2017;10:225-235. doi:10.2147/MDER.S140846. Accessed October 3, 2022.

34. Good L, Grimmond T. Burnson J, et al. Exposure injury reduction strategies: results that protect lives. *J Assoc Occ Health Prof.* 2018;38(4):10-13.

35. At the sticking point: when sharps safety features fail to protect. Patient Safety E-lerts, Feb 3, 2014. ECRI, Meeting Point, PA. www.ecri.org/components/PSOCore/Pages/E-lert_020314.aspx?tab=2. Accessed October 3, 2022.

36. Gruden M, Grimmond T, Hurst BJ, Crutchfield L. The importance of utilizing root cause analysis when investigating and reporting sharps injuries and safety device malfunctions. *J Assoc Occup Health Prof.* 2020;41(1):16-20.

37. US Department of Labor, Occupational Safety and Health Administration. OSHA Bloodborne pathogens. Standard 1910.1030. Jan. 18, 2001. www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051. Accessed October 3, 2022.

Terry Grimmond is the director of Grimmond and Associates, Microbiology Consultancy in New Zealand; MaryAnn Gruden is an occupational health consultant in McMurray, Pa.; Bobbi Jo Hurst is an employee health and infection control RN at Orthopedic Associates of Lancaster in New Holland, Pa.; and Lydia F. Crutchfield is the President Emeritus of the Association of Occupational Health Professionals in Healthcare in Charlotte, N.C.

The authors have disclosed no financial relationships related to this article.

DOI-10.1097/01.NURSE.0000927508.69410.3c