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FORUM

Safeguarding global anticoagulant supply and access

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Abstract

Anticoagulants are essential to health care, yet their global supply is inherently fragile. Reliance on animal-derived heparin creates vulnerability to contamination, animal disease, and logistical disruption, whereas synthetic alternatives like warfarin and direct oral anticoagulants face mounting manufacturing and geopolitical risks. The COVID-19 pandemic exposed how these intersecting threats can converge during a crisis, causing critical shortages. To build resilience, a systemic shift is required: developing nonanimal-derived anticoagulants, diversifying production geographically, establishing protected supply corridors, reducing high-carbon footprint manufacturing processes, and creating equitable allocation frameworks. Anticoagulants must be recognized as essential medical assets, necessitating sustained investment and international coordination to ensure reliable access for all health systems, particularly before the next pandemic or global shock.

KEYWORDS
anticoagulants, drug shortages, heparin, supply chain management, warfarin

1 | INTRODUCTION

Anticoagulants are foundational to health care, enabling cardiac and vascular surgery, hemodialysis, extracorporeal life support, and the prevention and treatment of thrombosis. Without reliable access to anticoagulation, clinical care would be compromised. Presently, anticoagulant manufacturing supply chains are built more for cost efficiency than resilience [1]. Discussions of vulnerability have traditionally focused on heparin and low-molecular-weight heparins (LMWHs) because of their animal source, but similar structural weaknesses—geographic concentration, a fragile manufacturing base, and opaque supply chains—also affect oral anticoagulants such as

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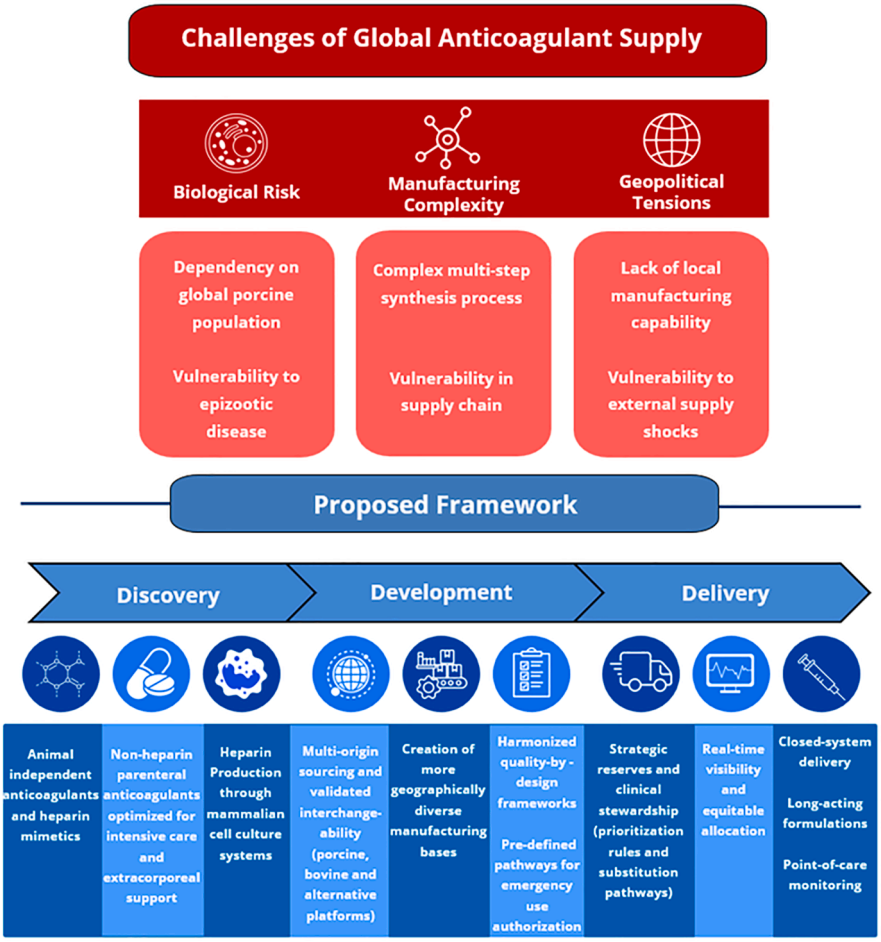

FIGURE Challenges of global anticoagulant supply with a proposed framework of anticoagulant discovery, development, and delivery.

warfarin and direct oral anticoagulants (DOACs). Securing anticoagulant supply requires coordinated intervention across diversification, transparency, innovation, and stewardship (Figure).

2 | A REPEATING CYCLE OF CRISIS

Commercial heparin production historically relied on bovine sources until concerns surrounding bovine spongiform encephalopathy in the late 1990s prompted regulatory withdrawal of bovine-derived heparin from several markets, including the United States, effectively narrowing global supply to porcine sources. An estimated 60% to 80% of the world's crude heparin, derived exclusively from porcine intestinal mucosa, still originates from China [2]. The 2007-2008 heparin contamination crisis remains a seminal event in heparin usage. The introduction of oversulphated chondroitin sulphate—a contaminant linked to upstream crude heparin supply originating in China—resulted in hundreds of adverse reactions and approximately 80 deaths in the United States, with additional fatalities internationally [3,4]. A third major disruption emerged with the African swine fever epidemic beginning in 2018, causing the loss of a large proportion of China's pig herd. Such a massive reduction in herd size significantly constrained the global supply of crude heparin precursor for years [5,6]. The COVID-19 pandemic served as another unanticipated global stress test for medical supply chains. The emergence of COVID-19-associated coagulopathy [7,8], together with international guidelines recommending at least prophylactic anticoagulation for hospitalized patients, with therapeutic-intensity anticoagulation in selected subgroups and within evolving trial evidence [9], triggered an increase in global demand for all anticoagulation drugs [10]. This demand exposed a long-standing vulnerability in global health security: the fragility of the heparin supply chain. Simultaneously, pandemic-related lockdowns and transportation disruptions delayed shipments of porcine intestinal mucosa and constrained production of finished heparin products across multiple continents, compounded by clinically significant LMWH demand in certain regions, such as Italy [11]. As of late 2025, the US Food and Drug Administration (US FDA) continues to report active shortages of heparin sodium injection involving multiple major manufacturers such as Baxter Healthcare and Fresenius Kabi USA [12]. Evidently, global anticoagulant availability remains tightly coupled to epizootic disease, geopolitical tensions, logistical disruption, and pandemic-driven demand surges.

3 | AN EVOLVING CHALLENGE: MULTIPLE CATEGORIES OF RISK

Heparin's biological origin represents its main vulnerability. Complete dependence on a healthy global porcine population creates acute susceptibility to animal disease outbreaks and disruptions to supply chains. Although heparin shortages were primarily caused by biologically related risk factors, warfarin and DOACs exemplify industrial and geopolitical fragility. Warfarin production depends on a limited number of facilities synthesizing coumarin intermediates, many of which are in Asia. Disruptions in chemical supply, regulatory shutdowns, or trade restrictions can rapidly compromise availability, particularly in low-resource settings where warfarin remains a mainstay because of cost. DOACs, often perceived as less vulnerable because they are fully synthetic, introduce a different form of risk. Their manufacture relies on complex, multistep synthesis pathways that have a high carbon footprint [13], specialized reagents, and proprietary intellectual property. Production is therefore restricted to a small number of high-technology facilities. During the COVID-19 pandemic, export controls and port closures in China [14] led to medical product supply strain [15], revealing limited surge capacity and substitution flexibility. Concurrently, the monthly volume of oral anticoagulants and parenteral anticoagulants in US hospitals grew significantly more than in the prepandemic period [16]. Since some DOACs, such as apixaban and edoxaban, remain under patent protection, alternative manufacturers cannot readily compensate for supply interruptions; cost barriers and formulary constraints also limit switching back to warfarin or parenteral agents. Patent and exclusivity timelines for DOACs vary by jurisdiction and influence the number of manufacturers and the ability to scale supply during disruptions. In the United States, dabigatran has long entered generic competition (with US FDA first-generic approvals recorded in 2020), and rivaroxaban has US FDA first-generic approvals recorded in 2025, whereas apixaban is still expected—by the originator—to face US generic entry later (from April 1, 2028), despite earlier loss-of-exclusivity timelines reported in some European settings. Importantly, a generic entry does not necessarily eliminate vulnerability because the active pharmaceutical ingredient and manufacturing capacity may remain concentrated. At the same time, wider uptake of (generic) DOACs may further contract the warfarin market, increasing the risk of supplier exit and episodic shortages—an important concern because warfarin remains essential for selected high-risk groups (eg, mechanical heart valves and high-risk antiphospholipid syndrome). Resilience planning should therefore expand affordable DOAC access where appropriate, while deliberately sustaining warfarin and international normalized ratio monitoring capacity through protected procurement and redundancy incentives. The ongoing transition of key DOACs to generic status in many markets introduces a new dynamic. Together, these dynamics demonstrate that biological and synthetic anticoagulants are linked through clinical substitution pathways and shared global manufacturing dependencies.

4 | A PROPOSED FRAMEWORK FOR ANTICOAGULANT SUPPLY RESILIENCE

4.1 | Drug discovery: reducing dependence on animal-derived heparin

The long-term solution to vulnerabilities inherent in animal-sourced heparin lies in the development of fully synthetic [17] or chemoenzymatically engineered alternatives [18]. Approved synthetic alternatives, including fondaparinux, bivalirudin, and argatroban, can bypass animal sourcing requirements. In practice, these nonheparin parenteral options are variably registered and reimbursed across jurisdictions, and in many countries remain restricted by cost, procurement limitations, and critical-care supply constraints—so they cannot be assumed to provide reliable substitution capacity during a heparin or LMWH shock. Recent scientific advances in chemoenzymatic synthesis have brought fully synthetic heparin analogues closer to clinical use [19]. Pioneering research using recombinant heparin biosynthetic enzymes has demonstrated the feasibility of producing heparin-like compounds with precisely defined chemical structures and consistent anticoagulant activity. Parallel advances in producing heparin through mammalian cell culture systems further broaden the landscape of potential biosynthetic platforms [20]. However, presently these agents face significant constraints: higher manufacturing costs, synthetic complexity, and the need for therapeutic monitoring, thus limiting access and affordability of these agents as viable alternatives for heparin and LMWHs for routine use in resource-limited healthcare settings.

The hemagglutinin type 1 and neuraminidase type 1 (H1N1), severe acute respiratory syndrome, and COVID-19 pandemics have demonstrated that coagulopathy is a complex immunothrombotic process [21]. Moreover, the recent COVID-19 pandemic highlighted the need for nonheparin parenteral anticoagulants specifically optimized for intensive care and extracorporeal support, as well as a shift in the prescribing choice of anticoagulation drugs [22,23]. Future discovery efforts should prioritize anticoagulants with predictable pharmacokinetics in critical illness, simplified monitoring surrogates, partial reversibility or intrinsic safety switches, and reduced reliance on hepatic or renal clearance. In extracorporeal membrane oxygenation, targeted inhibition of factors such as FXI, FXII, or kallikrein may ultimately reduce dependence on antithrombin-mediated anticoagulation. Host-directed or pleiotropic agents that combine anticoagulant, antiplatelet, and anti-inflammatory effects may reduce the need for high-dose heparin in severe viral illness. Drug discovery in this space overlaps with work on complement inhibitors, NETosis modulators, and endothelial-stabilizing therapies, and could be explicitly aligned with pandemic coagulopathy indications to reduce pressure on heparin supply during future crises.

4.2 | Drug development: cost-efficient and resilient manufacturing

Diversification of raw material sourcing represents a foundational step. Development of multispecies heparin platforms incorporating porcine, bovine, or ovine sources under harmonized modern quality standards would allow rapid pivoting in response to epizootic disease affecting a single animal reservoir. Historical concerns regarding bovine heparin are being reassessed, considering contemporary purification and analytical technologies, and regulatory consideration by the US FDA for controlled reintroduction is progressively increasing [24]. Investment in regional purification, fractionation, and fill-finish hubs would shorten supply chains and provide buffering against border closures. Emerging continuous-manufacturing platforms for complex biologics and polysaccharides may further enhance efficiency, allow rapid surge scaling, and improve batch-to-batch consistency compared with traditional batch processing. Critically, these measures are unlikely to emerge from market forces alone; they require government-backed contracting, financing, and regulatory coordination that strongly values redundancy and continuity over lowest-unit-cost procurement. Governments and global health agencies should incentivize geographically diverse manufacturing through targeted policy and investment mechanisms. Establishing regional processing and manufacturing hubs in Europe, the Americas, and the Asia-Pacific regions for converting crude heparin into active pharmaceutical ingredients and finished formulations would build essential manufacturing redundancy and mitigate risks of single-region disruption.

For synthetic and bioengineered anticoagulants, platform-based manufacturing approaches offer additional resilience. Modular enzyme immobilization systems and adaptable bioreactor infrastructure could support the production of multiple glycosaminoglycan products across interpandemic periods, maintaining economic viability while preserving surge capacity. Regulatory development programs for such platforms will require robust comparability datasets addressing anticoagulant activity, structural fidelity, impurity profiles, immunogenicity, and heparin-induced thrombocytopenia risk relative to conventional heparins. The past lessons of the oversulfated chondroitin sulfate contamination crisis demonstrate that manufacturing standards should be elevated preemptively. Harmonized quality-by-design frameworks, updated pharmacopeial monographs for novel heparin analogues, and predefined pathways for emergency use authorization during supply crises would reduce the need for ad hoc regulatory responses under pandemic pressure.

4.3 | Drug delivery: innovation and strategy from production to patients

Although the World Health Organization (WHO) model list of essential medicines includes heparin, enoxaparin, and warfarin [25], this formal listing should be translated into operational protections. During public health emergencies, these should include prioritized logistics access (protected transport corridors and expedited customs clearance), explicit safeguards against export bans, and the creation of strategic stockpiles—so anticoagulant supply is not delayed by border closures, trade disputes, or competition with routine commercial shipments.

Geographic diversification of manufacturing and raw material sourcing is essential to reduce single-point dependencies. Regulatory frameworks should incentivize regional production hubs and facilitate controlled diversification of biological sources, including bovine-derived heparin under modern safety standards. For synthetic agents, flexible licensing and multiregion manufacturing strategies could reduce reliance on a small number of proprietary facilities. Regional distribution hubs for purification, fill-finish, and warehousing can shorten transport distances and reduce exposure to international shipping disruptions. Establishing strategically located regional stockpiles would further buffer hospitals against temporary transportation failures and allow redistribution within regions when local shortages arise. Digital supply chain monitoring is increasingly important for securing last-mile delivery [26]. Real-time tracking of inventory levels, shipment locations, and projected demand at national and regional levels would allow early identification of transport bottlenecks and enable proactive rerouting of supplies before clinical shortages emerge.

Transparency and quality assurance are equally critical. End-to-end traceability of anticoagulant supply chains, supported by real-time reporting of production volumes, active pharmaceutical ingredient origin, and batch testing outcomes, would allow earlier detection of emerging shortages or quality risks. Existing regulatory shortage reporting systems and databases, such as those maintained by the US FDA and European Medicines Agency, provide valuable information but remain fragmented and lack real-time coordination. Integrating such systems across manufacturers, distributors, and hospitals would reduce reliance on reactive, institution-level stock management and facilitate coordinated responses to disruption.

4.4 | Optimizing anticoagulant distribution and global equity

Prefilled, closed-system delivery devices offer additional advantages in high-risk infectious environments. Such systems reduce contamination risk, handling errors, and wastage, particularly when health care workers operate under extreme workload and personal protective equipment constraints. In intensive care units, standardized premixed ultrafractionated heparin infusions with smart-pump integration [27] can reduce dosing variability and titration errors, potentially enabling safer administration without compromising efficacy. Subcutaneous small-molecule anticoagulants or other nonparenteral options could theoretically reduce reliance on heparin for lower-risk cohorts during pandemics, reserving parenteral agents for the sickest patients. However, these approaches require thorough clinical evaluation in acute infectious settings, as existing data from chronic indications may not extrapolate to severe viral illness.

Integration of drug delivery with point-of-care monitoring offers opportunities to optimize dosing precision. Real-time anti-Xa assays or viscoelastic testing may reduce over-anticoagulation and -unnecessary dose escalation. In the extracorporeal membrane oxygenation setting, future codevelopment of anticoagulants with circuit-embedded sensors capable of monitoring coagulation dynamics and microthrombus formation could permit tighter titration and lower maintenance dosing, indirectly easing supply pressure.

Packaging and presentation formats are an underrecognized lever of resilience. Multidose LMWH vials (eg, Enoxaparin [Lovenox], available in prefilled syringes [30, 40, 60, 80, 100, 120, and 150 mg]) may reduce packaging intensity, cold-chain volume, and procurement friction and can improve dose availability during sudden demand surges. However, these formats require strong governance to avoid new safety failures—particularly dosing/labeling errors under workforce strain and infection-control concerns if multi-dose vials are used across patients. Where implemented, multidose presentations should be paired with clear single-patient assignments when feasible, standardized preparation protocols, and audit mechanisms to ensure that a supply-side gain does not convert into a medication-safety loss.

Lastly, anticoagulant shortages invariably disproportionately affect low- and middle-income countries (LMICs) lacking substantial purchasing power or strategic stockpiles. Pandemic preparedness planning must explicitly integrate equitable allocation mechanisms for anticoagulants, modelled structurally on successful COVAX frameworks for vaccine distribution [28]. Allocation should be based on objective population need and disease burden rather than market purchasing power, and implementation should be supported by dedicated international funding mechanisms ensuring low- and middle-income countries can reliably procure these essential medicines. Environmental sustainability is also inseparable from pharmaceutical resilience. Livestock-derived products contribute to greenhouse gas emissions and zoonotic risk, whereas chemical synthesis imposes environmental costs and may also reflect high carbon risk. Investment in sustainable bioprocessing, green chemistry, and responsible agriculture strengthens both drug security and planetary health, aligning anticoagulant production with broader health system and climate goals [29].

5 | CONCLUSION

Securing our global anticoagulant supply chain requires systemic change—from reactive crisis management toward proactive and coordinated resilience building. Heparin's dependence on animal biology, warfarin's reliance on narrow manufacturing networks, and DOACs' concentration in a limited number of high-technology facilities demonstrate the global systemic fragility of anticoagulation supply and accessibility. The next major shortage may arise from climate disruption, geopolitical conflict, or industrial failure as readily as from a pandemic. Safeguarding anticoagulant supply, therefore, requires a conceptual shift—from treating these agents as standard therapeutics to recognizing them as strategic medicines deserving of policy attention, investment, and international coordination. Diversified production, transparent governance, technological innovation, and equitable access must form the foundation of future resilience. The challenge ahead is to ensure that the WHO "Essential Medicines" designation translates into secure, equitable access by implementing interoperable manufacturing standards, strengthening regional capacity, and establishing pragmatic substitution pathways that can be activated before shortages disrupt patient care.

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DECLARATION OF INTEREST

The authors have no conflicts of interest.

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