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Original article

Perspectives on the use and availability of chimeric antigen receptor T cells (CAR-T) and cell therapies: A worldwide cross-sectional survey by the worldwide network for blood and marrow transplantation (WBMT)

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ABSTRACT

Chimeric antigen receptor T cell therapy (CAR-T) cells represent a new generation of autologous, allogeneic and personalised cell-based therapies that have revolutionised the treatment of B cell haematological malignancies. Despite their significant effectiveness in treating challenging relapsed and refractory diseases, access to this cutting-edge treatment remains a critical issue globally, even in high income countries. To gain insights into these challenges, the Worldwide Network for Blood & Marrow Transplantation (WBMT) initiated a survey focused on the state of CAR-T and cellular therapy availability worldwide. The survey aimed to identify the

Abbreviations: ALL, acute lymphoblastic leukaemia; ARM, alliance for regenerative medicine; ATMP, advanced therapy medicinal products; CAR-T, chimeric antigen receptor T cells; CRS, cytokine release syndrome; EMA, European medicine agency; FACT, foundation for the accreditation of cell therapy; FDA, food drug administration; GMP, good manufacturing practice; HSCT, haematopoietic stem cell transplant; I-CANS, immune effector cell-associated neurotoxicity syndrome; JACIE, joint accreditation committee ISCT-Europe & EBMT; MHRA, medicines and health regulatory Agency; MPHO, medical products of human origin; WBMT, worldwide network for blood & marrow transplantation; WHO, world health organization; SOHO, substances of human origin (SOHO).

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accessibility, manufacturing capabilities, apheresis, accreditation, reimbursement, presence of regulatory frameworks and legal oversight of these cell-based therapies.

The survey included questions on demographics, the respondent's centre, CAR-T availability, details about haematopoietic stem cell transplant programs, supply and indications for CAR-T, quality assurance, and information about other cell and gene therapy products beside CAR-T. Conducted online over three months in 2023, the survey garnered 181 complete responses from various geographical regions, from North America, Asia, Europe, South and Central America, Australia and New Zealand, and Africa.

Our findings suggested a promising level of awareness and interest in CAR-T therapy globally, even in lower-income regions. However, survey respondents cited cost as the primary barrier to access, alongside infrastructure and governmental support issues. The survey also highlighted the varying reimbursement strategies across regions, with costs in Europe and North America being relatively similar while Asia showed more variability. There was also variability in the regulatory and accreditation frameworks associated with delivery of these novel therapies

As CAR-T therapy continues to grow, innovative solutions such as global partnerships, in-house production, and the establishment of cellular therapy centres in developing countries are essential. Addressing the challenges of access requires a comprehensive approach that combines efforts to lower costs, enhance healthcare infrastructure, and foster international collaborations, ensuring that CAR-T therapy becomes available to all who need it.

1. Introduction

The use of living cells as a therapeutic option to treat diseases has been a cornerstone of medical therapeutics since the advent of safe blood transfusion more than a century ago. Unequivocal proof of its efficacy and safety has since been demonstrated with the safe, effective and widespread use of haematopoietic stem cell transplantation (HSCT) and donor lymphocyte infusions marking the advent of the field of cellular immunotherapy. This increasing routine use of cellular therapies especially chimeric antigen receptor T (CAR-T) cells in the standard care of patients has revolutionised the treatment of B cell malignancies including acute lymphoblastic leukaemias (ALL), lymphomas and myelomas [1]. CAR-T cells belong to a new generation of autologous and personalised advanced therapy medicinal product (ATMP) which has led the way in terms of marketing approval by various national regulatory agencies including the Food Drug Administration (FDA) in USA, the European Medicine Agency (EMA) in Europe, Medicines and Health Regulatory Agency (MHRA) in UK, in Japan and Singapore. Despite impressive efficacy in hard to treat relapsed and refractory disease, access to CAR-T treatment remains a major issue worldwide even in high-income countries [2,3]. There is the often-quoted reason of affordability and the current costs for commercially approved CAR-T therapies are indeed substantial. However, other factors which would directly impact upon access are likely to be involved for countries or centres wanting to commence CAR-T programmes—for example the necessary infrastructure that needs to be in place for treating patients with CAR-T due to the potential for life threatening cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (I-CANS). Such relevant issues may vary across centres, regions, countries and worldwide.

To understand this situation better, a CAR-T and Cellular Therapy survey was initiated by the Worldwide Network for Blood & Marrow Transplantation (WBMT). This purpose of the survey was to better understand the worldwide landscape with regards to the availability of both commercially approved and investigational CAR-T therapy as well as other forms of advanced cell-based therapy (example being mesenchymal stromal cells). The survey also sought to collect data with regards to issues pertaining to accessibility, manufacturing capabilities, apheresis, accreditation, reimbursement, presence of regulatory frameworks and legal oversight of these cell-based therapies.

WBMT is an umbrella organisation composed of a federation of 21 regional and international societies working in the field of HSCT and cellular therapy. WBMT is a non-governmental organization in official relations with the World Health Organization (WHO). Its aim is to promote global excellence in all aspects of HCT from donor issues to accreditation as well as the rapidly evolving related field of cellular therapy [4]. One of its primary goals is to ensure equity in access to HSCT and cellular therapy worldwide, especially in countries with low or no activity and to this end has focused on establishing new transplant programs in countries as well as the infrastructure and support needed for such transplant and cellular therapy activities. In order to achieve this, since 2006, WBMT has regularly published worldwide transplant activities containing information on number of HSCT, donor types and indication by disease. There is also the intention of incorporating cellular therapies activity into this worldwide database [5,6].

This data gathering exercise will facilitate our discussions with our affiliated partner-WHO with the aim of achieving equity of access to life saving cell-based treatments, especially CAR-T worldwide. It will also help WBMT in understanding the landscape of cell therapy across different regions in terms of the crucial scientific, clinical, and regulatory components needed to achieve this equity of access.

2. Methods

2.1. Study design, data collection and validation

This survey initiated by WBMT was conducted with the assistance from UT Health San Antonio. This was an online survey-based cross-sectional study. Survey questions were formulated and overseen by a steering committee project leads (Koh, Aljurf, Greinix). The 1st draft of the online survey was prepared and shared with the Executive Committee of WBMT and the Graft processing and Cellular Therapies Subcommittee for feedback and comments. The survey questions were then modified and finalised based on comments received. Selected co-authors piloted the survey, assessed the design and checked the feasibility and validity of the questions. We invited participating centres via emails through academic societies and associations to invite their members to report their data in 2023. The finalized online survey was made available online for a duration of 3 months in 2023. The survey output consists of backend meta-information detailing the submission and a total of 55 queries intended to obtain details from the survey respondents. The list of questions is presented in Table 1. Briefly, we included questions surveying the following: (1) Demographics of the respondent, (2) Information about the respondent's centre, (3) Availability of CAR-T, (4) Information about Haematopoietic Stem Cell Transplant (HSCT) program, (5) CAR-T Supply and Indications, (6) Quality Assurance: Regulation, Accreditation and Patient Safety and (7) Information about other Advanced Therapy Medicinal Products (ATMPs).

The administration and data collection of this survey was overseen by the steering committee together with UT Health San Antonio while all subsequent data analysis and interpretation was performed by the

Table 1
List of questions.

Field 1	Field 2	Field Category
StartDate	Start Date	Survey System
EndDate	End Date	Checksums
Status	Response Type	
IPAddress	IP Address	
Progress	Progress	
Duration (in seconds)	Duration (in seconds)	
Finished	Finished	
RecordedDate	Recorded Date	
ResponseId	Response ID	Unique Response Identification
RecipientLastName	Recipient Last Name	Idle Fields
RecipientFirstName	Recipient First Name	
RecipientEmail	Recipient Email	
ExternalReference	External Data Reference	
LocationLatitude	Location Latitude	Background metadata
LocationLongitude	Location Longitude	
DistributionChannel	Distribution Channel	
UserLanguage	User Language	
Q_RecaptchaScore	Q_RecaptchaScore	
Q2_1	Demographics: - 1. Name of Hospital/Institution/Centre:	Demographics
Q2_2	Demographics: - 2. Name of Respondent/Responsible Individual filling the survey	
Q2_3	Demographics: - 3. Email of respondent/responsible individual	
Q2_4	Demographics: - 4. City where Hospital/Institution/Centre is based	
Q2_5	Demographics: - 5. Country where Hospital/Institution/Centre is based	
Q3	6. Type of Hospital/Institution/Centre: Academic Teaching vs District/Community	Centre Information
Q4	7. If Other-please specify. Eg: Blood Bank, Cell Therapy Manufacturing Facility	
Q5	8. Is your Hospital/Institution/Centre under Public/Governmental or Private healthcare?	
Q6	Please elaborate further if needed, especially if private:	
Q7	9. Is CAR-T therapy available at your Hospital/Institution/Centre?	CAR-T Availability
Q8	10. If CAR-T therapy is not available -Are you aware of any available CAR-T therapy in your country	
Q9	If Yes; please elaborate with as much details as possible:	
Q10	11. If CAR-T therapy is not available- are there plans for CAR-T to be made available?	
Q11	If Yes; Please indicate rough timelines (e.g. in 1 year, etc.)	
Q12	12. If CAR-T therapy is not available, please elaborate with as much detail what barriers there exist which prevent implementation (e.g. cost, governmental support, no company presence in the country, etc.)	
Q13	13. Is there a Haematopoietic Stem Cell Transplant (HSCT) Program at your Hospital/Institution/Centre?	HSCT Program Information
Q14	If Yes; please indicate if this is allogeneic or autologous or both:	
Q15	If No; are there any other allogeneic HSCT programs in your city/country? Please provide details:	
Q16	14. If CAR-T treatment is available–Is the CAR-T treatment part of the Transplant Program?	
Q17	15. If answer to 14 is No; please elaborate further. For example- is the CAR provided as part of a comprehensive cell therapy centre separate from the hospital transplant program?	
Q18	16. What type of CAR-T products are available in your hospital/institution/centre/country?	CAR-T Supply and Indications
Q19	17. Please specify the exact approved commercial CAR-T products which are available in your centre/hospital or country. (check all that apply)	
Q20	Any others? Please specify:	
Q21	18. Please specify the exact non-commercial or in house manufactured CAR-T products that are available in your centre/hospital or country:	
Q22	19. Which CAR-T products have been approved for use by your country regulatory or drug agencies? (check all that apply)	
Q23	20. What year was CAR-T therapy first made available in your hospital/institution/centre or in your country?	
Q24	*Commercial CAR-T products at your centre or country:* (skip this section if no commercial CAR-T products available)	
	21. Are these CAR-T products used in standard clinical care of patients or/and in clinical trials? (check all that apply)	
Q25	If in Standard clinical care; please specify the actual CAR-T product used in standard clinical and provide details below:	
Q26	If in Clinical trials; please specify the actual CAR-T product in clinical trial and provide details below:	
Q27	22. What are the clinical indications that are approved/accepted for CAR-T treatment at your centre? (check all that apply)	
Q28	If Solid Tumours; please specify:	
Q29	If other indications; please specify:	
Q30	23. If possible, what is the cost of these non-commercial CAR-T products? (leave blank if unable to answer):	
Q31	24. How are the CAR-T cells reimbursed in your country?	
Q32	25. Please elaborate further (e.g. National Health System, part insurance/part self pay):	
Q33	26. How are commercial CAR-T products classified in your country by your regulatory/drug agency?	Quality Assurance: Regulation, Accreditation and Patient Safety
Q34	If other; please specify:	
Q35	27. Who oversees the release and issue of commercial CAR-T products in your institution?	

(*continued on next page*)

Table 1 (*continued*)

Field 1	Field 2	Field Category
Q36	28. For Q26, It would be helpful to elaborate this process further if possible:	
Q37	29. Are there National Regulations overseeing Blood, Cells, Tissue, and Organs?	
Q38	30. If National Regulations are present-please elaborate further below if possible including what the regulations cover (research or clinical or both)	
Q39	31. If no national regulations are present-what framework is there in place to oversee the clinical process and safety of CAR-T therapy?	
Q40	32. Is there an accreditation process available for CAR-T in your hospital/centre/country?	
Q41	33. If there is an accreditation available for CAR-T, please elaborate further below (e.g. FACT-JACIE):	
Q42	*Non-Commercial (Investigational and In house manufactured) CAR-T products* (skip this section if no investigational/ non-commercial CAR-T products available) 34. Are these CAR-T products used in standard clinical care of patients or/and in clinical trials? (tick all that apply)	CAR-T Supply and Indications
Q43	If in Standard clinical care; please specify the actual CAR-T product used in standard clinical and provide details below:	
Q44	If in Clinical trials; please specify the actual CAR-T product in clinical trial and provide more details below:	
Q45	35. How are these cell therapy products made available in your hospital/institution/centre/ country?	
Q46	If Others; please elaborate further:	
Q47	36. Where are these products manufactured?	
Q48	If Others; please elaborate further:	
Q49	37. Are these investigational or non -commercial CAR-T products manufactured according to GMP guidelines?	
Q50	38. Please elaborate further if possible, how these CAR-T cells are manufactured:	
Q51	39. Are these CAR-T products produced in partnership/ collaboration with a company/ academic group?	
Q52	If Yes; please specify and elaborate further if possible:	
Q53	40. If possible, what is the cost, if any of these non-commercial CAR-T products? (leave blank if unable to answer)	
Q54	41. How are the costs for these CAR-T cells reimbursed in your country?	
Q55	42. If possible, please elaborate further how these costs are reimbursed:	
Q56	43. How are these non-commercial CAR-T products classified?	Quality Assurance: Regulation, Accreditation and Patient Safety
Q57	If Others; please elaborate further:	
Q58	*Other Advanced Cell Therapy Products:* 44. Are you aware of any other Cell Therapy products for clinical use including clinical trials in your hospital/institution/centre? (e.g. mesenchymal stromal cells, dendritic cell vaccines)	Other ATMPs
Q59	45. Are there any other Cell Therapy programmes that you are aware of which is in active clinical use or in clinical trials in your country?	
Q60	46. Please specify all the cell therapy products that are currently in clinical use including clinical trials in your hospital/ institution/centre or country. (please check all that apply)	
Q61	If Others; please elaborate further:	
Q62	47. Are there any cell therapy products besides CAR-T that have been approved and authorised by your national regulatory agencies?	
Q63	48. If the answer to Q46 is Yes; please specify which products or elaborate further:	
Q64	49. Where are these products manufactured?	
Q65	If Others; please elaborate further:	
Q66	Are these other cell therapy products manufactured according to GMP guidelines?	
Q67	*Patient Safety:* 50. How long are patients monitored and data collected after CAR-T or any cell therapy product and by whom? (e.g.: mandatory 15 years and by the transplant centre)	Quality Assurance: Regulation, Accreditation and Patient Safety
Q68	51. Are there any systems in place: pharmacovigilance, cellulo-vigilance that collects the safety and side effects of these cell therapy products post infusion?	
Q69	52. If possible, please elaborate further:	
Q70	53. Is there a Registry: local or national that collects data for cell therapy products?	
Q71	54. If possible; please elaborate further:	
Q72	55. Is there any other helpful information that you would like to provide?	Miscelleanous

WBMT team. There was an initial quality check to ensure that the survey was completed properly and that there were no duplicates. The collected responses were filtered to obtain only unique responses, resulting in a total 181 accepted responses used to tabulate this study, together with several submissions containing partial or incomplete responses to selected questions

This study was carried out in accordance with General Data Protection Regulation (GDPR 2016/679). There was no patient data requested in this survey or any identifiable questions asked related to patient

information or management. All responses were anonymised and analysis only broken down to country level.

2.2. Participating centres (Demographics and institutional information)

A total of 181 qualifying accepted responses were collected via the survey link. Fig. 1 summarizes the demographics of participating centres. The geographic locations of the cities of the participating centres were plotted on Google Maps and presented in Fig. 1A, with larger circles indicating a higher density of survey respondents coming from the corresponding city. Fig. 1B shows the relative distribution of the participating centres across geographical regions, with respondents coming from North America (51 %), Asia (23 %), Europe (14 %), South and Central America (6 %), Australia and New Zealand (5 %), and Africa (1 %). We also sought to find out more about the respondent's hospital/institution/centre. There were 139 (76.7 %) Academic Teaching Hospitals, 21 (11.6 %) District/Community Hospitals, 3 standalone clinics (1.65 %), and 18 (9.9 %) that indicated others (Fig. 1C). 113 (62 %) of these institutions were Public/Governmental and 66 (36 %) private organizations.

2.3. Analysis

Wherever appropriate, the absolute numbers are shown for specific questions. Descriptive statistics were used to analyse results in this study. All responses have been anonymized.

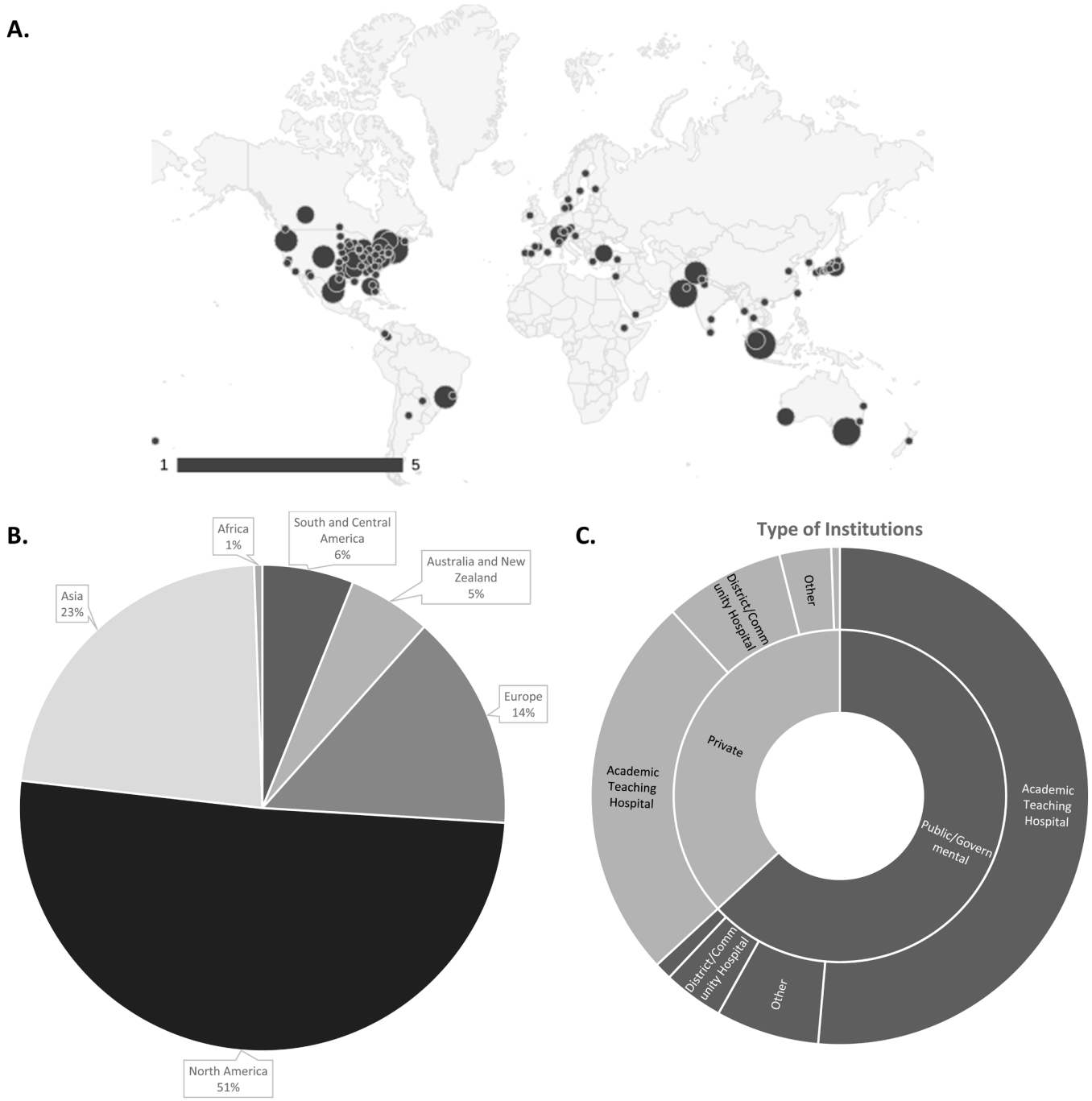


Fig. 1. Demographics and institutional information.

3. Results

3.1. Availability and awareness of car-T therapy

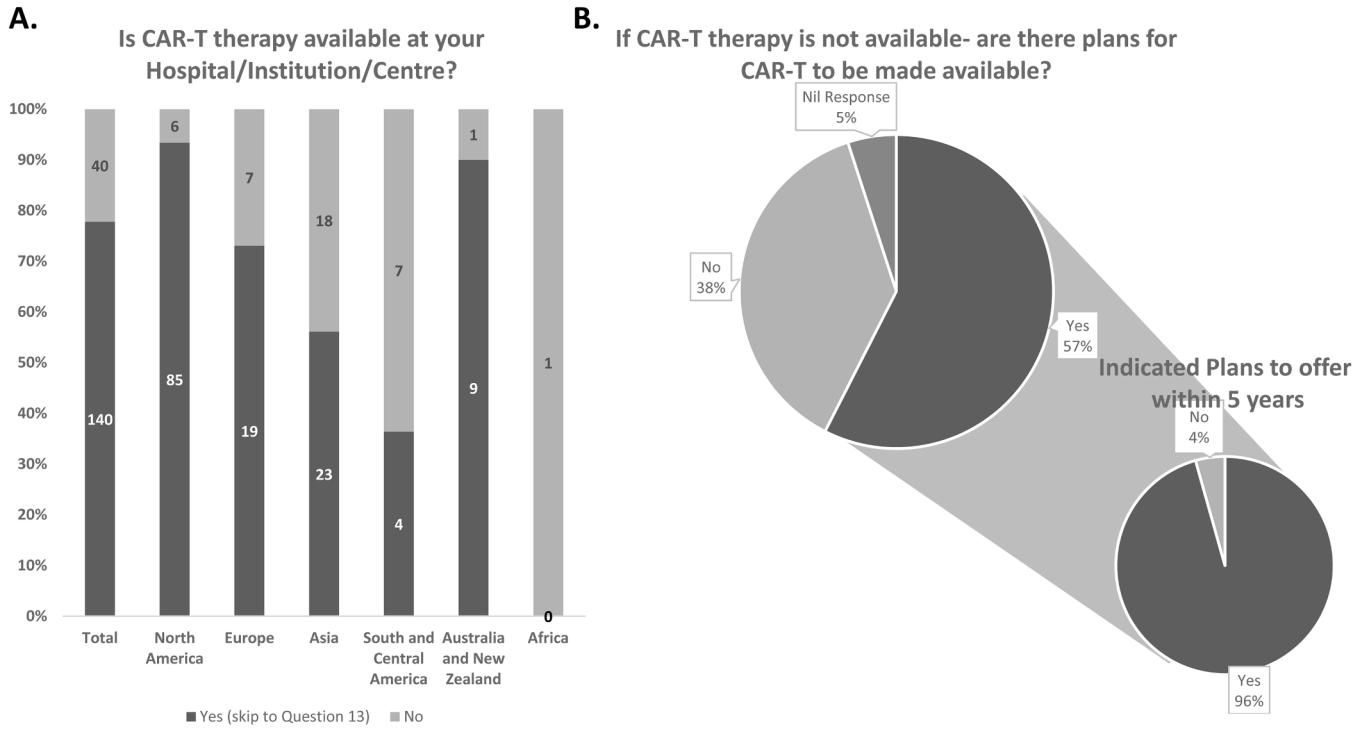
Across all the centres that provided a response to the availability of CAR-T therapy at the respondent's hospital/institution/centre, 140 responses out of 180 respondents answered yes. The relative distribution is shown in Fig. 2A for North America (85/91), Europe (19/26), Asia (23/41), South and Central America (4/11), Australia and New Zealand (9/10), and Africa (0/1). While respondents from the Global North (representing developed economies as defined by the United Nations Trade and Development) [7] economies including North America, Europe and Australia and New Zealand show good availability with a majority of centres (70–93 %) having access to CAR-T therapy, respondents from the Global South representing less developed economies (Asia, South and Central America, Africa) have about half or fewer centres with CAR-T access. However, In the 40 responses that answered 'No' to the availability of CAR-T at their hospital/institution/centre, 22 responses (55 %) indicated that they plan to offer CAR-T within the next 5 years (Fig. 2B).

3.2. Barriers to implementation

Survey respondents were asked to identify barriers preventing CAR-T therapy implementation and to elaborate further. Fig. 2C presents a word cloud illustration and frequency rank of words used in the survey responses. The following words were noted in the Top 10: Cost (17), Support (6), Government (4) and Infrastructure (3). Other reasons provided include distance to CAR-T therapy as well as political instability.

3.3. HSCT programs

We also queried the survey respondents on the presence of HSCT programmes at their hospital/institution/centre. Of the 179 responses, 162 answered yes and 17 answered no. The figures across the different



C.

Rank	Weight	Word
1	17	cost
2	6	support
3	4	car-t
4	4	country
5	4	government
6	4	high
7	3	company
8	3	hospital
9	3	infrastructure
10	3	process

Fig. 2. Existing availability and plans for CAR-T therapy provision.

regions are as such: North America (82/90), Europe (22/26), Asia (37/41), South and Central America (11/11), Australia and New Zealand (10/10), Africa (0/1), (Fig. 3A). Survey respondents were then asked if CAR-T treatment availability was linked to the Transplant Program. Of the 176 total responses, the majority (133 or 75 %) indicated that CAR-T availability was part of the HSCT program with only a handful (15) indicating a standalone program independent of HSCT, and 28 answered that CAR-T was not available. Fig. 3B shows the relative distribution of answers across the regions. In majority of the centres in North America, Europe and Australia and New Zealand, CAR-T treatment was linked to the HSCT program whereas, in Asia and South and Central America, there is a greater mix of centres offering CAR-T treatment linked with the transplant program and others where the CAR-T provision is independent from the transplant program.

3.4. Types of car-t products available

In terms of the types of CAR-T products available in the hospital/institution/centre/country from the survey respondents, 26 out of 177 (14.4 %) have no CAR-T products, 15/177 (8.3 %) only have non-commercial CAR-Ts (including in-house and investigational products), 48/177 (26.5 %) only have approved commercial CAR-T products while the majority 88 (48.6 %) have both commercial and non-commercial CAR-T products (Table 2).

3.4.1. Commercial car-t products

For Commercial CAR-Ts: 69 responses indicated that CAR-Ts were used in only in standard clinical care, 10 responses indicated that CAR-Ts were only used in Clinical trials, and 67 responses reported CAR-T use in both standard clinical care and clinical trials (Table 2). The most common approved clinical indications were Acute Lymphoblastic leukaemia (129/151, 85.43 %), Diffuse large B cell Lymphoma (126/151, 83.44 %), Mantle Cell Lymphoma (81/151, 53.64 %) and Multiple Myeloma (78/151, 51.66 %) (Table 2).

3.4.2. Non-Commercial car-t products (Investigational and in-house manufactured)

With regards to the use of non-commercial CAR-T products, most were used in clinical trials (76/98, 73.79 %) although a significant number are also being used as part of standard clinical care (22/98, 21.36 %) (Table 2). The survey sought further information on the manufacture of these products. Nearly half of the respondents (54/113, 52.43 %) reported that the products were manufactured by another centre in their country, 25 (24.27 %) respondents indicated that the products were manufactured in another country and imported to their centre by companies in the context of a clinical trial, and 17 responses (16.50 %) reported in-house manufacturing within the hospital/centre (Table 2). These in-house products were variously described as being manufactured on site in Good Manufacturing Practice (GMP) dedicated facilities or with the use of closed systems, particularly the CliniMacs Prodigy system by Miltenyi Biotec mentioned most frequently.

3.5. Reimbursement

Survey respondents were asked to provide the costs of commercial and non-commercial CAR-Ts, plotted in Figs. 4. For commercial CAR-T in routine use, the answers were, comparable across all worldwide regions costing USD$ 300,000 to 500,000 range while CAR-Ts (both non-commercial and commercial) provided through trials were covered by the trial sponsors. For Non-commercial CAR-T, the majority of answers noted that costs were covered by the trial sponsor, while responses that indicated costing ranged from US$40,000 to $180,000 with no further elaboration (Fig. 4B and 4D).

The most common mode of reimbursement for commercial CAR-T was a combination of government payor, private health insurance and self-paying (82 out of 144 responses) being the predominant mode in North America, while 'Government covers the cost' fully is the norm (at 38 responses) for Europe and Australia. (Table 2, Fig. 4A& 4C). The picture is more heterogenous for Asia and South America with responses indicating governmental support, self-funding or private insurance alone or together with a combination of the above.

3.6. Regulatory oversight, accreditation

All responses did indicate the presence of some regulatory framework or oversight with regards to cell and gene therapy products although the survey did not go into detail on the specifics (Fig. 5A and 5B). Some respondents from the Global South were unclear about their existing regulations and the scope it encompasses and whether it applied to research and laboratory handing versus clinical use.

The requirement for compliance to accreditation was reported in nearly all respondents (128 out of 149 responses) and this was so in nearly all centres in Europe, North America, and Australia and New Zealand with accreditation measures in place (Fig. 5D). This was not the case for Asia (12 of 27), South and Central America (4 of 8) with nearly 50 % of responses indicating that this was not needed or that they were unaware of it.

Respondents were also asked about whether systems were in place for pharmacovigilance and biovigilance (also called cellulo-vigilance) and the post-infusion safety of the cell therapy products. Only 6/139 responses indicated that this was not necessary while 133/149 indicated that this was present. This vigilance program is divided between the

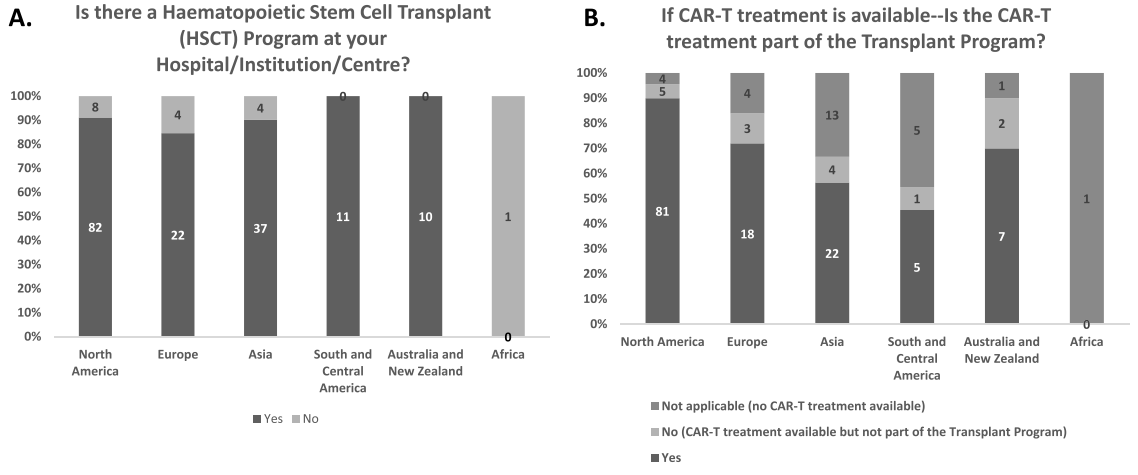


Fig. 3. HSCT Programs as useful infrastructure for CAR-T program development.

Table 2
CAR-T supply and indications.

Category	Question	Options	Total No. of Responses	% Responses
Survey Respondents				
	Total Attributable Responses with complete demographics		181	100
CAR-T Supply and Indications				
	16. What type of CAR-T products are available in your hospital/institution/centre/country?		177	97.79005525
		Both	88	48.61878453
		Approved Commercial CAR-T products (e.g. Kymriah, Tescarta, etc.)	48	26.51933702
		Non commercial CAR-T including in house manufactured and investigational products	15	8.287292818
		No CAR-T products available (Go to question 41)	26	14.36464088
Commercial CAR-T products at your centre or country:			151	
	21. Are these CAR-T products used in standard clinical care of patients or/and in clinical trials?		146	96.68874172
		Standard clinical care, Clinical trials	67	44.37086093
		Clinical trials	10	6.622516556
		Standard clinical care	69	45.69536424
	22. What are the clinical indications that are approved/accepted for CAR-T treatment at your centre? (check all that apply)			
		Acute lymphoblastic leukaemia	129	85.43046358
		Diffuse Large B cell Lymphoma	126	83.44370861
		Mantle Cell Lymphoma	81	53.64238411
		Multiple Myeloma	78	51.65562914
		Solid Tumours (e.g. Glioblastoma Multiforme)	21	13.90728477
		Other indications (e.g. autoimmune disease)	10	6.622516556
	24. How are the CAR-T cells reimbursed in your country?		144	95.36423841
		Combination of the above	82	54.30463576
		Government covers the cost	38	25.16556291
		Private Health insurance	17	11.25827815
		Privately funded/Self paying	7	4.635761589
Non-Commercial (Investigational and In house manufactured) CAR-T products			103	
	34. Are these CAR-T products used in standard clinical care of patients or/and in clinical trials? (tick all that apply)		98	95.14563107
		Clinical Trials	76	73.78640777
		Standard Clinical Care	22	21.3592233
	35. How are these cell therapy products made available in your hospital/institution/centre/country?		113	109.7087379
		Manufactured in house in the hospital/centre	17	16.50485437
		Manufactured by another centre in my country	54	52.42718447
		Manufactured from another country and imported to my hospital/centre	25	24.27184466
		Others	17	16.50485437
	36. Where are these products manufactured?		109	105.8252427
		Blood Transfusion Service	1	0.970873786
		Dedicated Cell Therapy facility	25	24.27184466
		Manufactured elsewhere and provided to us	64	62.13592233
		Stem Cell processing laboratory as part of the transplant program	9	8.737864078
		Others	10	9.708737864
	39. Are these CAR-T products produced in partnership/collaboration with a company/academic group?		103	100
		Yes	84	81.55339806
		No. Made entirely within the hospital/centre/institution	19	18.44660194
	41. How are the costs for these CAR-T cells reimbursed in your country?		117	113.592233
		Combination of the above	47	45.63106796
		Free as part of a grant funded clinical trial	29	28.15533981
		Government covers the cost	13	12.62135922
		Private health insurance	7	6.796116505
		Privately funded/Self paying	5	4.854368932
		Sponsored by a company or partner organisation	16	15.53398058
	43. How are these non-commercial CAR-T products classified?		116	112.6213592
		Investigational Cellular Therapy product	93	90.29126214
		Pharmaceutical or Medicinal Product	17	16.50485437
		Others	6	5.825242718

commercial company collecting the data (22/149) or systems in place as part of the local or national guidelines (111) (Fig. 5E). We also invited the respondents to specify the duration of patient monitoring and data collected post CAR-T infusion. A range of 15–30 years was indicated across North America, Europe, Asia and South and Central America. Interestingly responses coming from Australia and New Zealand indicated a degree of uncertainty over the requirements. (Fig. 5F)

With regards to the facility responsible for release and issue of commercial CAR-T products, (113 /143 responses) centres reported this as Stem Cell Processing Lab, 21/143 from Pharmacy and 9/143 from the Blood Bank (Fig. 5C). Looking at the geographical distribution, centres from Australia (9) only use Stem Cell Labs for CAR-T product release, whereas the pharmacy was used for Product Release in North America (10), Europe (8) and Asia (3). Some regions also reported the use of blood banks for product release, namely Asia (5), South and Central America (2), Europe (1) and North America (1) (Fig. 5C).

3.7. Other advanced cell therapy products

Besides CAR-T cells, we were interested in other types of advanced cell therapy products in view of rapid advances in this field. From the 116 responses obtained, the most common were mesenchymal stromal cells (MSCs) (45/116), Gene Therapy for Thalassemia or Sickle Cell Anaemia (20/116), CD34+ haematopoietic stem cells for other indications (11/146) and induced pluripotent stem cells (iPSC) (3/146). There were also 37 responses for Others.

4. Discussion

The aim of this survey was to capture a snapshot of the diverse and

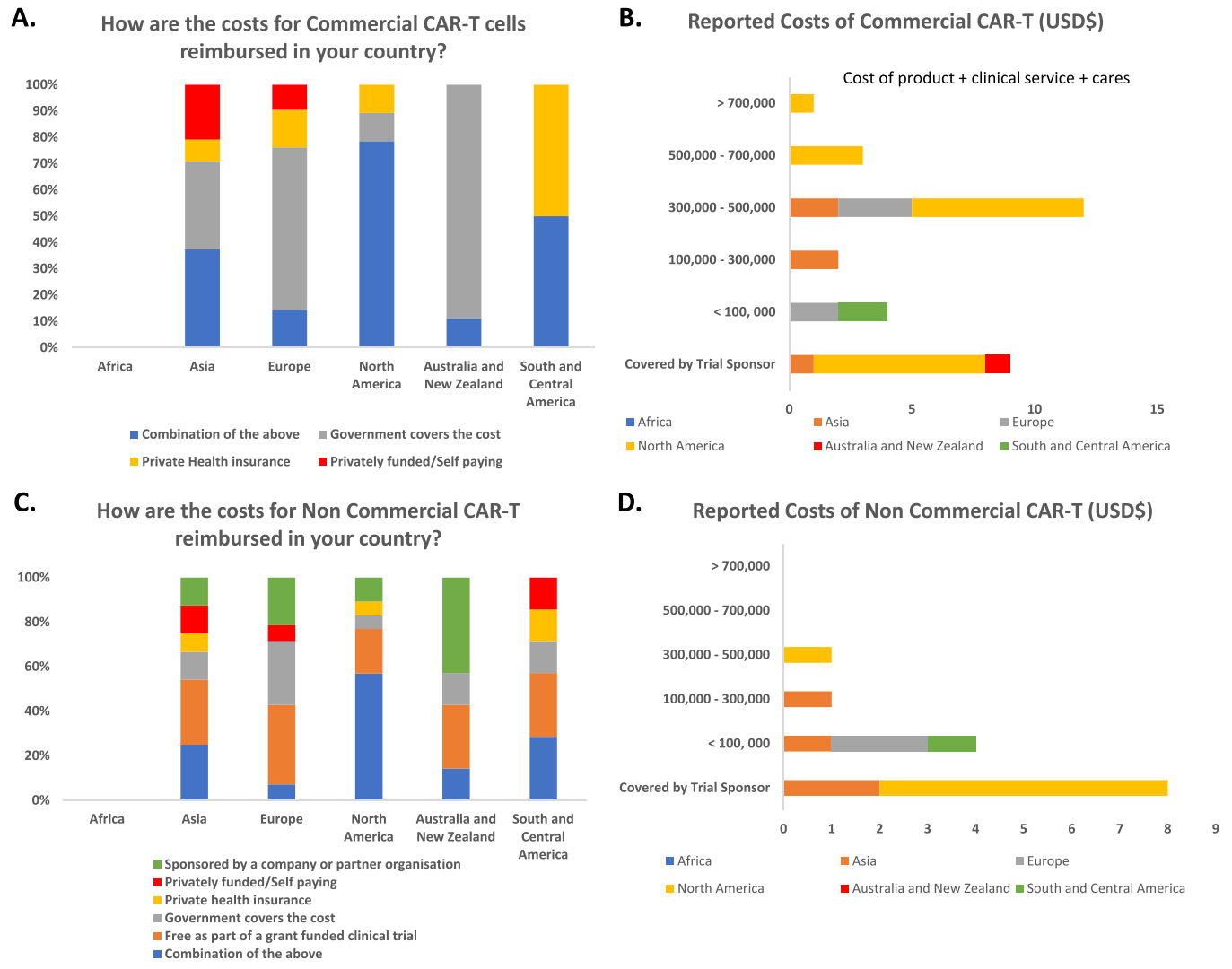


Fig. 4. CAR-T availability and Costs – Commercial and non-commercial.

heterogenous worldwide landscape for the utilisation of CAR-T therapy. During the time period of this survey, several commercial CAR-T products have already been approved by national regulatory agencies (NRAs) in high income countries (USA, UK, EU) for a few years with country level establishment of highly variable pathways for routine utilisation and reimbursement according to national health systems, including Health Technology Assessment (HTA) agencies [8]. This is for the treatment of B-ALL, B cell lymphomas and more recently, for multiple myeloma. However, there remains a paucity of knowledge for the uptake and availability of such novel treatments in other parts of the world, especially in low income and lower middle-income countries where such diseases are not uncommon. The resounding efficacy of CAR-T therapy and the relentlessly impressive advance of cell and gene therapies (including gene therapy for haemoglobinopathies like sickle cell anaemia and thalassemia which are far more prevalent in these lower income countries) combined with its high cost has led to an urgent need to aim for equity of access to these lifesaving and life changing treatments. This survey is a first step in trying to understand this situation better by looking at all the essential elements required for a cell and gene therapy program: knowledge, regulation, reimbursement, presence of HCT programs and pharmacovigilance.

The results of this survey are initially promising in terms of the knowledge and awareness of CAR-T therapy worldwide including in low income and lower middle-income countries in Africa, Asia and South America. Nonetheless, there should be caution in this interpretation as there is likely bias due to the distribution of this survey via a transplant and cell therapy network. WBMT as an umbrella organisation of largely HSCT and cell therapy regional and international organisations implies a respondent base that will probably already have HSCT programs. Knowledge and awareness of CAR-T would therefore be expected to be high in such cases as there is close linkage between the 2. Having said that, this survey did include some organisations within the umbrella of WBMT like the International Society of Blood Transfusion (ISBT) or the International Society for Cell and Gene Therapy (ISCT) where there may not be such a focus on HSCT. Moreover, the survey does capture responses from across all 6 WHO regions which would allow for a global analysis and interpretation of the survey results.

It is overall, cautiously optimistic that there is considerable worldwide interest and awareness of CAR-T therapy. It is even more encouraging that most respondents think this will be offered within 5 years although these may represent opinions rather than an in-depth prior analysis of the survey.

To further improve the depth and breadth of analyses, future studies should aim to explore specific areas with a more targeted approach. Additionally, gathering of input from complementary sources like academic research and industry reports should be undertaken to provide a more comprehensive picture.

Respondents from regions that do not have CAR-T availability unsurprisingly highlighted cost as the over-riding barrier to implementation. The shift to decentralization approaches to manufacturing may

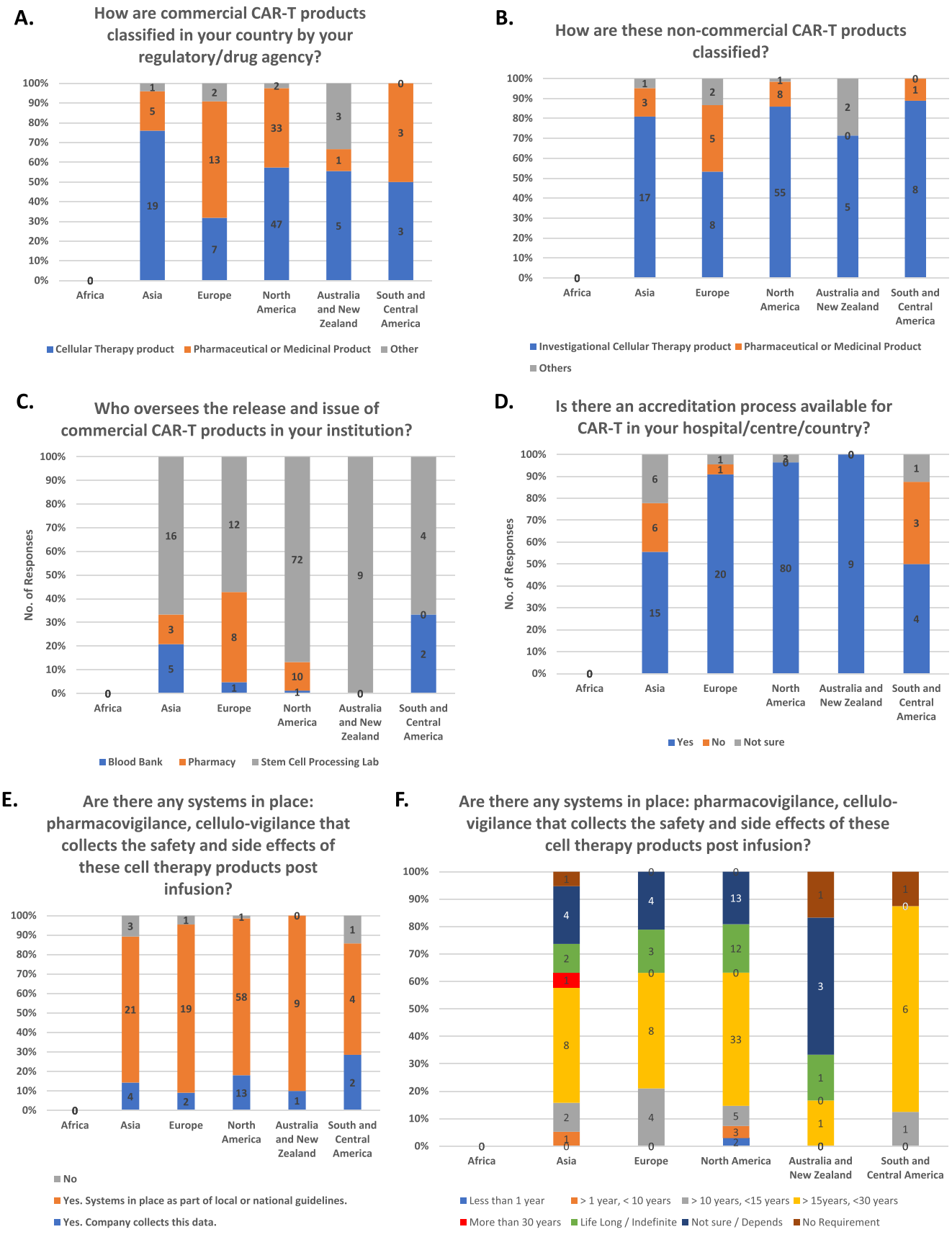


Fig. 5. Regulations and standards applied for CAR-T provision.

present a less costly and more efficient approach to CAR-T access compared to centralized manufacturing models [9]. The success of India's Homegrown CAR-T Cell Therapy has brought hope to lower-middle-income countries that CAR-T production can be achieved domestically to bring costs to about one-tenth of the cost of approved CAR-T cell products in the developed countries [10]. It is however important to note that cost was not the only barrier identified, but that infra-structure and governmental support were also seen as major factors impeding the introduction of CAR-T.

In terms of the model of CAR-T delivery, while the survey may present some biases, it does reflect the prevailing model adopted by the majority of authorized commercial CAR-T providers, in Europe and North America, where practices often align to FACT-JACIE accreditation, and contrasts with the more diverse approaches as seen in Asia [11].

The survey results confirm the dichotomy of availability and regulatory approval for commercial CAR-T products in developed countries (representing the Global North) and a heterogenous situation in Asia, South America and Africa representing the Global South. This unequal access associated with the barriers indicated above presents a complex scenario for governments and health systems to address. Nonetheless, the need for and importance of having access to this novel treatment has resulted in a resourcefulness in trying to meet this challenge. Here-the presence of closed systems, especially the Prodigy system by Miltenyi has enabled in-house manufacturing of CAR-T products for clinical use as a substitute for the non-availability of commercial CAR-T products. In addition, partnership between countries, particularly those who have developed their proprietary CAR-T products but not available for routine commercial use is another important enabler [12]. It would be interesting to monitor this development and how this evolves over the next few years. It is likely that the current barriers for availability of commercial CAR-T products are driving an innovative pathway towards alternative methods of offering such novel treatments.

Commercial CAR-T products are currently regulated as medicinal products under most jurisdictions, representing a notable shift in the approach of regulatory oversight compared to traditional cell-based therapies like blood transfusions and HSCT. This change also reflects the growing involvement of pharmaceutical companies in the field of cellular therapies. However, there is significant debate if this model is optimal, as advocates argue that CAR-T therapies should align more closely with the principles of altruism associated with Medical Products of Human Origin (MPHO) supply [13].

Our survey findings also indicate a lack of clarity among some respondents about the national regulations and frameworks governing CAR-T therapy. All responses did indicate the presence of some regulatory framework or oversight, but this may only cover the more traditional MPHOs like blood, tissue and organs in some regions in Asia, Africa and South America. In addition, there is variability in the need for assessment of competency and accreditation in these regions. (Okamoto et al.)

Currently, the US FDA requires a monitoring period of 15 years post CAR-T therapies as part of pharmacovigilance, similar to the long-term vigilance measures required for transfusion medicine, which can last between 10 and 30 years [14]. This is to capture any potential long-term side effects, such as tumorigenesis or other unexpected toxicities [14]. The commitment to long term vigilance necessitates discussions on cost, workforce and accountability and whether these are the responsibilities of the CAR-T commercial companies or national health systems. International societies like the European Society for Blood and Marrow Transplantation (EBMT) have taken the lead and set up a multinational EBMT Registry, which is tied to JACIE accreditation and requires mandatory reporting as part of compliance. Centres must report data on patients treated with CAR-T therapies at baseline, 100 days, 6 months, and then yearly up to 15 years. In addition, in many European countries, this mandatory reporting is linked and a condition to reimbursement by health authorities [15]. Worldwide, as the survey shows, this reporting practice can vary, including the duration as well as, and whether mandatory vs voluntary.

Though we have not explored this in detail in our current study, the highly specialized workforce roles and labour-intensive nature of cellular therapy manufacturing also contribute significantly to the barriers in improving access to cellular therapies [16]. Societies and international organisations can play an important role in helping centres navigate the workforce development challenges. For example, the Alliance for Regenerative Medicine (ARM) has published a Workforce Report, providing a landscape overview, highlighting the gaps and proposing recommendations for cell and gene therapy workforce development [17]. Academic societies, such as the International Society of Cell and Gene Therapy (ISCT) and the Association for the Advancement of Blood and Biotherapies (AABB), have also developed certificate programs to develop workforce core competencies in the field.

5. Conclusion

The high cost was predictably the most identified factor for respondents as a barrier to CAR-T access. In high-income countries like the U.S. and Europe, where healthcare systems and insurance policies may absorb some of these costs, access is more feasible for patients, but this still places a financial burden on both individuals and healthcare systems. In low-income countries or regions with less-developed healthcare infrastructure, such costs are largely unaffordable without external funding, and mechanisms in place for support. The total cost not only includes the CAR-T itself, but also the additional costs involved in the entire patient journey and treatment including the treatment of CAR T toxicities (CRS) with agents like tocilizumab. It is imperative that governments and health officials examine the current mechanisms of healthcare provision as a matter of urgency, especially to anticipate this rapidly expanding field of cell and gene therapy. Other novel ways of funding and access include private-public partnerships involving pharmaceutical companies who manufacture these products. However, it is critically important that such partnerships should abide by the ethical principles of a therapeutic product derived and classified as a substance of human origin (SOHO) while encouraging innovation and balancing profit with social responsibility[13]. Technological advancements can also play an important role in cost reduction. For example, the initial results of allogeneic CAR-Ts for autoimmune disease applications highlight the promise of an off-the-shelf allogeneic CAR T model which could reduce costs by eliminating the need for apheresis, reducing logistics costs, and increasing production scalability [18]. The delivery *in vivo* CAR gene using nanocarriers or viral vectors represent another strategy to produce CAR T cells directly in the patient's body, with the possibility of bypassing the complexity and high manufacturing cost associated with current *ex vivo* CAR-T manufacturing [19]. However, significant questions and challenges still remain for these novel strategies, with ongoing research efforts and industry investments required for these to become a reality in the practical clinical setting.

In terms of addressing the necessary infrastructure, one of the primary aims for WBMT is to promote and help with the setting up of HSCT programs worldwide. It has achieved success in doing so in countries worldwide (including Paraguay, Myanmar, Lithuania) [20] and this essential infrastructure will be a critical enabler for CAR-T access by ensuring the presence of apheresis capabilities, cell processing laboratories and hospitals with intensive care units (ICUs) for patient monitoring due to the risk of severe side effects like CRS and ICANS.

Another issue of importance highlighted by the survey is the need for robust national regulatory frameworks that will provide the governance for the safe use of these novel cell-based products, especially when countries are moving towards non-commercial products manufactured in house or provided by another party. This is currently being addressed by WHO and has included practical implementation workshops, the most recent of it was in Oman [21,22]. Importantly, this needs to be linked to the proper training and expertise of manpower to ensure that

delivery and patient care remains safe. International partnerships and training initiatives, both part of the mission of WBMT could also help in this respect.

Any look into a novel treatment will also need to be cognizant of the current global disparities in cancer care. In many parts of the world, cancer care itself is already limited, with many patients lacking access to basic chemotherapy or targeted therapies or HSCT, let alone cutting-edge treatments like CAR-T. There should therefore be equal focus by governments and health authorities on such innovative treatments but also in improving the level of cancer care including supportive treatments like appropriate access to antibiotics and safe blood transfusion.

Moving forwards and in summary, innovative solutions to improve equity of access should be explored and these include:

- **Global collaborations and partnerships**: Pharmaceutical companies, non-governmental organizations, and governments engaging in private-public partnerships to expand access.
- **In house and decentralised production**: By establishing partnerships between existing CAR-T centres in high-income countries with academic and medical centres in low-income countries together with technology transfer, novel CAR-T products could be made available aided by the concurrent advances in ancillary closed systems (eg CliniMacs Prodigy, Cocoon and a new generation of tuneable bioreactors). A longer-term plan for these countries would also be to consider manufacturing capacity for their countries, especially in light of the advancement of other cell and gene therapies.
- **Regulatory strengthening and worldwide harmonisation:** A key step in addressing this challenge is the ability for regulatory agencies in each country to be able to approve such novel therapies. This will require training and education as well as regulatory reliance between agencies. It should nonetheless be emphasised that regulatory approval is only the first step to ensure access and clinical use in patients. There remains the hurdles of pricing and modalities for subsidy and reimbursement, which have been highlighted in the survey.

In conclusion, while CAR-T therapy offers hope for many cancer patients, its **availability and equitable access** remain significant challenges, especially in lower-income regions. Addressing these barriers requires a multifaceted approach that includes lowering costs, improving healthcare infrastructure, increasing training, fostering international collaborations, and promoting ethical distribution models. Ultimately, making CAR-T therapy accessible to all who need it will require global cooperation and innovation to overcome the complex financial, logistical, and regulatory obstacles

Conflicts of interest

CC reports honoraria from BMS, Jazz Pharmaceuticals, Kite / Gilead, Miltenyi Biotec, Novartis

NW reports honoraria from BMS, Kite / Gilead, Miltenyi Biotec, Novartis, Pierre Fabre, Therakos

FSG reports honoraria from Novartis, Gilead/Kite, AstraZeneca, Johnson&Johnson.

MBCK reports honoraria from Gilead/KiTE

The remaining authors declare no competing interests.

CRediT authorship contribution statement

Eddie HP Tan: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Resources, Methodology, Investigation, Formal analysis, Data curation. **Mahmoud Aljurf:** Writing – review & editing, Validation, Supervision, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Fazal Hussain:** Writing – review & editing, Validation, Software, Project administration, Methodology, Funding acquisition, Formal analysis, Data curation. **Christian Chabannon:** Writing – review & editing, Validation, Supervision, Formal analysis, Conceptualization. **Nina Worel:** Writing – review & editing, Validation, Methodology, Formal analysis, Data curation, Conceptualization. **Daniel Weisdorf:** Writing – review & editing, Validation, Supervision, Methodology. **Ibrahim Yakoub-Agha:** Writing – review & editing, Validation, Supervision, Methodology, Conceptualization. **Sebastian Galeano:** Writing – review & editing, Validation, Supervision, Methodology, Investigation. **Fermin Sanchez-Guijo:** Writing – review & editing, Validation, Supervision, Methodology, Investigation, Formal analysis. **Laurent Garderet:** Writing – review & editing, Validation, Supervision, Methodology. **Yoshiko Atsuta:** Writing – review & editing, Validation, Supervision, Methodology. **Annalisa Ruggeri:** Writing – review & editing, Validation, Supervision, Methodology. **Nada Hamad:** Writing – review & editing, Validation, Supervision, Methodology. **Sharukh Hashmi:** Writing – review & editing, Validation, Supervision, Methodology. **Cristobal Frutos:** Writing – review & editing, Validation, Supervision, Methodology. **Yoshihisa Kodera:** Writing – review & editing, Validation, Supervision, Methodology. **Adriana Seber:** Writing – review & editing, Validation, Supervision, Methodology. **Carmem Bonfim:** Writing – review & editing, Validation, Supervision, Methodology. **Dietger Niederwieser:** Writing – review & editing, Validation, Supervision, Methodology. **Damiano Rondelli:** Writing – review & editing, Validation, Supervision, Methodology, Investigation. **Hildegard Greinix:** Writing – review & editing, Visualization, Validation, Supervision, Resources, Methodology, Investigation, Conceptualization. **Mickey BC Koh:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

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