Methods to Include the Organizational Impacts in Health-Economic Evaluations: Experience From CAR-T in France

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OBJECTIVE

> This study aims **to describe the methods used to evaluate the organizational impact in the health economic analyses in France**, through the example of CAR-T cell therapies.

> This study aims **to identify key areas of improvement for future health-economic evaluations**, in the integration and valuation of organizational impacts.

METHODOLOGY

> **Descriptive review of economic opinions from the HAS** (French HTA body) medico-economic commission (CEESP), published **from January 2019 to December 2023 on CAR-T cell therapy** [1-6].

> Elements leveraged to measure the **organizational impacts were identified through HAS' three macro-criteria** [7] that document organizational impacts.

RESULTS

> **The three macro-criteria and associated CAR-T's organizational impacts are listed below :**

Macro-criteria 1
Impacts of the health technology on the **care process**

- Patient eligibility tests modify times prior to the initiation of the process.
- Pre-treatments prior to a single infusion of CAR-T cells modify the content and the duration of the care process.
- Impact on the type of equipment, as the product needs to be stored at a temperature below -150°C in liquid nitrogen.

Macro-criteria 2
Impacts of the health technology on the **capabilities and skills required of stakeholders** to implement the care process

- Impact on healthcare professionals' skills due to CAR-T cell handling and side effect training.
- Impact on hospitals, which must meet criteria requiring adaptations to administer these therapies.
- Impact on the need for close collaboration between healthcare centers, as CAR-T cells are stored at low temperatures and miscommunication is not an option.

Macro-criteria 3
Impacts of the health technology on **society or the community**

- Impact on safety due to the need to treat waste like CAR-T cell blood bags.
- Environmental impact caused by the transportation from the hospital to the production CAR-T cell center.

> **Six economic opinions published by HAS on CAR-T cell therapies were analyzed.**

Product	Indication	Date of CEESP opinion
YESCARTA (axicabtagene ciloleucel)	Treatment of diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma in adults	15th January 2019
BREYANZI (lisocabtagene maraleucel)	Treatment of diffuse large B-cell lymphoma (DLBCL), high-grade B-cell lymphoma (HGBCL), primary mediastinal large B-cell lymphoma (PMBCL), follicular lymphoma grade 3B (FL3B) in adults	19th December 2023
ABECMA (idécabtagène vicleucel)	Treatment of relapsed and refractory multiple myeloma in adults	23rd November 2021
TECARTUS (brexucabtagene autoleucel)	Treatment of relapsed or refractory B-cell acute lymphoblastic leukaemia in people 26 years and over.	8th June 2021
KYMRIAH (Tisagenlecleucel)	Treatment of relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged up to 25 years	15th January 2019
CARVYKTI (ciltacabtagene autoleucel)	Treatment of relapsed or refractory multiple myeloma in adults	13 December 2022

> All these manufacturers claim to have an impact on the healthcare organization. **CEESP recommended** that the manufacturers of YESCARTA, ABECMA and KYMRIAH made **a specific study to quantify the organizational impact** of the introduction of their products in France. However, to date, only YESCARTA manufacturer, made an organizational impact study called "IMPA-CT".

> **The organizational impacts caused by the CAR-T cell therapy are :**

- Impact on the time to enter in the care process, on the number and type of consultations caused by the examinations needed to determine the patient's eligibility to CAR-T
- Impact on the skills of healthcare professionals involved in the care process due to the need for training in CAR-T cell therapies
- Impact on hospitals administering CAR-T cell therapies in terms of equipment and infrastructure (e.g., pharmacy, cryogenic storage)
- Impact on the care process in terms of pre-treatments (e.g., apheresis, bridging therapy and lymphodepleting chemotherapy)
- Impact on the patient accommodation post CAR-T infusion, which must be close to the hospital for surveillance
- Impact on patient follow-up frequency, with strict monitoring at 1, 3, 6, 9, and 12 months after CAR-T cell administration.
- Impact on adverse events, caused by the occurrence of specific adverse events (e.g., cytokine release syndrome)
- Impact on transportation of the patient and the CAR-T cells

> **Consideration of organizational impact in six economic opinions :**

Organizational impacts	YESCARTA	BREYANZI	ABECMA	TECARTUS	KYMRIAH	CARVYKTI
Eligibility checkup						
Personal training	X	X	X	X		
Equipment and infrastructures	X		X	X		X
Pre-treatments	X	X	X	X	X	X
Patient accommodation	X	X	X		X	X
Specific adverse events	X	X	X	X	X	X
Follow-up	X	X	X	X	X	X
Transportation	X	X	X	X	X	X

> **The organizational impacts identified by the manufacturers impacted cost categories and introduced new expenses from a health insurance perspective**, as recommended by CEESP.

> Other organizational impacts like the **transport of cells to the production site and to the hospital are covered by the CAR-T cell therapy acquisition costs** that range from 251 750 € to 420 000 € per dose.

> **CAR-T cell therapy administration costs** range from 20 494.76 € to 27 092.77 € per patient, also including some organizational impacts like CAR-T cell storage or patient's accommodation, versus around 3 000 € for standard treatments (chemotherapy).

> **However, a hospital perspective could be relevant to take into account for specific impacts** (e.g., time of administration, time spent by healthcare professionals and infrastructure or equipment costs).

> CEESP made two important reservations concerning the underestimation of TECARTUS costs (post-progression care costs and eligibility costs), one important reservation concerning an incoherence between efficiency and cost data in CARVYKTI evaluation and one minor reservation concerning the use of old data of ABECMA, given that the context has changed considerably. **Concerning all the new costs categories, CEESP has no reservations.**

> **A patient perspective can comprehensively measure CAR-T organizational impacts** by considering their effects on quality of life, particularly from long-term treatments. The organizational impacts of CAR-T therapies also affect patients' quality of life due to the single infusion involved.

CONCLUSION

> All the CAR-T evaluations measured the organizational impacts in terms of costs, only IMPA-CT study measured the organizational impacts in terms of time. In addition to the HAS methodological guide concerning the definition of organizational impacts, evaluate costs and quality of life associated with CAR-T cell therapy would harmonize and improve the evaluation of its organizational impacts.

REFERENCES

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