

Freedom of Information Request

Ref: 21-621

15 December 2021

By Email

Dear Sir/Madam

Thank you for your request for information under the Freedom of Information Act 2000. The Trust's response is as follows:

- We can confirm that we do hold the information you are requesting

From information online I understand University Hospitals Bristol is able to provide Chimeric Antigen Receptors Cell Therapy (CAR-T) for acute lymphoblastic leukaemia for children and young people up to the age of 25 and CAR-T for adults with large B-cell lymphoma.

We are not commissioned or accredited to provide CAR-T Cell therapy to patients under the age of 18. The CAR-T cell service is 18+ only.

We are currently able to provide treatment to adults with

- B-cell Acute lymphoblastic leukaemia (B-ALL) ages 18-25 years
- Mantle Cell Lymphoma
- Diffuse large B-Cell lymphoma
- Transformed follicular lymphoma or other low grade lymphoma
- Primary Mediastinal B-cell Lymphoma
- Richter's Transformation may be considered on a case-by-case basis

From this can you provide data for the following time frames: the latest financial year April 2020- March 2021 and if possible a full year that was before coronavirus as I realise many procedures were affected due to covid and might not be a fair reflection on what normally happens, so the financial year April 2018- March 2019. We would appreciate any information on the following.

- **Who is University Hospitals Bristol's current head of department for cell therapy?**

Dr Caroline Besley is CAR-T Lead, Dr Rachel Protheroe is the Stem Cell Transplant and Cellular Therapy Programme Director

- **How many patients have been admitted for cell therapy (monthly or annually)?**

First non-trial patient had their cells returned in May 2019. We were not commissioned to provide the service prior to this.

April 2019 – March 2020: 11 infusions

April 2020 – March 2021: 17 infusions

Further patients have been referred for therapy and for one reason or another did not make it to infusion.

• On average how many procedures do these patients have?

This is not a first line therapy, so patients have already been through a number of cycles of treatment and procedures before they are eligible for CAR-T.

After referral for CAR-T and approval for treatment:

• Pre-leukapheresis investigations:

- Virology bloods
- Lung function test
- ECHO
- Dental review
- Vein assessment

• Leukapheresis

• Some patients then have bridging therapy if necessary

• Re-leukapheresis if necessary

• Pre-infusion work up:

- Restaging PET scan or bone marrow aspirate
- Lung function test
- ECHO

• Admission to ward for

- Lymphodepletion
- Cell return
- Post-infusion monitoring
- Follow up assessments
- COVID swabs

• What are the costs involved for CAR-T for acute lymphoblastic leukaemia for children and young people up to the age of 25. (if applicable with a break down e.g. treatment costs, nurse costs, in and outpatient costs etc)

We are not commissioned or accredited to provide CAR-T cell therapy to children.

• What are the costs involved for CAR-T for adults with large B-cell lymphoma. (if applicable with a break down e.g. treatment costs, nurse costs, in and outpatient costs etc)

Our costing data is not detailed enough to answer the query. To attempt to calculate this would also be out of the time frames for responding to FOI's.

What we can provide is the costing that was produced by a number of first wave centres (including us) on what we estimate Car T cell costs to be, please find this below.

Cost

1. Pay: Direct

Medical Staff £24,146

Nursing (ward) £16,507

Nursing (non ward) £8,979

Pharmacists £3,906

Therapists £2,879

Counsellors £1,642

1. Pay: Direct £58,058

2. Pay: Indirect

Radiologists £1,045

Radiographers £685

Pathologists £4,016

Laboratory Scientists £3,235

Quality manager £3,201

Admin support £3,200

2. Pay: Indirect £15,382

3. Non-pay exc (ATMP) high cost drugs

Clinical Supplies £7,968

Pathology laboratories £15,715

Other non-pay £5,987

3. Non-pay exc (ATMP) high cost drugs £29,670

Grand Total £103,110

• **What are the outcomes for these patients? (% of patients where the treatment has helped etc)**

Our current measure of efficacy is one year progression-free survival.

Of all patients infused >12 months ago, 23 were alive one year post their infusion. Of these, 6 patients were deemed to have progression-free survival.

• **Do University Hospitals Bristol provide any other types of cell therapy?**

• Epstein Barr Virus Cytotoxic T Lymphocytes

• Mesenchymal stem cells

(Also Tumour Infiltrating Lymphocytes as part of a clinical trial)

• **If yes, what are the number of patients, procedures and costs?**

EBV CTLs – we have treated 4 patients with a total of 6 infusions

MSCs – We do not have this information. Costs Please note, the Trust does not hold the data in a format that would enable us to fully respond to your request to the level of detail required and a manual trawl for this information would significantly exceed the 18 hours limit set down by the FOI as the reasonable limit. Section 12 of the FOIA provides that we are not obliged to

spend in excess of 18 hours in any sixty day period locating, retrieving and identifying information in order to deal with a request for information and therefore we are withholding this information at this time.

• Is University Hospitals Bristol working with any manufacturers or suppliers for cell therapy?

Yes

• If yes, the name of the company and how long you have been working together

Kite and Novartis are the companies that manufacture and supply the CAR-T cells we use. They have been supplying us since the service was commissioned.

Imperial in Hammersmith supply MSCs. Length of agreement unknown.

EBV CTLs come from different suppliers. We have an agreement with Fisher as of recently, but the relationship likely predates this

This concludes our response. We trust that you find this helpful, but please do not hesitate to contact us directly if we can be of any further assistance.

If, after that, you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to:

Director of Corporate Governance
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
BS1 3NU

Please remember to quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Publication

Please note that this letter and the information included/attached will be published on our website as part of the Trust's Freedom of Information Publication Log. This is because information disclosed in accordance with the Freedom of Information Act is disclosed to the public, not just to the individual making the request. We will remove any personal information (such as your name, email and so on) from any information we make public to protect your personal information.

To view the Freedom of Information Act in full please click [here](#).

Yours sincerely

**Freedom of Information Team
University Hospitals Bristol and Weston NHS Foundation Trust**