

Use of the new French ‘Organizational Impact Map’ published by the Haute Autorité de Santé (HAS) to evaluate the organizational impact of immune-checkpoint inhibitors in advanced cancers

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Introduction

Context

French Health Technology Authority, Haute Autorité de Santé (HAS), is composed of two commissions involved in drug evaluation: the Transparency Commission and the Economic Evaluation and Public Health Commission. An organizational impact (OI) can be mentioned or claimed in dossiers submitted to these commissions. In December 2020, the HAS published an organizational impact map to clarify the aspects associated with the OI of health technologies. The HAS presented a definition and different criteria which can be explored.¹

OI is defined as an effect, consequence, result or repercussion created by a health technology on the characteristics and functioning of an organization or a set of organizations involved in the care of users.

Study rationale

Immune-checkpoint inhibitors (ICIs) have a different mechanism of action than conventional chemotherapies. ICIs have considerably modified management of advanced cancer patients and evidence of long-term survival benefit has been published.^{2,3} Differences in safety and quality of life for patients treated with ICIs have also been published.^{4,5} ICIs are reimbursed in France in multiple indications and the hindsight allows us to have sufficient data to explore the impact on the organization of the care system.

Study objective

To assess OIs of ICIs in advanced cancers care in France using the ‘Organizational impact map’ published by the HAS.

Methods

This study was performed in two steps: a literature review and interviews with health care stakeholders. The 3 parts of the organizational impact map were completed:

- Assessment context
- Macro criteria and criteria
- Stakeholders concerned

Literature review

Transparency Commission’s opinion on ICIs were investigated to assess the context for all ICIs reimbursed in France.⁶

A targeted literature review based on the OI map was performed to identify publications mentioning the criteria and stakeholders concerned. Pubmed, google, French health authority agency website, French and European clinical guidelines and regional health institutional agencies websites were searched. All identified OIs were classified into the 3 macro-criteria (MC) of the map.

Table 1. Macro-criteria and criteria of the organizational impact map		
Macro-criteria	Criteria	
MC1: Impacts on the care process	1.1	Modifies times prior to initiation of the process
	1.2	Modifies process pace or duration
	1.3	Modifies timing or content
	1.4	Modifies number or type of staff involved in the process: quantitative view of human resources
	1.5	Modifies the type or frequency of use of products, devices, materials, equipment, infrastructures and information systems used in the process: view in terms of material or digital resources
	1.6	Modifies the quality and safety of the environment or context in which the process takes place
MC2: Impacts on the capabilities and skills required of stakeholders to implement the care process	2.1	Modifies the stakeholder’s required skills (knowledge, know-how and social skills), and expertise associated with the delivery or provision of care
	2.2	Modifies the ability to share and transfer skills, knowledge, know-how with other stakeholders
	2.3	Modifies scheduling and planning capacities for health care services or the patient or carer
	2.4	Modifies scheduling and planning capabilities between care structures or combinations of stakeholders
	2.5	Modifies stakeholders’ working or living conditions
	2.6	Modifies the terms, nature or source of stakeholders’ funding
MC3: Impacts on society or the community	3.1	Impact on community in terms of health and safety
	3.2	Impact on social inequalities or accessibility of care
	3.3	Impact on social or work relationship or in terms of society as a whole
	3.4	Impact on environmental footprint

Interviews

The semi-directed interview framework was tested with a clinician. Then, interviews with healthcare stakeholders were conducted with a minimum of 20 participants objective. During the interviews, stakeholders were asked to give their feedback about possible impact of ICIs on each criteria. When they identified an impact on a criterion, they had to specify when it was observed (during the learning phase, the routine phase or both) and to rank the impact between minor, moderate or major.

Results - Literature review

Part 1: Assessment context

- According to Transparency Opinions, in all ICIs assessment for advanced cancers (n=20), there was a conventional care solution available. However, in 3 opinions, the medical need was partially covered.
- ICIs changes the existing conventional care

Part 2: Macro-criteria and criteria

Table 2. Criteria observed in the literature

Macro-criteria	Literature review	
MC1: Impacts on the care process	1.1	
	1.2	
	1.3	
	1.4	
	1.5	
	1.6	
MC2: Impacts on the capabilities and skills required of stakeholders to implement the care process	2.1	
	2.2	
	2.3	
	2.4	
	2.5	
	2.6	
MC3: Impacts on society or the community	3.1	
	3.2	
	3.3	
	3.4	

Impact retrieved in the literature

1.2. Process pace: differences with cytotoxic chemotherapy and evolution over time. Treatment with ICIs is longer than with chemotherapy and the duration of care is unknown.

1.3 Process content: pre-therapeutic biological assessment, adverse event interview, emergency prescription.

1.4 Type of staff: care has been transfer in one-day stays and more recently for some patients in home care, organ expert were required for adverse events management.

2.1 Stakeholder’s required skills and expertise: Training for adverse events diagnosis and management, multidisciplinary consultation meeting.

2.2 Shared and transferred skills: Organ specialist to manage adverse events. General partitioners are less involved in the care management.

2.3 Scheduling and planning capacities for health care services: increased activity for one-day stays and hospital pharmacies.

2.4 Scheduling and planning capabilities between care structures or stakeholders: Organ specialists only in specific centres, switch from conventional hospitalisation to one-day stays

2.5. Stakeholders’ working or living conditions: increased quality of life for patient, hope of recovery.

2.6. Terms funding: ICIs are funded out-of-DRG (disease-related group) or with early access program while previous treatment could be funded through the DRG tariffs or non-hospital fund.

3.2 Social inequalities or accessibility of care: Clinical trials only in majors cities, inequalities in out-of-DRG drug access.

3.3 Social or work relationship: Hope, work return.

Literature publications did not enable us to identify with precision the period for each impact (i.e. learning or routine phase).

Part 3: Stakeholders concerned

Multiple stakeholders were or are concerned with ICIs organizational impact:

- Hospital stakeholders: oncologists, organ specialist, nurses, pharmacists
- Non-hospital stakeholders: general practitioners, nurses
- Organization: hospital, one-day stays department, oncology department, home care

Conclusions

This preliminary work, using the French organizational impact map, enabled us to identify OIs related to ICIs in France. Results were similar for most criteria between the literature review and the interviews. On the contrary to the literature review, an impact was presented from most stakeholders for the type or frequency of use of products, devices, materials, equipment, infrastructures and information systems used in the process: view in terms of material or digital resources and on community in terms of health and safety. Two criteria were challenging for stakeholders: impact on community in terms of health and safety and impact on environmental footprint.

Further research to define a consensus on outcomes of quantitative interviews will help to determine most important OIs. In addition, an in depth exploration on the impact classification (i.e. minor, moderate, major) will enrich the results. The qualitative analysis of interviews is also required to understand which criteria needs to be explored.

References

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4. Nishijima TF. Et al., *Oncologist*. 2017; 22(4): 470-79

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Results - Stakeholder’s interviews

I. Interviews - Stakeholder’s characteristics

Table 3. Stakeholder’s characteristics

		Healthcare stakeholders n=22
Sex	Men (n, %)	10 (45%)
	Women (n, %)	12 (55%)
Profession	Oncologist (n, %)	5 (23%)
	Pneumologist (n, %)	2 (9%)
	Urologist/Nephrologist (n, %)	1 (5%)
	Dermatologist (n, %)	2 (9%)
	Immunologist / Internist (n, %)	3 (14%)
	General practitioner (n, %)	1 (5%)
	Patient association president (n, %)	1 (5%)
	Pharmacist (n, %)	4 (18%)
	Nurse (n, %)	3 (14%)
	Local hospital (n, %)	1 (5%)
Work institution	University hospital (n, %)	10 (45%)
	Private hospital (n, %)	7 (32%)
	Home care facilities (n, %)	1 (5%)
	Patient association (n, %)	1 (5%)
	Regional institutions (n, %)	2 (9%)

22 healthcare stakeholders have been interviewed.

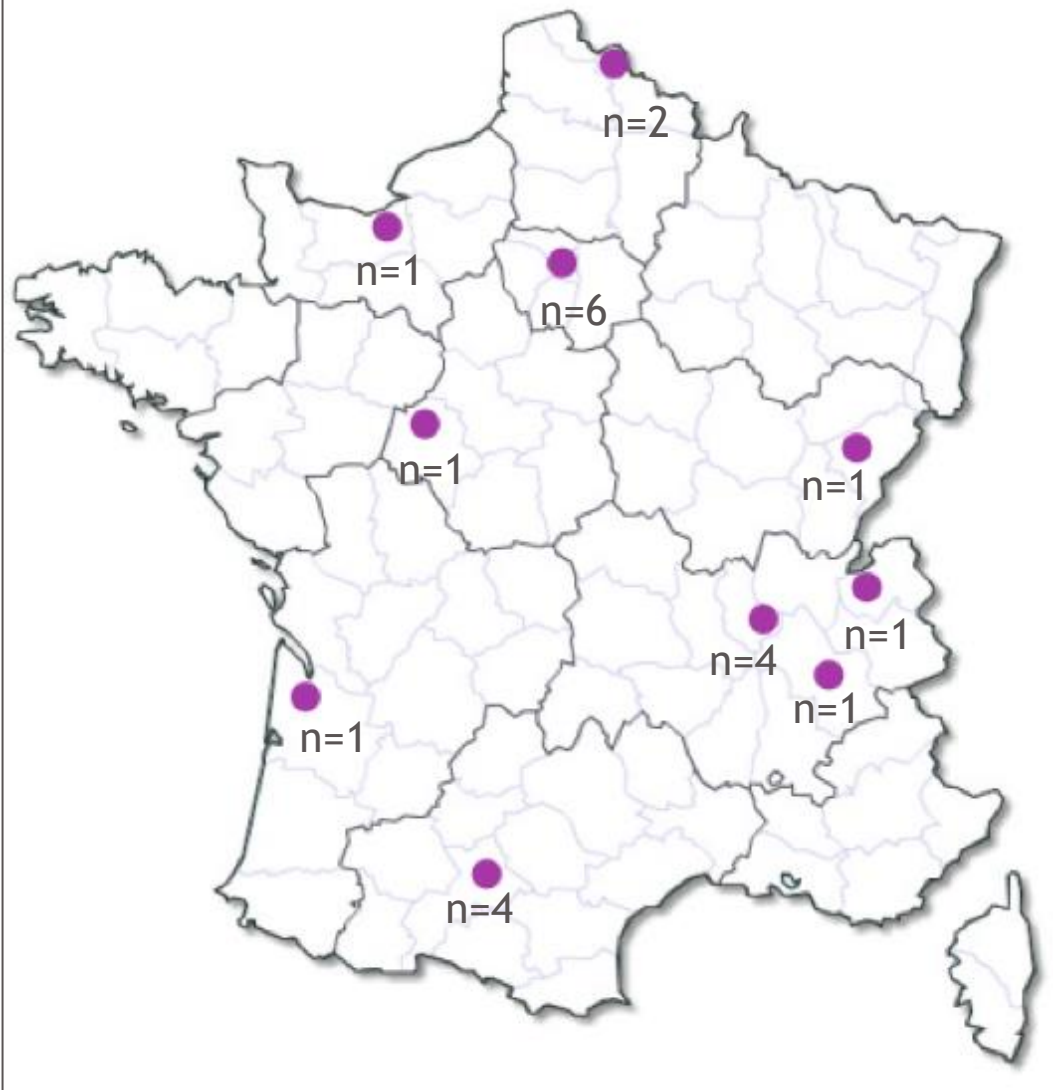


Figure 1. Location of healthcare stakeholders

II. Interviews - Outcomes

Table 4. Stakeholder’s interviews results

Macro-criteria		Headcount	No impact	Impact	Don’t know
MC1: Impacts on the care process	1.1	23	52%	48%	0%
	1.2	24	4%	96%	0%
	1.3	24	25%	75%	0%
	1.4	23	39%	61%	0%
	1.5	23	35%	61%	4%
	1.6	22	55%	45%	0%
MC2: Impacts on the capabilities and skills required of stakeholders to implement the care process	2.1	25	8%	92%	0%
	2.2	22	9%	91%	0%
	2.3	23	13%	83%	4%
	2.4	23	30%	70%	0%
	2.5	27	22%	78%	0%
	2.6	22	41%	41%	18%
MC3: Impacts on society or the community	3.1	23	35%	52%	13%
	3.2	25	28%	68%	4%
	3.3	23	30%	70%	0%
	3.4	22	14%	41%	45%

Headcount differed between criteria since stakeholders could describe different impact according to the period (i.e. learning and routine phase) or give different perspective (for example them and for the patient)

An impact was observed in at least 70% headcount for 8 criteria. For these criteria, the impact was defined as major for most stakeholders in 7. For the 1.3 criterion, the impact was defined as minor for 22%, moderate for 39% and major for 39%.