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Cytokine Release Syndrome: The Patient, Carer, and Healthcare Professional Experience

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Summary

Cytokine release syndrome (CRS) is a potentially life-threatening systemic inflammatory response associated with T-cell engaging therapies

Market research interviews were conducted and reports from an ad hoc working group of patients and patient advocates were reviewed

Patient, healthcare professional, and carer insights were collected around key burdens and unmet needs related to CRS

Stakeholders expressed varying levels of interest and concern around the use of digital solutions for CRS remote monitoring

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Background

- Cytokine release syndrome (CRS) is a significant inflammatory toxicity syndrome associated with the infusion of T-cell engaging immunotherapies.[1,2]
- Symptoms and severity range from mild, flu-like symptoms to severe, life-threatening, systemic inflammation.[1,2]
- As a risk associated with T-cell engaging therapies that requires mitigation, CRS may present a challenge to the adoption of new immunotherapies in the treatment of hematologic malignancies.[3]
- In this research, the CRS experience of patients, carers, and healthcare professionals (HCPs) was explored to understand the key burdens and opportunities to improve patient care and the patient experience.

Market research interviews were conducted and reports from focus groups were reviewed

- Existing insights from disease-level patient journeys (follicular lymphoma, diffuse large B-cell lymphoma, and multiple myeloma) were reviewed to identify key research questions.
- An ad hoc CRS patient working group was formed, consisting of patients with CRS experience and representatives of local and global patient organizations from Belgium, Canada, the UK, and the US. Reports from the patient working group were evaluated in conjunction with existing disease-level insights.
- Market research interviews were conducted (Nov 2022–Jan 2023) in Austria, Germany, the UK, and the US to address the key research questions with patients, carers, and HCPs.
- Patient and carer insights were collected via short video homework tasks and 60-minute virtual interviews.
- HCP insights were collected via 60-minute, web-enabled, telephone in-depth interviews.
- Outputs were reviewed and validated by the CRS patient working group.

A total of 34 HCPs with varying degrees of CRS experience were interviewed, along with nine patients and three carers (Table 1; Table 2)

- All patients had experienced CRS (Grade 1–3) as a result of chimeric antigen receptor (CAR) T-cell or bispecific antibody therapy.

Table 1. Interview participant demographics.

N (%)	United Kingdom	United States	Germany	Austria	Total
Hematologist-oncologists	8 (33.3)	8 (33.3)	5 (20.8)	3 (12.5)	24 (100)
Nurses	4 (40.0)	4 (40.0)	2 (20.0)	–	10 (100)
Patients	3 (33.3)	6 (66.7)	–	–	9 (100)
Carers	1 (33.3)	2 (66.7)	–	–	3 (100)

Table 2. Healthcare professional practice settings.

	United Kingdom		United States		Germany		Austria		
	Hematologist-oncologists	Nurses	Hematologist-oncologists	Nurses	Hematologist-oncologists	Nurses	Hematologist-oncologists	Nurses	Total
Major academic (CAR T-cell) center	–	–	4	2	–	–	–	–	6
Affiliated teaching hospital	–	–	1	–	–	–	–	–	1
Private practice	–	–	1	1	–	–	–	–	2
Community hospital	–	–	2	1	–	–	–	–	3
University hospital	8	3	–	–	4	4	7	2	28
Specialist cancer center	–	1	–	–	–	–	–	–	1
Office-based	–	–	–	–	4	–	1	–	5

Insights were based on five focus areas

Patient education and information

- Awareness and knowledge of CRS was good among the patients who participated in the market research, but education on CRS was still considered a key element to support patients who will be treated with T-cell engaging immunotherapies.
- Patients noted the life-threatening potential of CRS but were willing to accept the risk considering the potential clinical benefit of active treatment.
- HCP communication to patients focused on CRS being an expected occurrence, the need for in-patient admission and/or close monitoring in some cases, and the critical role of carers.

CRS diagnosis and management

- Generally, HCPs were familiar with CRS and the procedures for its monitoring and management, but the variability in time to onset, severity of symptoms, and potential impact on quality of life (QoL) warranted caution.

CRS in different healthcare settings

- Logistics emerged as a common barrier, as most T-cell engaging therapies are administered at larger, academic hospitals. Local, community-based clinics require further training and support to adequately monitor for and manage CRS in the community setting.

Digital literacy and the role of technology in mitigating/monitoring/managing CRS

- Patients, HCPs, and carers were aligned on their preferences for remote monitoring for CRS (**Table 3**). All three groups expressed the need for simple, easy-to-use solutions that integrate seamlessly with existing systems and do not cause undue concern with false alarms, complex technical set-up, or patient user experience.
- Patients were open to adopting new technologies if they added tangible benefit to their QoL, avoided additional logistical burden, and improved their experience. They emphasized the need for prompt and assured access to their medical team in case of emergency.
- HCPs expressed a range of opinions on the feasibility of adopting digital solutions. Some were open to using new tools and saw the potential for alleviating resource challenges. Others had reservations about interoperability and overwhelming patients with detailed data.

The carer perspective

- Carers expressed concern when the chance of the patient experiencing potentially fatal CRS was mentioned by HCPs as part of initial consultations. However, carers ultimately accepted that the benefit of treatment outweighs the risk of CRS.
- Disjointed contact when the patient is in hospital can be worrying for carers, and they put a significant amount of trust in HCPs. The importance of the carer was acknowledged by patients and HCPs, and interest was expressed in developing solutions to support patients who do not have carer support.

Table 3. Preferences for digital solutions used for remote patient monitoring as part of CRS management, as expressed by patients, carers, and HCPs.

Desire	Avoid
Simple, intuitive solutions	Excessive alerts and notifications
Reliability and accuracy	Too many devices
Integration with existing care pathways and systems	Replacing access to the HCP team with a digital solution
Guaranteed priority access to medical staff	Feeling promotional
Improvement to the patient experience	Forcing digital solutions on all patients

There are many opportunities to improve the patient experience of CRS

- Digital solutions used for remote monitoring as part of CRS management need to be framed as an additional precaution rather than a substitute for in-person, HCP-led care. Usability of such solutions should be prioritized and considered from the perspective of patients, carers, and HCPs.
- Solutions should not add to the existing workload of HCPs but provide support with managing patients remotely. Potential benefits should be communicated clearly on a macro (healthcare system) and micro (local practice setting) level to encourage adoption, such as the potential to reduce pressure on bed capacity and nursing resource.
- Effort should be made to make adoption available across all patient types, regardless of socioeconomic background.
- Patient engagement should be prioritised by giving the patient ownership of their health data, and better education on changes in their vital signs and the recommended course of action. This is key to improving the patient experience and clinical outcomes.

Conclusions

- There is a good level of awareness among patients, carers, and HCPs of the risks associated with CRS and the potential impact on QoL. Patients with hematological diseases are generally more willing to accept the risk of high potential toxicity for a treatment with potential clinical benefit.
- HCPs with experience in administering cellular immunotherapies are confident in monitoring and managing CRS. However, the unpredictable nature of CRS needs to be addressed and the associated logistical burden reduced to further improve confidence.
- There is value in adopting digital solutions for CRS monitoring and management. Concerns remain around interoperability and data stewardship, as well as integration and validation within current hospital systems. Patients' concerns regarding the usability of such digital solutions and assured data privacy also need to be addressed as part of solution development in the CRS space.

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Disclosures

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