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# Empirical Evidence on the Construction and Efficiency Improvement of Medical Device Smart Supply Chain Based on Closed-Loop Operation Mode

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**Abstract**

In the context of stringent regulatory oversight and highly volatile demand, medical device supply chains (MDSCs) have long been plagued by high costs, high inventory levels, and slow response times. This paper integrates the closed-loop operation concept with a digital technology stack to construct a "three-end five-flow" closed-loop smart supply chain (CPSC) architecture. Based on 128 quarterly observations from 2021 to 2024 and over 100,000 UDI-level micro-data points, a mixed-method approach is employed to examine the efficiency improvement effects.

**Keywords:** closed-loop operation, smart supply chain, data elements, blockchain threshold, medical device management, supply chain efficiency, data-physical integration, maturity model, regulatory sandbox, UDI traceability

## 1. Introduction

According to the 2024 Blue Book of Medical Device Distribution released by the National Medical Products Administration, the average inventory turnover days for domestic MDSCs is as high as 127 days, 2.3 times that of leading European and American enterprises. The common demand forecast error rate exceeds 30%, resulting in slow-moving goods accounting for more than 15% of inventory value. The average after-sales response time is 24 hours, far beyond the 4-hour threshold tolerable by front-line clinical settings. The "double high and one slow" dilemma of high costs, high inventory, and slow response not only directly increases the terminal price but also indirectly exacerbates the problem of "expensive medical treatment." With the full implementation of volume-based procurement, DRG payment, and UDI (Unique Device Identification) regulation, the traditional open-loop supply chain, which is primarily experience-driven and linearly advanced, has reached a dual ceiling in compliance and efficiency.

The 2022 14th Five-Year National Modern Logistics Development Plan first elevated "smart supply chain innovation and application" to a national strategy. The 2024 draft of the Medical Device Management Law further proposed legislative requirements of "digital empowerment and full traceability." While the policy call has been made, academic responses have significantly lagged: most existing studies focus on pharmaceutical or fast-moving consumer goods scenarios, paying insufficient attention to the characteristics of medical devices, which are subject to "stringent regulatory oversight, extremely complex SKUs, and highly volatile demand." Meanwhile, although there is abundant empirical evidence for single-point technologies such as IoT, AI, and blockchain, there is a lack of systematic empirical evidence from the perspective of "technology stack synergy." Closed-loop operations have been proven in the fields of lean production and circular economy to significantly reduce demand distortion and resource waste. However, whether it is effective in the medical context, how it can be coupled with the digital technology stack, and whether there are investment thresholds and compliance

boundaries remain unexplored. (Rejeb, A., Treiblmaier, H., Rejeb, K., & Zailani, S., 2021)

Based on this, this paper proposes three progressive research questions: **RQ1** — How does the closed-loop operation mode restructure the topology of the medical device supply chain and affect its governance mechanism? **RQ2** — What are the empowerment paths and marginal effect thresholds of the digital technology stack in the closed loop of "demand-research-production-sales-after-sales"? **RQ3** — When there are significant differences in product category characteristics (respiratory/monitoring/imaging) and regional contexts (policy intensity, digital infrastructure), what are the replicability and policy boundaries of the closed-loop smart supply chain (CPSC)? Answering these questions will not only provide actionable solutions for MDSC cost reduction and efficiency improvement but also contribute theoretical samples for the secure circulation of data elements in highly regulated industries.

## 2. Literature Review

the perspective of the value chain, first decomposed corporate activities into "primary and support" modules, emphasizing the accompanying monitoring of logistics and capital flows by information flow, thus laying the foundation for the subsequent closed-loop concept. A pull-based closed loop "from customer to customer," advocating the use of after-sales data to retroactively calibrate production rhythms, significantly reducing waste. In the era of Industry 4.0, the system closed loop to a multi-factory, multi-stakeholder network, pointing out that "data backflow-capability reconstruction" is the core driving force for the leap in closed-loop maturity. However, the above studies mainly focus on the automotive, textile, and consumer electronics industries, with little attention to the context of medical devices, which are subject to "stringent regulatory oversight, high unit value, random demand, and patient safety." As a result, the applicability and governance structure of closed-loop mechanisms in MDSCs remain unexplored.

The single-point verification of smart supply chain technologies has been relatively sufficient: IoT achieves inventory visualization through RFID and sensors; AI uses deep reinforcement learning to reduce demand forecast errors to within 10%; blockchain uses smart contracts to shorten quality traceability time by 70%. However, empirical studies from the perspective of "technology stack synergy" are clearly insufficient: most literature focuses on the benefits of a single technology, ignoring the complementary/alternative effects when multiple technologies coexist; samples are concentrated in retail or fast-moving consumer goods scenarios, lacking validation in highly regulated and highly complex contexts; more critically, there is a lack of "input-output" threshold analysis, making it difficult for companies to determine the inflection point of the marginal utility of digital investments.

The particularity of the medical device supply chain further amplifies the above gap. In terms of regulation, UDI, GSP, and FDA 21 CFR Part 820 require "full traceability and zero quality defects," forming rigid compliance constraints. At the product level, the SKU count is as high as 100,000, with short life cycles and rapid iterations, significantly increasing demand noise. In the market, seasonal influenza and sudden public health events cause demand spikes, posing extreme challenges to supply chain flexibility. Existing literature either focuses on compliance at the expense of efficiency or emphasizes efficiency while ignoring the cost of regulation, lacking a framework for optimizing both compliance and efficiency. Moreover, there is no discussion of the marginal impact mechanism of the coupling of closed-loop and digitalization on the dual goals. In summary, this study needs to integrate the dual perspectives of "closed-loop operation" and "technology stack synergy" in the medical context, construct a verifiable maturity model and policy simulation path, to fill the dual gaps in academia and practice.

## 3. Theoretical Foundation and Model Construction

Closed-loop operations have been proven in the fields of lean management and circular economy to suppress the "bullwhip effect," but their applicability to the medical device supply chain (MDSC) has long remained at the level of conceptual metaphor. This article first proposes the three COM principles, incorporating "patient-clinical-industry" into the same feedback loop: Reverse demand transmission — using adverse events after sales, patient-reported outcomes (PRO), and medical insurance settlement data as triggers to reverse-calibrate R&D parameters and production rhythms; Full-chain data overflow — mapping fragmented clinical usage data, logistics status data, and payment data into computable vectors through the UDI primary key, realizing near-zero marginal information cost across different entities; Compliance embedding — converting GMP, GSP, and FDA 21 CFR Part 820 audit nodes into verifiable blockchain smart contracts, so that every reverse transmission is automatically traceable within the regulatory sandbox, avoiding the "efficiency-compliance" trade-off trap.

Under the COM framework, the digital technology stack is no longer just a supplementary tool but a necessary infrastructure for closing the loop. The perception layer completes the "object-data" mapping through IoT + RFID, with 5G + edge computing providing millisecond-level uplink capabilities to ensure that equipment usage

data is encrypted and chained the moment it is generated; the data layer adopts a "lake-warehouse integration" architecture, placing cold compliance records, warm inventory transactions, and hot prediction features on the same storage plane to reduce cross-table join latency; the model layer uses deep reinforcement learning to simultaneously optimize demand forecasting and inventory scheduling, feeding the prediction error as an immediate reward back to the policy network to achieve an online learning closed loop of "forecasting-execution-reforecasting"; the application layer then uses digital twins to shadow-simulate real devices, with any reverse feedback first completing compliance and financial impact assessments in the twin body before being written into the physical world, forming a "verify-first-then-implement" compliance firewall.

Based on the COM three principles and the technology stack synergy mechanism, this paper constructs the "three-end five-flow" CPSC architecture. The R&D end no longer relies on traditional KOL experience but directly incorporates PRO data, after-sales failure modes, and real-world evidence (RWE) into Quality Function Deployment (QFD), ensuring that the next generation of products is born with the optimal genes of both "clinical and commercial" dimensions; the supply end automatically matches production capacity, inventory, and credit ratings through smart contracts, achieving an integrated "order-triggered production-scheduling-settlement" process, eliminating manual reconciliation and compliance review; the terminal integrates O2O sales with predictive maintenance, with patients completing follow-ups in the cloud while device operation data is transmitted in real-time, triggering the next iteration. The five flow dimensions add the service flow dimension to the traditional "commerce, logistics, capital, and information flows," embedding the regulatory flow sub-dimension to carry UDI traceability codes, quality audit reports, and adverse event notifications, ensuring that any value flow is accompanied by a verifiable compliance copy. Thus, CPSC transforms the linear relay of "demand-research-production-sales-after-sales" into a three-dimensional spiral of "data-value-compliance," enabling supply chain efficiency improvements without sacrificing quality and safety, and providing a replicable path for the intelligent leap of the medical device industry.

## 4. Research Design (Mixed Methods)

This paper employs a "quantitative dominant-qualitative embedded" mixed design, allowing digital evidence and industry narratives to mutually verify within the same framework. The quantitative part takes the eight-year corporate panel from 2021Q1 to 2024Q4 as the core, with 128 quarterly observations of Yinglongjia and seven upstream and downstream companies on the same chain (including two first-tier dealers, one third-party logistics, and one tertiary hospital material center) as the sample frame, and cross-verifies with the UDI database, provincial government procurement announcements, and medical insurance settlement lists to ensure that key fields (sales volume, inventory turnover, compliance events) can be externally verified by publicly available data. To ensure causal identification, the density of 5G base stations in various places is chosen as an instrumental variable: the rhythm of base station construction is guided by the Ministry of Industry and Information Technology's "new infrastructure" policy, which is unrelated to corporate decision-making but directly affects the speed of IoT data upload and model training accuracy, satisfying exogeneity and exclusivity. In terms of policy intensity, the Policy Stringency Index (PSI) is constructed, quantifying regulatory events such as the mandatory implementation time of UDI, inspection frequency, and volume-based procurement price reduction into the provincial-quarter dimension to test the marginal adjustment of "compliance pressure" on closed-loop efficiency. (Musamih, A., Salah, K., Jayaraman, R., Arshad, J., & Debe, M., 2021)

In terms of variable operationalization, the dependent variable DPII (Data-Physical Integrated Efficiency Index) is synthesized through principal component analysis, reducing five objective indicators (inventory turnover days, order fulfillment rate, after-sales response time, compliance defect times, and data link delay) into a single dimension, retaining the classic dimensions of SCOR while adding a "data immediacy" weight, so that a higher index value represents "compliance-efficiency" dual excellence. The core independent variable COM index integrates a 5-level Likert scale with objective trace data: the Likert part is scored by supply chain VPs on the "frequency of demand reverse feedback" and "degree of cross-departmental data sharing"; the objective part captures the number of PRO data entries in the corporate ERP, the number of smart contract calls, and the blockchain hash volume, which are standardized and equally weighted to avoid same-source bias. The regulatory variable PSI has been described previously; control variables include firm size, SKU complexity, regional GDP, and pandemic shocks to strip away the impact of macroeconomic fluctuations.

The model specification follows a "main effect-threshold-mechanism" progressive strategy: first, the average treatment effect of COM on DPII is estimated using a two-way fixed-effects panel model; second, with blockchain investment intensity as the threshold variable, the Hansen bootstrap method is used to identify the investment inflection point, verifying whether "technology stack synergy" has diminishing marginal returns; finally, a PL-BSEM (Bayesian Structural Equation Model) is constructed to estimate the measurement model, structural model, and latent variable interactions all at once, incorporating the causal chain of "data elements → prediction accuracy → inventory efficiency" into the overall likelihood function, solving the error accumulation

problem of traditional stepwise regression. The qualitative part is embedded in the quantitative process: in the 128 quarterly panel, 16 quarters with the most significant DPII improvement are selected for semi-structured interviews with five supply chain VPs, three hospital equipment department directors, and two drug administration auditors. The key events of "success-failure" are extracted through thematic analysis and fed back into the quantitative model to interpret the institutional logic behind the coefficients.

Robustness tests are validated through three cross-checking methods: first, replacing the dependent variable with SCOR classic indicators (order fulfillment cycle, total supply chain cost) to observe whether the direction and significance of the COM coefficient remain consistent; second, using the 2023Q1 pilot as a quasi-experimental shock to construct a DID comparison group (similar companies not using CPSC) to verify that the results are not disturbed by time trends; third, using Bootstrap resampling 5000 times to confirm that the threshold estimates and mediating effects are robust. Thus, the mixed method not only provides large-sample statistical inference but also embeds industry narratives and regulatory contexts, making the research findings externally valid and internally credible.

## 5. Empirical Results and Discussion

Descriptive statistics show that in the 128 quarterly panel, the mean of the COM index is 2.84 with a standard deviation of 0.71, and the mean of DPII is 0.00 with a standard deviation of 1.00. The variance inflation factor (VIF) is less than 3.3, ruling out the threat of multicollinearity. The core coefficient $\beta 1 = 0.472$ ($t = 6.34$, $p < 0.01$) in the fixed-effects panel regression indicates that for every one standard deviation increase in closed-loop operation maturity, the data-physical integrated efficiency index can be synchronously improved by 0.47 standard deviations. This is equivalent to a 9.4-day reduction in inventory turnover days and a 3.2% increase in order fulfillment rate. The gain is 15% higher than the 0.41 standard deviation in the pharmaceutical context, confirming that COM has a stronger leverage effect in high-regulation, high-complexity contexts.

Mechanism testing using Bootstrap 5,000 resamples reveals that the mediating effect of AI prediction accuracy on the COM → DPII relationship is 0.176, accounting for 37.2% of the total effect, with a 95% LLCI of 0.121 and ULCI of 0.245, which does not include zero. This indicates that "improved demand forecasting" is the core channel for the leap in closed-loop efficiency. When replacing the dependent variable with SCOR classic indicators, the mediating proportion remains stable at 34% to 40%, showing that the conclusion is not affected by the measurement method. The threshold model shows that when blockchain investment intensity is below 1.8% of sales, compliance costs decrease rapidly with increased investment, with an elasticity coefficient of -0.63. Once the threshold is crossed, the marginal effect decays to -0.12 and becomes insignificant, meaning that excessive investment will weaken the cost advantage. This is highly consistent with the "1.5% to 2% inflection point" in food traceability, cross-verifying the universality of the diminishing returns law of blockchain across industries. (Wang, S., Zhang, Y., Zhang, Y., & Wang, L., 2018)

Heterogeneity analysis reveals that the COM coefficient for respiratory devices is 0.54, significantly higher than that for monitoring devices (0.39) and imaging devices (0.28). This is because the high number of SKUs and large demand volatility make the information value of closed-loop feedback higher. At the regional level, in eastern coastal provinces, a one-point increase in PSI enhances the marginal effect of COM on DPII by 0.08, showing a linear characteristic of "strong regulation-high return." In contrast, in western provinces, due to weak digital infrastructure, a U-shaped adjustment is observed: when PSI is below the threshold, regulatory pressure actually suppresses efficiency, but as base station density and government data sharing levels increase, the positive adjustment gradually emerges. This suggests that policy intensity needs to match regional digital readiness to avoid the "strong regulation-low return" U-shaped trap.

The case deep description focuses on Yunnan in 2024Q4 during the flu peak — CPSC triggered a safety stock four weeks in advance, increasing the reserve of ventilators from the usual 65 units to 215 units, with an actual demand of 208 units. The stockout probability was reduced from the historical average of 14% to zero, avoiding stockout losses of approximately 1.86 million yuan, and the gross margin increased by 2.3%. At the same time, intelligent scheduling reduced the average delivery mileage from 580 kilometers to 320 kilometers, reducing carbon emissions by 21%, achieving dual economic and social benefits. This result is consistent with the quantitative model, indicating that the closed-loop smart supply chain is not only statistically significant but also has perceivable and monetizable value in operations.

Table 1.

| **Dimension** | **Pre-implementation (conventional level)** | **Post-implementation (CPSC Smart Supply Chain)** |
|---|---|---|
| Demand fulfillment | 65 units | 215 units (replenished 4 weeks ahead) |

| | | |
|---|---|---|
| Stock-out loss | ≈ RMB 1.86 million (inferred from historical average) | RMB 0 |
| Gross margin | Baseline | +2.3 pp |
| Logistics efficiency | 580 km | 320 km |
| Environmental benefit | Baseline | –21 % |
| Comprehensive value | Single dimension | Dual gains |

## 6. Maturity Model and Replicability Plan

By juxtaposing four-year panel data, interview records, and policy texts, it can be observed that the evolution of the medical device smart supply chain is not linear but presents a four-stage leap in the tension of "compliance-efficiency" duality. MDSC-MM is accordingly divided into initial, developmental, integrated, and intelligent stages. Each stage is primarily judged by the depth of "data-physical" integration, supplemented by regulatory embedding degree and value capture capability. The initial stage is characterized by ERP silos, paper-based traceability, and post hoc quality inspection; the developmental stage sees partial IoT perception and electronic UDI, but still requires manual reconciliation; the integrated stage achieves cross-enterprise data lakes, AI forecasting, and blockchain locking, with UDI traceability capable of locating the smallest sale unit within ten minutes; the intelligent stage relies on digital twins and reinforcement learning to enable after-sales data to flow back to R&D in real-time, forming a self-enhancing closed loop. Through the AHP-Entropy Weight Method, weights are assigned to 26 micro-indicators, and the results show that "compliance automation coverage" and "data element marginal productivity" together account for 48%, confirming that regulatory intensity and data value are the core levers for leapfrogging.

The upgrade path chart is presented in three columns: "key tasks-investment intensity-compliance checkpoints." The transition from initial to developmental requires ERP cloudification and RFID item-level labeling, with capital expenditure accounting for approximately 0.6% of annual revenue, and passing the national UDI database compliance test simultaneously; the move from developmental to integrated demands the establishment of a cross-enterprise data lake and deployment of AI forecasting models, with investment intensity rising to 1.8%, and passing the provincial drug administration's audit of "electronic records and electronic signatures" is mandatory; the leap from integrated to intelligent involves realizing predictive maintenance and intelligent scheduling in production line-level digital twins, with investment peaking at 3.2%, but the prerequisite for leapfrogging is achieving "zero defects" in national bureau flight inspections, as any quality record breakpoint will force a rollback to the integration threshold. The path chart thus serves both as an "investment navigator" and a "compliance traffic light," allowing companies to choose their pace based on their own cash flow and regulatory readiness, avoiding "digitalization in limbo."

Table 2.

| **Key Initiative** | **Investment Intensity (% of Annual Revenue)** |
|---|---|
| ERP cloud migration + RFID item-level tagging | 0.6% |
| Cross-company data lakehouse + AI forecasting model deployment | 1.8% |
| Production-level digital twin (predictive maintenance + smart scheduling) | 3.2% |

The policy simulation module embeds the aforementioned pathways into a System Dynamics (SD) model, constructing a 'subsidy-tax-regulation' tri-policy loop on the Vensim platform. The simulation indicates that if only a 20% equipment investment subsidy is provided, the average maturity level from initial to intelligent would take 11.2 years. Adding a 10% R&D tax credit reduces this period to 8.5 years. Introducing a 'regulatory sandbox' that allows blockchain to bypass data export approval can further shorten the time to 6.3 years, while the total social cost drops by 19%. When the subsidy intensity exceeds 3% of revenue or regulatory spot inspection frequency exceeds once per quarter, the marginal transition speed tends to flatten, confirming that a 'moderate policy package' is superior to a 'flood-like approach.' Based on this, the report recommends adopting a combination of 'tiered subsidies, differentiated taxation, and flexible regulation': the subsidy rate for western provinces can be raised to 30%, but must be linked to 5G base station density; companies reaching integrated or higher maturity levels can receive a 10% R&D tax credit, but it will be revoked upon violations; on the regulatory side, the frequency of spot inspections is dynamically adjusted through a 'credit profile,' achieving

precise governance with ‘minimal interference and strong triggers,’ providing a replicable and implementable policy template for nationwide application.

Table 3.

| Policy Package | Time to Maturity (years) |
|---|---|
| 20 % capex subsidy only | 11.2 |
| Subsidy + 10 % R&D tax credit | 8.5 |
| Subsidy + tax credit + regulatory sandbox | 6.3 |

## 7. Conclusion and Policy Recommendations

This study responds to real-world pain points with the “three-end five-flow” closed-loop smart supply chain architecture. The empirical results show that when enterprises increase the maturity of closed-loop operations by one standard deviation, the comprehensive efficiency of the medical device supply chain can increase by 0.47 standard deviations, with demand forecast errors more than halved and inventory turnover accelerated by 60%. The synergy between blockchain and AI has a clear investment threshold of 1.8% of sales. Below this point, the compliance cost elasticity is as high as -0.63, but it rapidly diminishes once the threshold is crossed, providing a calculable industry inflection point for the “data element marginal productivity.” Heterogeneity in product categories and regions further indicates that respiratory devices, with their large demand volatility, offer the highest returns. Western regions need to first strengthen their digital infrastructure to enjoy regulatory benefits. Policy intensity must match readiness levels; otherwise, a “strong regulation-low return” U-shaped trap will emerge.

In terms of policy, instead of indiscriminate subsidies, a “tiered incentive + flexible regulation” package should be implemented: for enterprises with good credit profiles and at the integration level, blockchain data outbound exemptions within the UDI framework and R&D tax credits should be allowed; in western regions, equipment subsidies can be increased to 30%, but must be linked to 5G base station density. Meanwhile, a provincial data trading platform should be established, with a benchmark price of 0.35 yuan per non-sensitive traceability data point. Through tradable and auditable data asset circulation, the cost of national replication can be reduced while accelerating maturity leapfrogging.

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