Lidocaine Shortage: Perspectives, Alternatives, and Pathways Forward

Supply chain issues, communication barriers, and regulatory inconsistencies cause problems for practitioners and patients.

WITH GEORGE J. HRUZA, MD, MBA, FAAD, AND JOEL L. COHEN, MD, FAAD, FACMS

Lidocaine, the widely used local anesthetic known for its effectiveness in blocking nerve signals and providing local anesthesia, has remained in shortage over the last few years.¹ Alarmingly, shortages of a number of drugs are lasting longer, with a nearly 30% rise in new drug shortages in the United States between 2021 and 2022.²

Lidocaine, an essential local anesthetic administered via injection or topical application, is vital during medical procedures, surgeries, and for pain management purposes.³ The lidocaine shortage in the United States has had significant implications for clinicians across various medical specialties, leading to postponed or canceled procedures, compromised pain management strategies, and challenges in ensuring patient comfort and facilitating procedures.⁴⁵

To shed light on the impact of the lidocaine shortage on dermatology practices, Practical Dermatology reached out to two renowned dermatologic surgeons: George J. Hruza, MD, MBA, FAAD, and Joel L. Cohen, MD, FAAD, FACMS. Dr. Hruza is Adjunct Professor of Dermatology and Otolaryngology at St. Louis University and Medical Director of Laser & Dermatologic Surgery Center in Chesterfield, MO. Dr. Cohen is the Director of AboutSkin Dermatology and DermSurgery in Englewood and Lone Tree, CO. Both experts have firsthand knowledge of the challenges posed by the shortage.

THE IMPACT OF THE SHORTAGE

The shortage of lidocaine has posed challenges for clinicians, particularly Mohs surgeons and dermatologic surgeons treating patients with serious skin cancers. Some of the obstacles practitioners face are detailed below.

Impact on medical professionals: Dr. Hruza highlighted the magnitude of the problem, stating, “One significant aspect of the shortage that just occurred to me is the immediate response it triggers among healthcare professionals,” he said. “When there’s a scarcity of lidocaine, everyone scrambles to secure whatever supply they can find to avoid being caught in a vulnerable situation. As a Mohs surgeon, lidocaine is an indispensable component of our procedures. The shortage brought us to a critical juncture where we were only two days away from having to halt operations entirely. It has been a real challenge for us because we’ve had to find alternative ways to anesthetize patients.”

Inconsistent availability: Clinics and hospitals have reported inconsistent availability of lidocaine, with sporadic restocking and limited quantities supplied. Dr. Hruza explained that the shortage experience varied across different practices: “Obtaining lidocaine with epinephrine has been particularly difficult, and there were even instances where plain lidocaine was unavailable. As a result, alternatives like bupivacaine had to be considered, but they have their own drawbacks. Unlike
LIDOCAINE SHORTAGE CAUSES

When examining the cause and duration of the lidocaine shortage, Dr. Cohen questioned the repeated delays and the underlying reasons for the shortage, as well as curiosity about the absence of shortages in Europe and Canada (regions that do not face the same supply issues that have been reported to him).

The shortage of lidocaine can be attributed to several factors, as highlighted in a report by US Senator Gary Peters:

- One significant factor is the complex global supply chain, as lidocaine is often manufactured overseas.

Currently, only two companies, Pfizer and Fresenius Kabi USA, manufacture lidocaine in the US, creating a manufacturing bottleneck. While 39% of lidocaine products in the US are manufactured domestically, there are no known domestic suppliers registered with the FDA for its active pharmaceutical ingredients. Disruptions in production, transportation delays, and regulatory challenges all contribute to the scarcity of lidocaine. Additionally, the low profit margins and complex manufacturing requirements of lidocaine pose challenges in production, leading companies to prioritize other higher-margin medications resulting in reduced lidocaine supply.

- The manufacturing push for COVID-19 vaccines also contributed to the shortage of lidocaine and other drugs. However, it’s important to note that lidocaine shortages existed before the pandemic due to supply chain management issues.

- Strict quality control standards enforced by the FDA can also lead to delays in lidocaine manufacturing. Every aspect of the manufacturing process, from raw materials to procedures, is strictly regulated to ensure patient safety. Factors such as market approval requirements, post-marketing surveillance, and recalls contribute to the complexity of the manufacturing process. Minor infractions can result in temporary production line shutdowns, further exacerbating the shortage. Additionally, restrictions on importing lidocaine, even if it is produced in the US and exported, have contributed to the scarcity.

- Additionally, the increased demand for lidocaine, driven by an aging population and advancements in medical procedures, as well as a “bump” in demand after the pandemic for procedures that were deferred by patients has outpaced the supply.

EXPLORING ALTERNATIVE STRATEGIES

Addressing the shortage of lidocaine requires proactive measures from healthcare professionals, policymakers, and pharmaceutical manufacturers.

One of the primary consequences of the lidocaine shortage is the need for clinicians to seek alternatives that may be less effective in providing the desired therapeutic outcomes. “To manage the shortage, practices have resorted to diluting lidocaine to extend their supplies,” Dr. Hruza said. “We also scrounge around for any other available local anesthetics, although lidocaine is preferred because it’s the best option compared to the alternatives.”

Dr. Cohen shared insights into his personal practice: “In my practice, we have seen an increased reliance on ProNox for analgesia. We also use bupivacaine alongside lidocaine for longer procedures like Mohs surgery between stages.”
When there’s a scarcity of lidocaine, everyone scrambles to secure whatever supply they can find to avoid being caught in a vulnerable situation."

Bupivicaine has a slower onset but longer duration, making it suitable for these types of procedures."

Both Dr. Hruza and Dr. Cohen emphasize the importance of recognizing and monitoring for signs of lidocaine toxicity and caution against mixing different anesthetics without thorough comprehension of the associated precautions and safe doses. "It is crucial to understand the sequence of signs and symptoms indicative of early to late anesthesia toxicity," Dr. Cohen said. "Initial symptoms like tongue numbness and lightheadedness can rapidly progress to visual and auditory disturbances, muscle twitching, unconsciousness, convulsions, respiratory arrest, and ultimately, cardiac arrest if left unaddressed."

EXPLORING LONG-TERM EFFORTS

Long-term efforts must be made to address the root causes of the lidocaine shortage and establish a consistent supply. Both pharmaceutical companies and regulatory agencies have a crucial role to play in mitigating the impact of shortages. Inconsistencies in regulatory environments, however, can create hurdles and bottlenecks. For example, importing lidocaine from Canada involves a more complex regulatory route and is more difficult than importing from China, even though Canada has more similar, stringent regulatory and quality requirements to those of the FDA than China does. Ordering local anesthetics from Canada, which adheres to similar quality standards as the United States, is not possible, while medications from China, are allowed.⁴

Dr. Hruza, who has actively engaged in various initiatives to tackle the shortage, including meetings with Pfizer, discussions with the FDA, and interactions with legislators, sheds light on the situation. He explained, "When it comes to importing medications from China, my understanding is that the FDA requires those medications to meet their standards." He continued, "The FDA may rely on agreements or deemed status with other agencies in China to ensure compliance. If Canada produces lidocaine, it is primarily intended for their own market. To export to the US, they would need FDA clearance, which may not be in place for lidocaine. Moreover, even if lidocaine was exported to Canada, it cannot be brought back into the US due to legal restrictions on reimportation of drugs."

The inconsistencies, Dr. Hruza said, present an opportunity to adjust strategy and incorporate flexibility. "During a shortage, it would be beneficial for the government to exercise flexibility in allowing imports from countries where lidocaine is readily available and where stringent manufacturing standards are in place, such as Canada or Western European countries. Collaboration with multiple countries could alleviate the shortage. Regulatory flexibility and incentives for new entries into the market could also help resolve the issue. Diversifying the supply chain for lidocaine production is also crucial, as it makes the supply chain more resilient to disruptions by establishing partnerships with multiple manufacturers and promoting domestic production." Establishing new factories or transitioning existing ones is a time-consuming and heavily regulated process, which explains why the shortage may persist until at least the end of this year and possibly into 2024. According to Dr. Hruza, Pfizer provided information about the expected recovery of lidocaine preparations, noting that 11 out of the 28 preparations are projected to recover, resulting in an 8 to 12-week supply to support the market.

SUMMARY

According to Dr. Hruza, the anticipated recovery of the supply of lidocaine preparations by Pfizer is a positive development. However, it is crucial to monitor the progress of these initiatives and ensure their effective implementation. By increasing information sharing and communication with key stakeholders in the process, practitioners hope to be able to better identify potential shortages in advance. Collaborative efforts can lead to better forecasting and demand management strategies. Additionally, investing in research and development to explore alternative local anesthetics or pain management techniques provides viable options during periods of lidocaine scarcity. These innovations bridge the gap and ensure quality care even in the face of shortages. **"