LDL Apheresis TOOLKIT

HEART UK
THE CHOLESTEROL CHARITY

Section 2

Setting up and protocols for a lipoprotein apheresis service

This section of the toolkit is divided into two parts, covering:

- **Requirements for setting up a lipoprotein apheresis service**
- **Protocols for establishing a service**

1. Requirements for setting up a lipoprotein apheresis service

This section covers the practical matters for establishing a service, including funding to cover treatment costs.

Space required

Ideally a purpose built/commissioned unit should be used for treating lipoprotein apheresis patients. However, funding restrictions make it important to explore other options for the potential location of a treatment site. The similarity to renal dialysis makes renal dialysis units a practical option for treating lipid patients. In Europe, numerous lipoprotein apheresis units are managed by nephrologists and patients are treated alongside renal dialysis patients. An alternative for treating patients is the use of blood transfusion facilities. Currently two of the therapeutic blood transfusion units in the UK treat lipoprotein apheresis patients. The advantage of using either of these options is that the necessary equipment, staff and skills will already be present.

Equipment required

- Treatment chairs/beds
- Cardiac monitoring (not essential but should be available)
- Blood pressure machines
- Resuscitation equipment
- PC with Internet access
- Staff facilities
- Store room

Apheresis machines

There are various different machines available in the UK for apheresis. These can broadly be divided into systems that remove lipoproteins from plasma and those that remove them from whole blood. The plasma based systems were the first to be developed in the 1980s, with whole blood systems being available since the 2000s.

All of the systems enable reductions of LDL cholesterol of between 60-75% and of lipoprotein (a) for 60-70%. The choice of system used is based on a variety of factors such as operator preference, duration of treatment, results obtained and patients' other medical conditions. As with all medical treatments, some patients are unable to tolerate some of the machines. This may be due to reactions to constituents in the system or to concurrent medication use. In addition, some patients may achieve better reductions in lipoprotein levels using a particular system. It is therefore advisable that more than one system is available in each unit.

The machines available and companies which supply them are as follows:

Plasma based

- Dextran sulphate-cellulose adsorption, Liposorber LA-15- Kaneka Pharma
- Double filtration plasma pheresis (DFPP) – Fresenius Medical Care and LINC Medical Systems Ltd
- Heparin extracorporeal lipoprotein precipitation (HELP) – B Braun
- Immunoadsorption - Miltenyi-Biotec Ltd

Whole blood

- Direct adsorption of lipoproteins (DALI) – Fresenius Medical Care
- Dextran sulphate-cellulose adsorption, Liposorber DL - Kaneka Pharma

Company details

(understood to be correct at the time of publication):

Kaneka Pharma Europe NV
Tromflaan 173
1160 Brussels
Belgium
T. 0032 2663 0304

Fresenius Medical Care (UK) Ltd
Nunn Brook Road
Huthwaite
Sutton-in-Ashfield
Nottingham, NG17 2HU
T. 01623 445100

Miltenyi Biotec Ltd
Almac House
Church Lane
Bisley, Nr Woking
Surrey, GU24 9DR
T. 01483 799800

B Braun Avitum UK
Thorncliffe Park
Sheffield, S35 2PW
T. 0044 114 2259067

LINC Medical Systems Ltd
The Greenlane Workshop
Greenlane
Countesthorpe
Leicester, LE8 5QQ
T. 01572 717515

Staffing

Lipoprotein apheresis patients need to be cared for by suitably trained staff. Nurses trained in renal dialysis or blood transfusion treatments will easily be able to acquire the skills needed to treat such patients. The recommended staffing levels from the HEART UK Apheresis Working Group are two nurses for every three patients. This is a higher nurse-to-patient ratio than often used in renal dialysis units, but many patients undergoing lipoprotein apheresis are quite unstable and have advanced cardiac problems. The ratio may be reduced in some stable homozygous familial hypercholesterolaemia patients being treated with lipoprotein apheresis for primary prevention.

Nurses should receive specialist training and should be employed at band 6, with a band 7 in charge of the unit. Examples of job descriptions for both bands 6 and 7 are featured in the toolkit as Appendices 2.1 and 2.2. Training on the use of the machines is given by the manufacturers, who also provide updates if techniques or software changes occur. Competency in the use of the machines is either assessed by the company providing the machine or should be assessed using locally agreed competency assessment forms. An example of such a form is included here as Appendix 2.3. Additional support staff, including secretarial support, will be required, dependant on the size of the unit and number of patients treated.

Medical supervision and support must be available at all times when patients are receiving lipoprotein apheresis. Individual units will decide how the medical supervision works in practice. However, a competent clinician must be able to attend emergencies as soon as called at all times. Immediate access to suitably trained staff in the event of an emergency either via the ‘2222’ or ‘999’ systems is required.

Units may be led by consultants from a variety of different specialities including nephrology, cardiology, lipidology and biochemistry. It is vital that links are established between specialities, as patients requiring apheresis are likely to need input from different specialists in order to optimise their care due to their increased risk of coronary heart disease (CHD). In addition, links with a reno-vascular surgeon who can form AV fistulas is important, as many patients requiring lipoprotein apheresis do not have adequate vascular access for the treatment and therefore require formation of an AV fistula.

Funding

Currently, there is no centralised funding for lipoprotein apheresis. In England, patients' treatment is funded by clinical commissioning groups (CCGs), and in Wales, by Local Health Boards. However, from April 2015, in England, the commissioning of services for homozygote FH patients will be the responsibility of NHS England (Specialised commissioning). Hopefully, this will be extended to heterozygote patients and those with other indications for lipoprotein apheresis in the near future.

Funding until 2015 (and beyond for non-homozygotes) has to be obtained from the local CCG. There is no specific national tariff for lipoprotein apheresis. However, there is a tariff for plasmapheresis which is used to fund lipoprotein apheresis treatments – SA13A (for adults) and SA13B (for children). This does not, unfortunately, provide enough money to cover the cost of the treatment.

Each lipoprotein apheresis treatment costs approximately £1,400. Please see the costing sheets for two of the apheresis systems at Appendices 2.4.1 and 2.4.2. Costs shown are indicative only, and these will vary depending on the equipment used. For equipment costs, please contact the relevant supplier as detailed in this section.

It is possible to obtain an agreement from local commissioners to pay an increased amount to help cover costs. This is achieved by recording patients who are receiving lipoprotein apheresis as 'regular day attenders', which is then charged at a locally negotiated price. The day-case and elective tariffs are much lower, so if activity is recorded as a day-case/elective the Provider would have to apply the national tariff. A six months notice period is required before the change can take place from the national tariff to a locally negotiated price, which then has to be agreed by the commissioners.

Harefield Hospital has been able to secure this additional funding from the NW London commissioners and as such has set a precedent which could be used by other centres to justify the increase in the charge for the service.

2. Protocols and service specification

Each unit needs to have an operational protocol or service specification, covering referral pathways, treatments, staffing, training and data collection. This will need to be written in accordance with other protocols or service specifications used in the Trust or unit and may be fairly brief or extensive in length. See Appendix 2.5 for an example from Royal Brompton and Harefield NHS Foundation Trust.

Documentation

All treatments must be adequately documented in the patients' notes. Existing units use a variety of treatment sheets to record all the serial numbers of the equipment used and the medications administered during the treatment.

A patient's GP needs to be informed that the patient is undergoing lipoprotein apheresis treatment. It is useful to send the GP an information leaflet, as few primary care practitioners are aware of the treatment or understand what is involved. Information leaflets can be produced and provided to both patients and health care professionals. An example is shown in Appendix 3.1.

GPs should also be given updates on how the patient's treatment is progressing, providing up-to-date lipid levels. A letter sent once or twice a year should be adequate. See Appendix 2.6 for a sample letter to an apheresis patient's GP.

Prescribing

All the lipoprotein apheresis systems require the use of a variety of prescription-only medicines in the set up and use of the machine. As stated above, most apheresis units are nurse-led. There are various methods of prescribing that can be used to facilitate treatments:

- Non-medical independent prescribing
- Patient Group Direction (PGD)
- Prescription charts
- Prescribing on treatment sheets

There are advantages and disadvantages with each of these options. The decision as to which option is used depends on the way individual units are run.

Many nurses are training as non-medical independent prescribers (NMIP). Once qualified, this enables them to prescribe any medications in the British National Formulary (BNF) that are included in their 'scope of practice'. As

an NMIP, a nurse is able to take on the responsibility of prescribing all the medication required for the apheresis treatment. However, the training to become an NMIP takes approximately six months, and the nurse then needs to be approved by the Trust in which s/he works before s/he can prescribe in clinical practice.

Patient Group Directions (PGD) enable suitably qualified nurses to supply and administer specific medications to a particular group of patients. Nurses have to achieve competency in caring for patients undergoing apheresis and then pass an assessment of their knowledge of what the PGD allows them to do. Use of the PGD enables the nurses working in the apheresis unit to supply and administer all the medicines required to carry out an apheresis treatment. They cannot administer anything which is not included in the PGD. The prescribing of any additional medication outside the PGD will therefore need to be assessed by appropriate medical staff.

Appendices 2.7.1 – 2.7.3 shows the following PGD sample documents from Harefield Hospital:

- PGD for the Clinical Nurse Specialist in Apheresis
- Training for the Clinical Nurse Specialist regarding use of the PGD
- Viva questions for the Apheresis PGD.

An in-patient prescription chart may be considered for use, dependant on local Trust rules. The medications required for the apheresis treatment can be prescribed by the medical staff and then signed for each time the patient attends treatment. Most prescription charts last for a period of 14 days, so the prescription would be valid for this number of treatments.

Finally, the medications required for each treatment can be prescribed and signed for on the treatment sheet used each time the patient attends lipoprotein apheresis. This requires a member of the medical staff to be present every day patients attend for treatment.

Apheresis registry

There is a national lipoprotein apheresis registry which has been set up jointly by HEART UK and the Royal College of Physicians. The aim is to include details of all the patients receiving lipoprotein apheresis in the UK. The registry consists of baseline data on each patient, including information about the indication for lipoprotein apheresis and past medical history. Three pages must be completed on an annual basis, containing average lipid results for each patient and information about any cardiovascular events that have happened during that year.

The registry is managed by HEART UK, which allocates a login and password to each centre. Each unit is responsible for entering their data. Data are anonymised and each unit can only access data concerning their patients. Patients may refuse to have their data entered and it is advisable to obtain written consent from patients before their data are entered. An example of a consent form for the registry is included in Appendix 2.8.