

Worldwide Shortage of Heparin



Aditya Patankar¹, Atul Laddu¹, and Jawed Fareed²

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Background

Heparin is a century-old anticoagulant that continues to play a key role in modern therapy. It is both effective and relatively safe, which has helped it remain widely used despite the introduction of several newer anticoagulants in recent years. Still, it has held its ground in hospitals and pharmacies around the world. Recently, however, troubling news has surfaced about a global heparin shortage caused by African Swine Fever, leading to understandable concern among physicians and pharmacists.

Objectives

- 1. Explore the causes and consequences of the global heparin shortage.
- 2. Investigate the roles and responses of key stakeholders such as the FDA, manufacturers, and clinicians.
- **3. Examine viable alternatives** to heparin and possible strategies to mitigate the shortage.

Methods

- 1. **Researched** the heparin (Figure 1) manufacturing process, and the reliance on pig intestines and Chinese suppliers
- 2. Studied previous heparin-related crises, such as contamination incidents and past shortages
- 3. Reviewed reports from health authorities
- **4. Analyzed** alternatives, including synthetic, animal-derived, and non-heparin anticoagulants
- 5. **Examined** the sites of action of heparin (Figure 2), clinical strategies for prioritizing heparin use and limiting overdose.



Results

1. Manufacturing and Supply Chain Issues

- China produces 80%+ of global heparin from pig intestines.
- The African Swine Fever cut China's pig population by over a third.
- Manufacturers like Fresenius Kabi have limited distribution, worsening shortages.
- The U.S. House Committee has urged the FDA to intervene.
- 2. Impact on Healthcare
 - Late 2019: Rumors of a heparin shortage after the manufacturers developed significant deficits of heparin, as reported by Cian P. McCarthy, MD, a cardiology fellow at the Massachusetts General Hospital (MGH)
 - The shortage was attributed to manufacturing disruptions, and an outbreak of African swine fever in China in August 2018 exacerbated the issue.
 - Unfractionated heparin (UFH) is essential for dialysis and heart surgeries—now threatened by supply constraints.
 - Hospitals are reserving heparin for critical cases, like pregnant or cancer patients.
 - Shortages have caused price spikes and increased risk of adulterated products

3. Alternatives and Research

- Argatroban and Bivalirudin are alternatives but are costly and lack reversal agents.
- Bovine and ovine-derived heparins are being reconsidered for FDA approval.
- Synthetic heparin is under development using enzymatic approaches to reduce animal dependence.

4. Global and Institutional Responses

- Hospitals are seeking non-Chinese suppliers.
- MGH implemented a VTE pathway, cutting heparin use by 84%.
- The FDA is under pressure to fast-track alternative anticoagulants.

Conclusion

Heparin remains a vital anticoagulant in modern medicine, but its global shortage—driven by supply chain disruptions, disease outbreaks, and manufacturing limitations—poses a serious threat to patient care. The crisis highlights the risks of over-reliance on a single geographic and biological source. Addressing this issue requires a multifaceted response:

- 1. Expanding the global supply chain
- 2. Investing in alternative and synthetic options
- 3. Prioritizing heparin use for critical cases.

Coordinated efforts by clinicians, researchers, manufacturers, and regulatory agencies are essential to ensure continued access to this life-saving drug worldwide.