Expansion of Indications for CAR-T Cell Therapy in Japan and the Evolution of Associated Challenges Analysis of the Current Situation Based on a Periodic Questionnaire Survey

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1. Background & Objectives

- CAR-T cell therapy for relapsed or refractory diffuse large B-cell lymphoma (DLBCL) has, since its inclusion in Japan's national health insurance system in 2019, seen an increase in the number of available products and manufacturing capacity. As a result, the number of treatment centers—particularly in urban areas—has expanded in Japan, and the therapy has become established as one of the treatment options.
- This questionnaire survey study aims to clarify the current status of CAR-T cell therapy and identify future challenges based on time-series survey data.

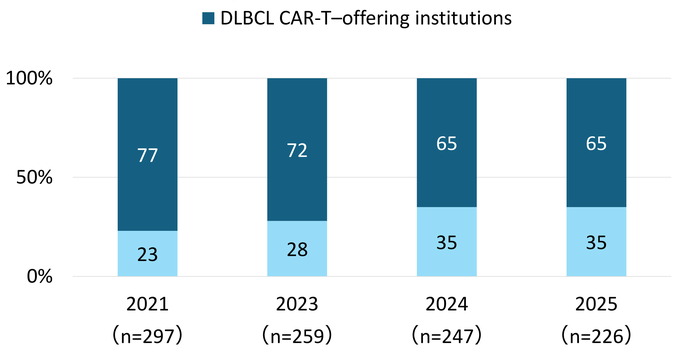
2. Methodology

- Interviews and online questionnaire surveys have been conducted since 2021 among clinical physicians who are registered members of Plamed Inc.
- The respondents were physicians who treat patients with DLBCL, and all collected data were anonymized prior to analysis.

Survey timeline

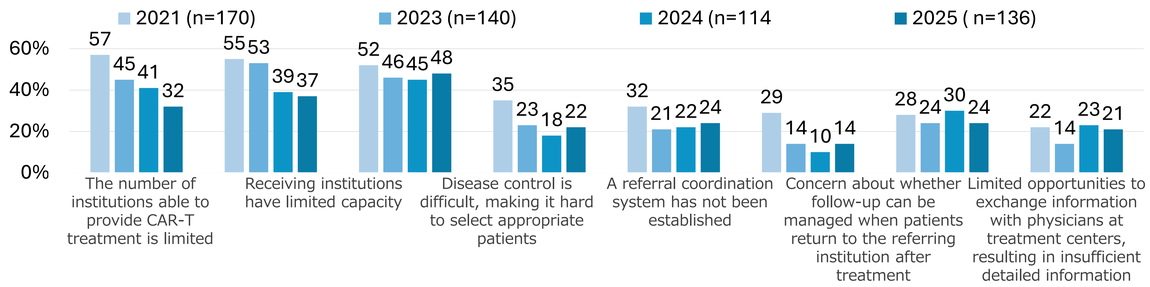
Year	Online questionnaire	Interviews
2021	8/17-8/23	10/2-11/20
2022	—	—
2023	9/5-9/12	9/11-9/22
2024	9/19-27	9/24-10/3
2025	8/12-8/25	9/3-9/11

Respondent background



3. Findings

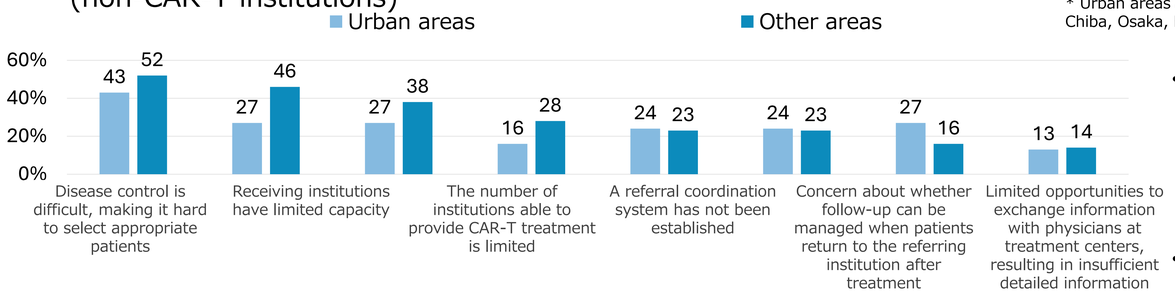
- Challenges in referring patients for DLBCL CAR-T treatment (non-CAR-T institutions) * Only the top items are shown.



- In 2021 and 2023, "The number of institutions able to provide CAR-T treatment is limited" and "Receiving institutions have limited capacity" were among the top challenges. However, with the increase in the number of institutions offering CAR-T and the expansion of manufacturers' production capacity, the number of physicians who perceive these as challenges has been decreasing year by year.
- At the same time, "Disease control is difficult, making it hard to select appropriate patients" had been among the top challenges since 2021. No major change was observed even in 2025, and it remains the most significant challenge at present.

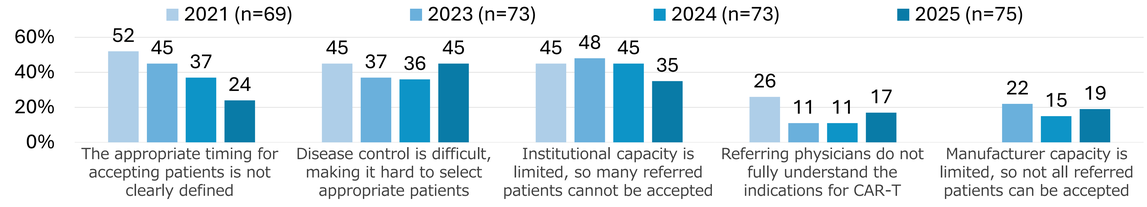
- Challenges in referring patients for DLBCL CAR-T treatment by area (non-CAR-T institutions)

* Only the top items are shown.
* Results for 2025 are indicated
* Urban areas are defined as Saitama, Tokyo, Kanagawa, Chiba, Osaka, Hyogo, and Kyoto.



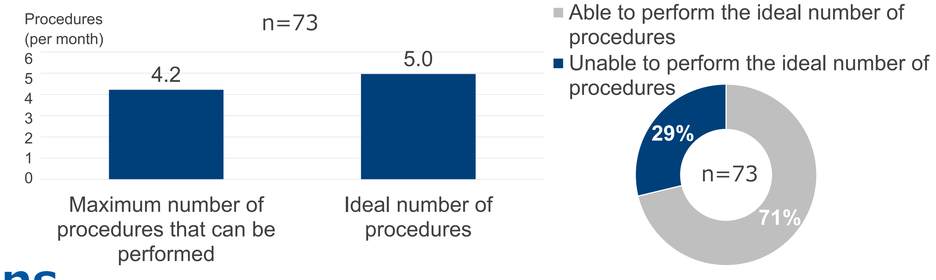
- When comparing by region, in areas outside major urban centers about 40–50% of physicians cited "Receiving institutions have limited capacity" and "The number of institutions able to provide CAR-T treatment is limited" as challenges, representing a difference of more than 10 percentage points compared with urban areas.
- Although some challenges have gradually been resolved over time, access to CAR-T remains an issue in certain regions.

- Challenges and concerns when accepting DLBCL CAR-T patients (CAR-T institutions)



- In 2021, the most significant issue was "the timing of patient acceptance," but this issue has gradually been resolved over the years. "Patient selection" and "limitations on the number of patients that can be accepted due to capacity constraints" remain ongoing challenges.

- CAR-T cell therapy treatment capacity



- The maximum number of CAR-T cell therapy procedures that could be performed per institution was 4.2 per month, while the ideal number was 5.0 per month.
- Although approximately 70% of institutions are able to perform the ideal number of procedures, some institutions still require capacity expansion. If CAR-T therapy is also introduced for autoimmune diseases in the future, the number of institutions facing capacity constraints is likely to increase.

4. Conclusions & Ramifications

Challenges related to referring patients for CAR-T cell therapy in DLBCL have been gradually resolved over time, and capacity and treatment access in particular have improved substantially overall. Meanwhile, "Disease control is difficult, making it hard to select appropriate patients" has shown no improvement over time and remains a challenge going forward. Looking at regional differences, as of 2025 capacity and treatment access remain issues in areas outside major urban centers, indicating a need to address regional disparities. At present, the number of CAR-T procedures that can be performed is not a major constraint. However, if CAR-T therapy begins to be used for solid tumors or autoimmune diseases in the future, the number of institutions facing capacity constraints is likely to increase.