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REVIEW

From blood banking to advanced therapeutics: reframing transfusion medicine in the era of cell and gene therapy in China

Yiming Ma[1] | Xiaofei Li[1] | Yu Jia[2]

[1]Department of Blood Transfusion, Beijing Friendship Hospital, Capital Medical University, Beijing 100050, China

[2]Institute of Blood Transfusion, Chinese Academy of Medical Sciences and Peking Union Medical College, Chengdu 610052, China

Correspondence
Yu Jia, Institute of Blood Transfusion, Chinese Academy of Medical Sciences and Peking Union Medical College, Chengdu 610052, China.
Email: j-yu@ibms.pumc.edu.cn.

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Abstract

Cell and gene therapy (CGT) is rapidly reshaping the therapeutic landscape in China, where approved commercial products, registered clinical trials, investigator-initiated studies (IITs), and hospital-based translational platforms are developing in parallel. This pattern is especially pronounced in cellular therapeutics, including immune effector cell therapies, stem cell-based products, and selected cell-derived therapeutics. As living and highly individualized therapeutic products, these interventions require not only robust manufacturing processes but also safe and coordinated implementation within hospitals. A critical challenge lies in the hospital-based interval between manufacturing release and bedside administration, encompassing product receipt, chain of identity control, chain of custody maintenance, storage oversight, clinical release, and post-infusion surveillance. In this context, transfusion medicine should be reconsidered beyond its conventional function in blood banking. Transfusion medicine, as a hospital-based discipline with well-established expertise in apheresis, product identification, cold-chain management, traceability, and transfusion safety, possesses a competency profile that aligns closely with the unmet governance requirements of cellular therapy programs. This review examines the Chinese institutional context and contends that transfusion medicine can function as a coordinating governance interface between manufacturing and clinical application. Reframing transfusion medicine in this way may help strengthen hospital-based therapeutic stewardship, improve implementation safety, and support the sustainable

development of advanced cellular therapies in China.

Keywords
cell and gene therapy; cellular therapy; transfusion medicine; hospital-based governance; clinical release; China

Highlights
- China's cell and gene therapy (CGT) expansion creates new hospital-based governance challenges.
- The interval from manufacturing release to infusion is especially vulnerable.
- Transfusion medicine offers expertise in identity, custody, and cold chain.
- Clinical release should integrate product status and patient readiness.
- Transfusion medicine may serve as a governance interface for CGT safety.

1. INTRODUCTION

Cell and gene therapy (CGT) has rapidly evolved from a highly specialized discipline to a major therapeutic domain spanning hematologic malignancies, inherited disorders, regenerative medicine, and immune-mediated diseases [1]. In China, this expansion has been notably dynamic, characterized by the simultaneous development of approved commercial chimeric antigen receptor T-cell (CAR-T) products, registered clinical trials, investigator-initiated studies (IITs), and hospital-based translational platforms [2, 3]. This parallel development has accelerated innovation and broadened access, while also generating a complex institutional environment in which multiple translational pathways may coexist within the same hospital [2–4].

Much of the current discussion on CGT remains centered on upstream issues such as vector design, potency, manufacturing scalability, and regulatory approval [1]. However, in clinical practice, major vulnerabilities often arise after a product leaves the manufacturing facility and before it is administered to the patient. These include product receipt, chain of identity verification, chain of custody maintenance, storage oversight, assessment of patient readiness, and post-infusion surveillance [5–7]. Such hospital-based processes are particularly important in China, where commercial products, academic protocols, and hospital-supported manufacturing programs may function concurrently, often through distinct organizational pathways yet within the same clinical institution [2, 3].

In this review, the term CGT is used in a pragmatic rather than a fully comprehensive sense. Our discussion focuses primarily on cell-based CGT products and selected cell-derived therapeutics, especially those requiring hospital receipt, handling, release assessment, and administration under controlled conditions. This includes immune effector cell therapies, stem cell-based products, and certain cell-derived therapeutics such as extracellular vesicle-based interventions. By contrast, the governance model proposed here is less directly applicable to all categories of *in vivo* gene delivery products, which may follow different hospital workflows.

In this context, transfusion medicine needs reevaluation beyond its conventional role in blood banking. As a hospital-based discipline with long-standing experience in human-derived therapeutic products, transfusion medicine has established expertise in apheresis, product identification, cold-chain management, traceability, and transfusion safety [5, 8]. This review explores the growing importance of these competencies in the implementation of hospital-based cellular therapy in China and argues that transfusion medicine may provide a practical governance interface between manufacturing and clinical use.

2. WHY TRANSFUSION MEDICINE MATTERS BEYOND BLOOD BANKING

Transfusion medicine is frequently perceived in a limited scope as a discipline concerned with blood collection, compatibility testing, and component issuance. In practice, however, it has long functioned as a specialty centered on the safe therapeutic application of human-derived cellular products in hospital settings. Long before the emergence of modern CGT, transfusion services had already established systems for identity verification, product qualification, storage control, transport monitoring, administration safeguards, and adverse-event surveillance [5, 8]. These functions are not incidental to the field, as they define its institutional logic.

This historical foundation is directly relevant to cell-based CGT. Unlike conventional pharmaceuticals, cellular therapy products are biologically dynamic, individualized or semi-individualized, and often highly sensitive to handling conditions [1]. Their clinical performance depends not only on manufacturing quality, but also on the processes that occur after the product leaves the manufacturing facility. Hospitals must preserve product identity, maintain chain of custody, ensure appropriate environmental conditions, verify administration readiness, and detect early

toxicities [5, 6]. These requirements closely resemble the principles that have long governed blood component management and therapeutic apheresis [5, 8].

Transfusion medicine represents a critical practical intersection between laboratory medicine and bedside care. In many hospitals, transfusion physicians and services are involved not only in product storage, but also in therapeutic apheresis, peri-procedural coordination, urgent consultation, hemovigilance, and multidisciplinary decision-making [8]. This is particularly relevant for immune effector cell therapies, in which leukapheresis, pre-analytical variability, timing of collection, and patient condition can substantially influence downstream manufacturing feasibility and clinical outcomes [8–10].

The evolution of international standards further facilitates a broader understanding of the field's scope. American Association of Blood Banks (AABB) standards for cellular therapy services extend beyond traditional blood banking to address collection, processing, storage, and administration across cellular therapy products [5]. Likewise, FACT-JACIE standards cover the entire cellular therapy pathway and emphasize concepts such as chain of identity, chain of custody, transport, and administration [6]. These developments suggest that transfusion medicine is increasingly aligned with the quality architecture essential for hospital-based cellular therapeutics.

The transition summarized in ***Table 1*** shows that the relevance of transfusion medicine to contemporary CGT resides not only in historical continuity, but also in its capacity to evolve into a governance discipline for advanced cellular therapeutics.

TABLE 1 From traditional blood banking to cellular therapy governance: the evolving scope of transfusion medicine

Domain	Traditional transfusion medicine	Transfusion medicine in the cellular therapy era
Primary therapeutic object	Blood components for immediate clinical support	Living cellular products and cell-derived therapeutics requiring longitudinal oversight
Core operational logic	Compatibility, inventory, and episode-based transfusion safety	Identity assurance, custody continuity, clinical release, and lifecycle governance
Source management	Blood donation and component preparation	Apheresis-based source collection, cellular starting material stewardship, and patient-linked product control
Product handling	Storage, matching, issuance, and bedside verification	Receipt verification, chain of identity, chain of custody, cold-chain oversight, and pre-administration readiness review
Time horizon	Short-cycle transfusion episode	Multi-stage pathway from collection to administration and follow-up
Safety framework	Transfusion reactions and hemovigilance	Product deviation management, infusion-related toxicity monitoring, and integrated biovigilance/therapeutic surveillance
Data structure	Donation-to-transfusion traceability	Longitudinal product-patient linkage across manufacturing, transport, release, administration, and outcome monitoring
Institutional role	Support service for blood products	Coordinating governance interface at the hospital boundary between manufacturing and clinical use
Key collaboration	Clinical departments, laboratories, and blood suppliers	Hematology/oncology, GMP platforms, pharmacy, intensive care, clinical trial offices, and hospital quality systems
Strategic identity	Blood banking and transfusion safety	Advanced therapeutics stewardship in hospital-based CGT programs

GMP, good manufacturing practice; CGT, cell and gene therapy.

3. THE CHINESE CONTEXT AND THE GOVERNANCE GAP IN HOSPITAL-BASED CGT

The rapid expansion of CGT in China has produced a distinctive translational landscape. Commercial CAR-T products, registered clinical studies, IITs, and hospital-based manufacturing platforms are progressing concurrently rather than sequentially [2, 3, 11]. This pattern differs from more centralized translational models, where product development, manufacturing, and clinical deployment are institutionally more separated. In China, hospital-based innovation remains a major driver of CGT development, directly contributing to operational complexity [2, 3, 12].

This complexity manifests across multiple levels. First, approved commercial CAR-T products have already entered routine clinical practice in China [2]. Second, IIT activity has expanded rapidly, allowing hospitals to explore novel cell-based interventions beyond currently approved products [3]. Third, certain hospitals are simultaneously building or operating good manufacturing practice (GMP)-like translational platforms, creating environments in which commercially manufactured products, academic investigational products, and in-house preparations may all coexist within the same institution [2, 3, 11]. These parallel pathways enhance flexibility and innovation; however, they also give rise to a heterogeneous operational environment in which product governance responsibilities may become fragmented.

Under these conditions, the key challenge extends beyond upstream manufacturing and regulatory approval. It increasingly lies in the hospital's ability to manage processes occurring after a product's arrival on site and prior to its administration to the patient [3, 13]. Manufacturing release confirms that a product has met predefined production and quality criteria, but it does not automatically resolve downstream clinical questions. A patient's

condition may change due to infection, organ dysfunction, disease progression, bridging therapy, or treatment delays. At the same time, the product itself may be subjected to risks during transportation, receipt, storage, or handoff within the hospital [13–15]. Therefore, the interval between manufacturing release and bedside administration should be recognized as a distinct hospital-based governance process that requires identity verification, chain of custody control, environmental oversight, and patient-specific readiness assessment [13–15].

This governance gap is particularly visible in Chinese hospitals because innovation is occurring close to the point of care. In such settings, the challenge extends beyond the mere feasibility of manufacturing a product to include whether hospitals have a stable internal mechanism to receive, verify, release, administer, and monitor highly specialized living therapeutics under routine clinical conditions [2, 3, 13]. The unmet need is an institutional coordinating layer capable of bridging the gap between product arrival and clinical use while preserving safety, traceability, and accountability [13, 16]. This is the context in which transfusion medicine may have particular relevance.

4. REFRAMING TRANSFUSION MEDICINE AS A COORDINATING GOVERNANCE INTERFACE

Against this background, the key question is which discipline is most suitably positioned to coordinate this hospital-based governance interface. In this context, transfusion medicine should be reframed not merely as a support service but as a hospital-based coordinating governance interface for advanced therapeutics. This does not imply that transfusion medicine should replace hematology, oncology, pharmacy, stem cell laboratories, or hospital GMP facilities. Rather, it suggests that transfusion medicine may provide an institutional and operational interface capable of integrating these functions within a coherent quality and safety pathway [5, 8, 13]. This proposed governance model is summarized in ***Figure 1***, which illustrates transfusion medicine as a hospital-based interface linking parallel CGT development pathways with clinical implementation, traceability, release assessment, and post-administration surveillance.

What uniquely positions transfusion medicine is not only the presence of relevant technical competencies but also the continuity of its institutional logic. Few hospital disciplines routinely manage human-derived therapeutic products through a connected sequence that includes source acquisition, product identification, controlled storage, pre-administration verification, bedside safety, and post-administration surveillance. This continuity renders transfusion medicine particularly well-suited to coordinate the hospital-side governance interface of cellular therapy, while other stakeholders continue to contribute disease-specific expertise, manufacturing capability, pharmacological oversight, or intensive care support.

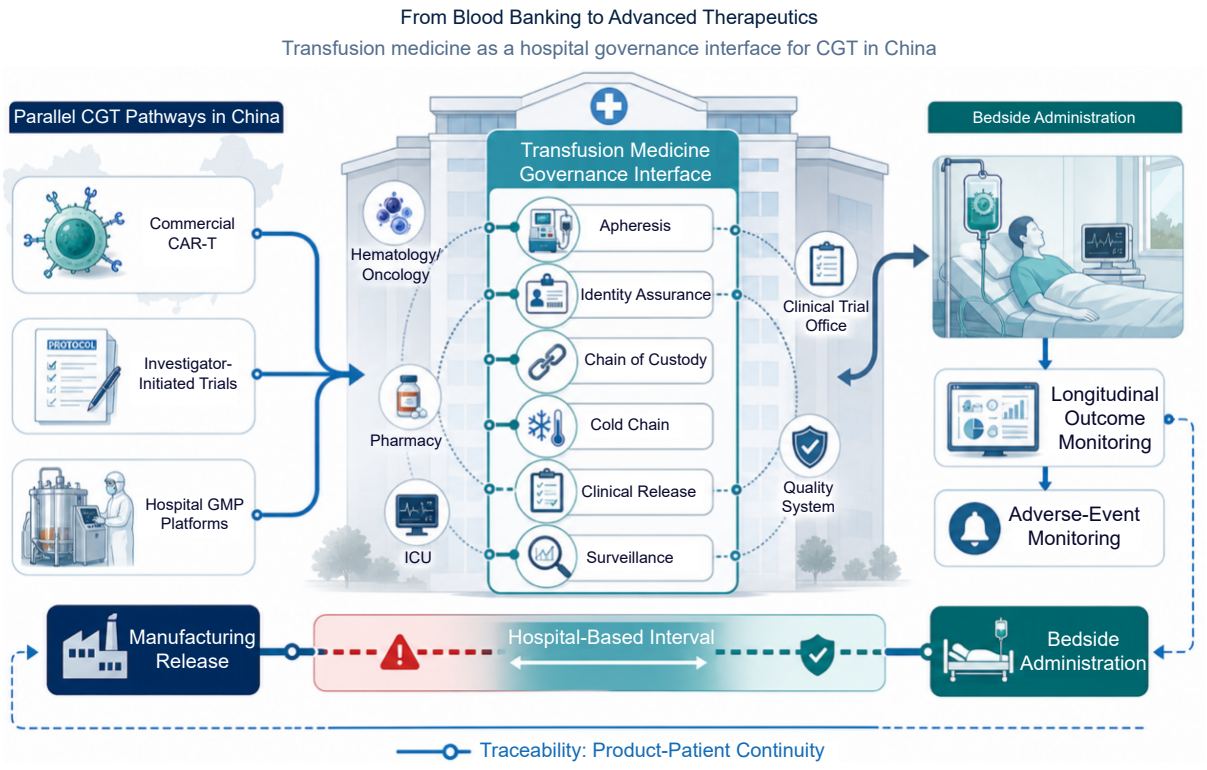

FIGURE 1 Transfusion medicine as a hospital-based governance interface for cell and gene therapy (CGT) in China. CAR-T, chimeric antigen receptor T-cell; GMP, good manufacturing practice; ICU, intensive care unit.

Its potential contribution begins with source collection and source management. Therapeutic apheresis and mononuclear cell collection are well-established practices within many transfusion services and are directly pertinent to immune effector cell therapies such as CAR-T and other autologous cellular products [8]. Collection requires patient assessment, timing coordination, procedural standardization, and documentation integrity, all of which may influence downstream manufacturing feasibility and final product quality [8, 9]. In this respect, transfusion medicine provides not simply technical support, but stewardship of source material at the initial hospital-linked stage of the therapeutic pathway.

Transfusion medicine also offers a robust basis for identity assurance and chain of custody control. Modern cellular therapy standards place substantial emphasis on precise labeling, thorough documentation, traceability, and handoff management across collection, transport, storage, and administration [5, 6]. These constitute standard operational requirements in blood banking and apheresis-based practices. Since many cellular therapy products are individualized or patient-specific, failures in identity verification can result in immediate and serious clinical consequences [5, 6, 16]. Here, the contribution of transfusion medicine lies in coordinating and implementing safeguards that preserve the integrity of the product-patient relationship throughout hospital handling.

A third area is storage, transportation, and environmental oversight. Cellular therapies and cell-derived therapeutics often depend on tightly controlled storage conditions, temperature monitoring, excursion management, and predefined responses to transport deviations [5, 6, 14, 16]. Many transfusion services currently employ multi-temperature storage systems and product traceability mechanisms under time-sensitive clinical conditions. This experience is highly transferable to commercial CAR-T products, stem cell-based investigational therapies, and cell-derived biologics requiring cold-chain protection [5, 14, 16]. In this domain, transfusion medicine can serve as a practical stewardship platform for the management of hospital-based product handling.

Most importantly, transfusion medicine may contribute to clinical release and post-administration surveillance. Clinical release differs from manufacturing release in that it requires a review of not only the product status but also patient readiness and treatment context, including infection, organ function, timing, and immediate infusion-related risks [13, 15, 17]. Following administration, structured surveillance is needed for adverse events, infusion reactions, and delayed complications [13, 17, 18]. Reframed for the cellular therapy era, these functions extend the established principles of transfusion safety into a more comprehensive model of therapeutic stewardship.

However, for transfusion medicine to assume such a role in China, internal transformations within the specialty will be necessary. The initial focus is on workforce development. Many transfusion teams remain highly experienced in blood component management and routine apheresis but have limited exposure to GMP principles, cellular manufacturing interfaces, investigational product governance, and therapy-specific toxicities [3, 13]. Therefore, training must be expanded to include cell processing concepts, clinical release logic, chain of identity management, immune effector cell toxicities, and the operational requirements of hospital-based translational studies [8, 13, 17].

The second is digital infrastructure and longitudinal traceability. Existing blood bank information systems are primarily designed for donor testing, inventory management, compatibility assessment, and transfusion episode documentation. They are not inherently structured to capture the extended trajectories of cellular therapy products, which may involve collection scheduling, manufacturing turnaround, transport tracking, receipt verification, release review, administration timing, delayed toxicities, and long-term follow-up [13, 15, 17]. In China, where hospital-based cellular therapy programs are rapidly expanding, transfusion medicine will necessitate digital platforms capable of linking product-level information with patient-level outcomes over time [2, 3, 13].

The third is institutional authority and multidisciplinary integration. A governance role cannot be maintained solely through technical competence alone; it requires formal recognition within hospital decision-making structures. In many institutions, transfusion medicine continues to serve primarily an operational role rather than a clinical governance role. The implementation of cellular therapy requires continuous interaction with hematology, oncology, pharmacy, intensive care, laboratory medicine, clinical trial offices, and hospital GMP platforms [3, 13]. For transfusion medicine to function effectively within this context, its role should be embedded within multidisciplinary therapeutic pathways rather than confined to isolated technical tasks [19].

Taken together, these considerations suggest that the future significance of transfusion medicine in China lies not only in supporting blood components or collection procedures, but also in serving as a coordinating hospital interface for cellular therapy stewardship. Its value derives not from disciplinary substitution, but from its ability to facilitate the integration of collection, verification, storage, release, and surveillance into a more coherent hospital pathway [2, 3, 8, 13].

5. CONCLUSION

Cell-based CGT is transforming both the therapeutic and organizational landscape of Chinese hospitals. As commercial products, IITs, and hospital-based translational platforms continue to expand in parallel, the central challenge is no longer limited to manufacturing advanced therapeutic products. It increasingly

concerns whether hospitals can govern these products safely and coherently once they enter the clinical pathway [2, 3, 11].

In this context, transfusion medicine deserves to be reconsidered beyond its conventional identity as a blood banking service. The specialty already possesses a set of competencies highly relevant to hospital-based cellular therapy, including apheresis experience, product identification, cold-chain oversight, traceability systems, and pre-administration safety control [5, 6, 8]. While these competencies do not independently resolve all challenges associated with CGT, they provide a strong institutional foundation for addressing one of the most vulnerable stages of implementation.

The central argument of this review is therefore not that transfusion medicine should simply be integrated into existing CGT workflows, but that it should be reframed as part of the governance architecture of advanced cellular therapeutics in China. With the support of by workforce redesign, digital modernization, multidisciplinary integration, and increased institutional recognition, transfusion medicine may enable Chinese hospitals to transition from fragmented operational handling to a more coherent model of therapeutic stewardship, quality assurance, and patient safety.

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AUTHOR CONTRIBUTIONS

Conceptualization, Yiming Ma; Writing – Original Draft Preparation, Yiming Ma; Writing – Review & Editing, Yiming Ma; Writing – Review & Editing, Xiaofei Li and Yu Jia; Critical Comments and Suggestions, Xiaofei Li and Yu Jia. All authors reviewed and approved the final manuscript.

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Not applicable.

INFORMED CONSENT STATEMENT

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Not applicable.

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