Adoption support resource – insights from the NHS

Health technology adoption programme
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1 Introduction

This resource has been developed to provide practical information and advice relating to NICE medical technologies guidance on the Spectra Optia Apheresis System for automated red blood cell exchange in patients with sickle cell disease. It is intended to be used by both clinical and non-clinical staff planning to implement this NICE guidance and start using this technology. It has been developed alongside the NICE resource impact report and template.

The Spectra Optia Apheresis System (Terumo BCT) is an apheresis and cell collection platform that can be used for automated red blood cell exchange, which separates out blood components using continuous flow and centrifugation. See the technology section for more information.

NICE's Adoption and Impact programme worked with NHS organisations to share their learning and experiences of using the Spectra Optia system for automated red blood cell exchange in patients with sickle cell disease. The learning gained from existing users is presented as a series of examples of current practice. They are not presented as best practice but as real-life examples of how NHS sites have adopted this technology. One contributing organisation estimated that it had saved around £500,000 by offering this service to 8 patients over 4 years. All sites reported significant improvements in patients' quality of life.

The information presented in this resource is intended for the sole purpose of supporting the NHS in adopting, evaluating the impact of adopting or further researching this technology.

The information presented is complementary to the guidance and was not considered by the Medical Technologies Advisory Committee when developing its recommendations.

The benefits of using the Spectra Optia system for automated red blood cell exchange as reported by the NHS staff involved in producing this resource include:

- no iron loading leading to savings through reduced need for iron chelation and reduced regularity of scans and tests to assess iron levels
- faster procedure time than manual exchange
- needed less often, and more effective at controlling sickle cell levels than both manual exchange and top-up transfusion
- reduced admission rates in patients having automated exchange for recurrent painful crisis
- high levels of reported patient satisfaction associated with better management of symptoms. This includes better quality of life for carers.

2 Current practice

NICE medical technologies guidance on the Spectra Optia Apheresis System for automated red blood cell exchange in patients with sickle cell disease describes the role of automated red cell exchange in managing sickle cell disease and should be referred to for further details.

The British Committee for Standards in Haematology guideline on the clinical use of apheresis procedures for the treatment of patients and collection of cellular therapy products recommends that elective red cell exchange should be considered in people with sickle cell disease for primary stroke prevention, secondary stroke prevention, elective surgery, painful crises in pregnancy, and in patients with severe disease who cannot have hydroxycarbamide.

The NHS sickle cell and thalassaemia screening programme, Sickle cell disease in childhood: standards and guidelines for clinical care, identifies the indications for regular long-term transfusion as primary and secondary stroke prevention, recurrent acute chest syndrome not prevented by hydroxycarbamide and progressive organ failure. It also suggests that top-up transfusions are the most common chronic transfusion therapy in paediatrics.

The West Midlands Quality Review Service overview report 2012/13 for adults with haemoglobin disorders noted inequity in access to automated exchange. Information from the sites indicated

that where there is no access to automated exchange, those patients needing regular transfusions are offered a combination of top-up transfusions and manual exchange.

3 Summary of NICE recommendations

NICE guidance on the use of Spectra Optia for automated red cell exchange in people with sickle cell disease who need regular transfusions recommends that the case for adoption is supported by the evidence. Cost modelling shows that in most cases, using Spectra Optia is cost saving compared with manual red blood cell exchange or top-up transfusion. The guidance recommends collaborative data collection to supplement the clinical evidence on some outcomes of treatment with Spectra Optia, in particular long-term data on how automated and manual exchange affects iron overload status and the subsequent need for chelation therapy.

4 Tips for adopting Spectra Optia

- Identify how the service and patient response to treatment will be measured. Collect baseline data and develop data collection mechanisms to monitor the impact of using the technology (see measuring success).
- Visit other automated red cell exchange services to explore their service models.
- Ensure that staff have structured training on the use, troubleshooting and quality assurance of the technology (see education).
- Ensure availability of skills to insert femoral lines and consider a departmental training programme to develop staff competency in peripheral line insertion under ultrasound guidance (see education).
- Ensure that care pathway mapping is done to identify and reduce potential delays in procedure running time.
- Develop local documentation to ensure a streamlined service.

5 Insights from the NHS

Homerton University Hospital NHS Foundation trust

The trust provides general and specialist hospital services and community health services in Hackney and the city of London. The hospital has almost 500 beds and employs over 3500 staff.

Automated red cell exchange with Spectra Optia is offered to adult patients with sickle cell disease during weekdays in the medical day unit. The unit has 1 machine used solely for this procedure and plans one per day. Forty six adults (11.4%) from a caseload of 350 patients currently receive this treatment.

Patients transition to the Homerton adult sickle cell service from the Royal London Hospital paediatric service which does not have automated red cell exchange.

Treatment indications are in line with the other sites (see patient selection). Generally patients have the procedure every 8 weeks. All patients have a personalised transfusion protocol which is printed on the unit prior to each procedure and used by the nurses to programme the machine. Printing from the hospital computer system ensures the most up to date protocol is used.

The steps involved in the procedure are the same as at Guys and St Thomas' and are explored within the care pathway mapping section, although at Homerton post-procedure bloods are taken before the lines are removed to maintain venous access until blood results are returned.

The team have developed a data sheet for automated red cell exchange transfusion containing details of all patients on the programme which is updated by the lead consultant and discussed at the sickle cell and thalassaemia haematology multidisciplinary team meetings.

Before adopting Spectra Optia for automated red cell exchange, 22 patients had regular manual red cell exchange and a very small number had top-up transfusions for certain indications.

Adoption was led by a consultant haematologist with special interest in sickle cell disease. The successful business case focused on reduction in inpatient bed days, use of iron chelation and better patient tolerability of treatment.

Adoption involved transferring the patients having manual exchange or top-up transfusions to automated red cell exchange. After this, all subsequent patients who met the criteria for automated red cell exchange were entered directly into the programme. The numbers of patients being offered the procedure continues to increase.

Initially, most patients had the procedure through femoral line access. As the service has developed, most procedures are done through peripheral line access.

All 13 nurses working on the day unit are trained to use Spectra Optia for automated red cell exchange. The training generally takes 6 to 8 weeks.

The team have analysed data on serial iron loading measures from liver MRI scans (Ferrisans) for 20 patients having regular automated red cell exchange over 3 years. This showed how people starting on automated red cell exchange with high iron levels experienced a sustained reduction in their iron burden. Those starting with no iron overload or mild overload did not accumulate any iron in 3 years of regularly having treatment. The team also noted how each patient responded to treatment over different periods of time, and that most patients' admission rates continued to fall 3 years after starting treatment.

The team undertook an analysis of admission rates (emergency day case, inpatient and emergency department) in the year before and in the 4 years after 8 patients commenced regular automated red cell exchange for recurrent painful crisis. Once the team had taken into account the costs of offering automated red cell exchange they estimated a saving of £480,000 for these 8 patients over 4 years due to reduced admissions.

In addition, the department has a recorded rate of allo-immunisation of 0.065 per 100 units of red cells.

Because demand is increasing, the team is developing a business case for an additional Spectra Optia machine and exploring the feasibility of offering an emergency 24-hour service. This would involve an on-all rota with the nursing team. If the case for a second Spectra Optia machine is successful, the team is planning to link with the East London and Essex haemoglobinopathy network to offer a network-wide service.

Guys and St Thomas' NHS Foundation Trust

The trust has over 1000 inpatient beds and provides a range of services for residents in the London boroughs of Lambeth, Southwark, Lewisham, Bromley, Bexley and Greenwich, as well as specialist services for patients from a wider area.

An adult automated red cell exchange service using Spectra Optia was established over 10 years ago and is managed by a consultant haematologist with special interest in sickle cell disease with support provided by a team of sickle cell nurse specialists and an apheresis nurse specialist. The service is provided on weekdays in the haematology day-case unit (emergency exchanges out of hours are done manually).

The unit has 4 Spectra Optia machines which are used for:

- red cell exchange

- plasma apheresis:
    - to treat thrombotic thrombocytopenic purpura (TTP)
    - for some neurological conditions
    - for some dermatological conditions.

The trust has a caseload of 828 adults with all types of sickle cell disease. Automated red cell exchange is provided to 86 people (including patients from other hospitals who only attend Guys and St Thomas' for their exchange). Treatment indications for patients currently on the programme are in line with the other sites (see patient selection). Automated exchange with Spectra Optia is offered on a case-by-case basis to young people with good venous access transitioning from the trust's paediatric sickle cell service.

Patients have a cross-match blood test 24 to 48 hours before the automated exchange. The procedure itself takes 3 to 4 hours and the patient is discharged when post-procedure blood results are acceptable. Five to 6 nurses provide cover until 16:30 and 2 nurses until 18:30 each day.

Before implementation of automated red cell exchange, patients were offered a mixture of top-up transfusions and manual exchanges as needed. Adoption was driven by a lead consultant haematologist with support from colleagues who considered automated exchange to be quicker, easier, safer and more effective than manual exchange, with less need for iron chelation.

The service was established in 2000. After demand for the service increased by 25–30% in 2014–15, team members visited other sites offering automated exchange to explore different models of working. As a result, capacity was increased by:

- Doubling the number of automated exchanges done on 1 machine per day from 1 to 2 (morning and afternoon).
- Increasing the nursing ratio of 1 trained nurse for: 1 automated exchange to 1 nurse, supported by a healthcare assistant, for: 2 simultaneous exchanges (where clinically safe and where one procedure is using peripheral access and the other femoral access). The team report this has allowed them to increase capacity to 4 exchanges per day.
- Aiming for predominantly peripheral access (located with ultrasound).
- Purchasing an additional Spectra Optia machine (following a more recent business case which focused on the role of exchange transfusions in the teenage population).

Treatment is split fairly evenly between femoral access and peripheral access, although 14 patients have the procedure via portacaths (for which they have regular antiplatelet therapy).

The manufacturer initially provided training. Now there is well-developed expertise in the unit, in-house cascade training is offered to new members of staff (see education). There is a high turnover of nurses so training provision is ongoing. The team reports that it takes 3 months to become proficient in using Spectra Optia for automated exchange and to be able to practice independently.

8 day-unit nurses and the sickle cell nurse specialists are trained in using the device. To reduce nursing time taken during set up, a number of healthcare assistants have been trained to load the necessary equipment into the machine.

Key details about all patients on the programme are stored in an Excel database which is managed and updated by the lead consultant haematologist after clinic appointments. This is used at the weekly patient progress meetings between the lead red cell exchange consultant and day-unit lead nurse (see measuring success).

The team reports that many patients ask for automated exchange because they see how it benefits other patients. There are plans to increase the number of automated exchanges via peripheral access and discussions on developing a 7 day 24 hour emergency service.

Central Manchester University Hospitals NHS Foundation trust

Manchester Royal Infirmary (MRI) is the largest of the 6 hospitals which make up Central Manchester University Hospitals NHS Foundation trust. The trust provides general hospital services to central Manchester residents as well as being a leading provider of tertiary and specialist healthcare services in Manchester and Trafford treating more than a million people every year. MRI is a specialist regional centre for sickle cell disease.

The trust offers an automated exchange service with Spectra Optia to adult patients with sickle cell disease on weekdays in the haematology day-case unit. If emergency treatment is needed out of hours, where possible the unit will stay open later or manual exchange will be done instead.

The service is led by a consultant haematologist with a special interest in sickle cell disease. Twenty-three patients currently receive regular automated red cell exchange, representing around 10% of all sickle cell patients under their care. Cases are considered individually alongside hospital selection guidelines and treatment is offered in line with the other sites (see patient selection).

The haematology day unit has 4 Spectra Optia machines which are used for automated red cell exchange, therapeutic plasma exchange and peripheral blood stem cell collection (auto collection and off donor collection). In 2014, 248 apheresis procedures were done of which 105 were automated red cell exchange.

Eight day-case unit nurses are trained in using the technology. Commonly, one patient is scheduled per day on the unit for the procedure to ensure staff have the capacity to safely manage treatment. The frequency of exchange varies for each patient but is generally every 4 to 8 weeks.

The consultant haematologist is responsible for assessing the effectiveness of the automated exchange procedure in each patient. Measures of effectiveness include prevention of clinical complications and reduction of hospital admissions. Response to treatment guides individual treatment regimens which are recorded and accessible to the day unit.

Before using the technology, MRI offered top-up transfusions with manual exchange if needed. This method had poor efficacy, led to iron accumulation and was associated with many practical difficulties, so there was a high clinical need threshold for offering these procedures.

The case for change was driven by the sickle cell specialist nurse with the support of the whole team. Shared learning from London hospitals that already offered the service and support from the manufacturer of Spectra Optia drove the case for adoption.

The staff were already familiar with Spectra Optia and adapted existing governance protocols and procedures for automated red cell exchange.

Savings were anticipated in hospital admissions and iron chelation therapy but these do not impact the day-case unit directly. Haematology took a whole service approach and balanced the losses by considering the gains from other areas of haematology work.

Approximately one third of patients receive red cell exchange via peripheral line and the remaining via femoral line.

The day-unit nurses trained in using Spectra Optia have a number of other roles and are not dedicated to the apheresis service. The unit provides a comprehensive ongoing training package for staff which takes around 3 months to complete and is consistent with training at the other sites.

The haematology department has seen significant benefits since the adoption of Spectra Optia for automated red cell exchange. There has been a reduction in readmission rates and patients' reported quality of life is improved.

The team have done an audit of 16 patients on the regular automated red cell exchange programme from 2006 – January 2015. The audit showed no significant iron accumulation in patients on the programme. In some cases patients with high levels of iron due to previous top-up transfusions have been successfully able to reduce iron to acceptable levels with iron chelation treatment despite continuing to receive RCE. Where there was an apparent rise in some patients, this may have been attributed to sporadic top-up transfusions.

Feedback on patient experience indicates that for many people automated red cell exchange has been life-changing, enabling meaningful employment and study. Many people have reported that the treatment has made them feel like they don't have sickle cell disease.

St George's University Hospital NHS Foundation Trust

St George's Hospital in Tooting is the main site of the trust, and offers planned automated red cell exchange on the haematology day unit on weekdays. The service is led by 2 consultant haematologists. It has 4 Spectra Optia machines used by 4 trained apheresis nurses for:

- red cell exchange (45 to 50 transfusions per month)
- plasma exchange (plasmapheresis), both albumin and plasma
- emergency leucopheresis
- stem cell harvesting.

Automated red cell exchanges are scheduled for every weekday. Up to 2 patients can be scheduled on 1 machine per day (morning and afternoon), and 6 procedures (red cell exchanges or plasmapheresis) can be done per day depending on staffing levels. The apheresis nurses run an on call rota enabling emergency apheresis 24 hours a day.

Most patients have the procedure through a large peripheral line. All other steps in the procedure are the same as detailed by the other sites and included in the care pathway mapping section.

Around 56 patients have regular automated red cell exchange. This includes patients from other hospitals who only attend St George's for their apheresis. The service is offered to adult patients and some adolescents (on a case-by-case basis). Patients offered red cell exchange at St George's

reflect the indications at the other sites (see patient selection). Patients on the programme have a 'procedure passport' which is used for each treatment.

The apheresis team meets monthly with the clinical haematology team to discuss all the patients on the programme and their transfusion parameters. Patient's procedure passports are updated accordingly.

The team recently replaced older machines, increased the number of machines and increased staffing to cope with increasing demands. The successful business case to increase the number of machines focused on the importance of ensuring a sustainable service.

Data from St George's indicate that automated red cell exchange is clinically efficacious in 80% of patients. Importantly, patient feedback consistently highlights how much the procedure has changed their life.

Birmingham Children's Hospital NHS Foundation Trust

Birmingham Children's Hospital has 361 beds and provides children's health services for young patients from Birmingham, the West Midlands and a wider area. The hospital has offered automated red cell exchange since 1998 and a service for regular procedures was set up in 2013. On weekdays in the day-case bay of the haematology oncology inpatient ward, 1 Spectra Optia machine is used for red cell exchange, plasma exchanges, leucodepletion and peripheral blood stem cell (CD34) collection.

The service is led by a consultant paediatric haematologist. There is a caseload of 400 patients with sickle cell disease. Fifteen currently have regular transfusions and of these two have regular automated red cell exchange. The youngest patient to have received a planned automated red cell exchange at the hospital was 6 years old, and the youngest enrolled on a regular programme was 9 years old.

A programme of regular automated exchange is offered for primary and secondary stroke prevention, recurrent painful crisis or acute chest syndrome not responding to hydroxycarbamide and severe multifocal avascular necrosis.

One week before a planned procedure, patients attend clinic for blood tests (including cross match) which will guide the procedure settings. One automated red cell exchange is done per day with an apheresis sister allocated to the patient and a second nurse available to collect and check blood and help manage any adverse events. An apheresis care pathway is used, which details the checks and

steps that must be done before a procedure is started. For paediatric patients, 4 to 8 units of blood are used. After the procedure, patients are discharged after at least a 30 minute rest and acceptable observations.

Each patient is monitored closely (see measuring success) and attends clinic at least every 6 months to review progress and complications.

Before the regular automated red cell exchange transfusion service was established in 2013, patients who needed routine transfusions had top-up transfusions. The regular automated red cell exchange service was part of the overall apheresis business case which was partially funded to increase the nursing team and create an apheresis specialist nurse post. Although automated red cell exchange costs more than top-up transfusion, adoption was supported because the department already had a Spectra Optia machine used for other procedures.

Peripheral lines are mainly used for access. When this cannot be achieved the procedure is cancelled and rebooked for a femoral line to be inserted in theatre under general or local anaesthetic (depending upon the patient's age and preference). Achieving vascular access with adequate flow is the main barrier to offering this service to more patients. In order to increase success and minimise distress, the same advanced nurse practitioner aims to insert a patient's peripheral line each time. In future the apheresis specialist nurse will also do this.

The main reason patients stop treatment with Spectra Optia is because they are not coping with vascular access problems. The team are currently exploring whether double lumen vortex ports could provide access for some patients. The flow rate capability and location of the port is important for suitability for this procedure.

Currently 6 nurses are trained to use Spectra Optia for automated red cell exchange. Establishment of a regular programme has provided a better opportunity for staff to maintain competence. The team anticipate that capacity can now been increased with the employment of an apheresis specialist nurse. To support the development of the service the apheresis sister visited a site in Bristol to look at its model of working.

Patients and their families often opt for top-up transfusions over automated red cell exchange, because only one cannula is needed and the patient is not restricted to a machine for 4 hours. The team are reviewing the information provided to patients and their families to ensure the benefits of automated red cell exchange are fully understood. To give continuity, the same apheresis nurse and the advanced nurse practitioner aim to be present for all red cell exchange procedures. Patients

and families who have been on a regular programme report an improvement in quality of life for the whole family.

Data from Birmingham about 3 patients having regular transfusion for multifocal avascular necrosis showed clinical improvement and stable ferritin levels in all patients. No patients needed iron chelation therapy. Frequency of treatment was every 6 to 8 weeks, lasting at least 1 year.

6 How to implement NICE's guidance on Spectra Optia for automated red cell exchange

The experiences of NHS trusts have been used to develop practical suggestions for how to implement NICE guidance on the use of Spectra Optia for automated red cell exchange.

Project management

This technology can be best adopted using a project management approach. NICE has produced the into practice guide which includes a section on what organisations need to have in place to support the implementation of NICE guidance in this way.

Project team

The first step is to form a local project team who will work together to implement the technology and manage any changes in practice.

Individual NHS organisations will determine the membership of this team and how long the project will last. In order to implement this guidance in an effective and sustainable way, consider the following membership of the team:

- Clinical champion(s): could be a senior clinician (consultant haematologist or nurse specialist) with an interest in sickle cell disease. They should have the relevant knowledge and understanding to be able to drive the project, answer any clinical queries and champion the project at a senior level.
- Project manager: could be someone in a clinical or managerial role who will be responsible for the day-to-day running of the project, co-ordinating the project team and ensuring the project is running as planned. This could be a sickle cell nurse specialist, day unit sister or matron.

- Management sponsor: will be able to help assess the financial viability of the project, drive the formulation of a business case and help to demonstrate the cost savings achieved. Involve a member of the finance staff, for example the directorate accountant, from the start.
- Day unit nurses and doctors and departmental vascular access teams will be valuable members of the project team because they will be providing the service.
- Clinical audit facilitator: to help set up mechanisms to collect and analyse local data related to the project metrics and audit needs. A nurse specialist, specialist registrar or senior house officer with interest in a project in this area could support this role.

Early questions that the team may wish to consider are:

- Which patients will be offered automated red cell exchange and from what geographical area?
- Are there enough eligible patients to warrant development of the service?
- Are there Spectra Optia machines already in use within the organisation and do they have spare capacity? The manufacturer has identified that in England there are 53 machines in use but 19 of these are not used for automated red cell exchange.
- How many machines will be needed to run an efficient and effective service?
- How will the necessary education (using the device and venous access) be provided?
- How will timely venous access be achieved?
- How will the project be funded?
- How will local metrics be identified and measured?
- Who will be responsible for collecting clinical data?
- What are the criteria for starting, continuing and stopping treatment?
- Are there any obvious challenges and how can these be overcome?

Care pathway mapping

Patient selection

The sites reported offering regular automated red cell exchange to patients in line with the BSCH guideline (2015) and including patients at high risk of stroke or with history of stroke and patients in whom hydroxycarbamide is not effective or is not tolerated and who have:

- recurrent painful crisis or acute chest syndrome
- pulmonary hypertension or sickle cell related kidney disease
- leg ulcer or severe priapism
- significant cardio respiratory problems where it is believed a sickle crisis would be particularly detrimental
- sickle cell related complications in pregnancy.

Maximising capacity

It is important for developing a service to be able to meet demand. Some sites were able to increase capacity to complete 2 procedures per day on 1 machine, where clinically safe to do so, by:

- Analysing the demand and capacity of the day unit to decide whether a standalone or integrated service would be most suitable.
- Addressing sources of delays:
    - Considering ways to ensure patients arrive on time.
    - Ensuring pre procedure blood tests and cross-match samples are taken with enough time to allow results and blood to be available.
    - Formally agreeing responsibility for line insertion. Ensure someone with the appropriate skills is available at the right time (see education). Using peripheral access may reduce delays as there is not a dependence on staff trained to insert femoral lines.
    - Ensuring staff can effectively troubleshoot the machine.
    - Reducing the impact of delays from other areas of the day unit.
- Developing a scheduling system with a staff plan:

  - Staggering procedure starts to maintain constant activity.
  - Planning nurse cover for the busiest times and if a procedure is delayed.

- Monitoring and regularly reviewing all patients to ensure treatment is beneficial. Protocols and criteria should be in place to guide stopping decisions.

Measuring success

In order to demonstrate the benefits of adopting Spectra Optia for automated red cell exchange it is important to take measurements before, during and after implementation. Some of these measures will not be routinely collected and sites must consider a data collection methodology that is appropriate to the service.

Homerton University Hospital NHS Foundation trust have developed a data sheet for automated red cell exchange transfusion: a real-world example to help monitor each of the patients on their programme.

Suggested measures from the sites involved in developing this resource include:

- patient demographics
- indications for starting treatment and related outcomes
- admissions rates (days in hospital)
- iron levels
- previous transfusions
- patient start date on the programme and any gaps
- haematological and biochemical parameters pre- and post-transfusion (including haemoglobin, haematocrit and haemoglobin 'S' percentage and pre procedure ferritin)
- side effects of the treatment and safety markers for example incidences of allo-immunisation
- sites of access.

All patients will undergo regular detailed clinical review which is documented in their medical notes and are frequently discussed at team progress meetings.

Overcoming implementation challenges

The table below shows the implementation challenges reported by NHS sites using Spectra Optia for automated red cell exchange.

Table 1: Reported implementation challenges when using Spectra Optia for automated red cell exchange

Implementation challenge	Solution
Capital and ongoing revenue costs.	Prepare a business case including full cost considerations for Spectra Optia for automated red cell exchange compared with the current service model. There is variation across the country in funding arrangements. Commissioners and providers are advised to work together to realise anticipated savings. See service commissioning.
Clinical confidence	Select appropriate metrics to demonstrate cost and clinical benefits, safety and demand.
Training in vascular access and using the machine.	Seek expertise and support from within the organisation, other external sites who offer the service and the manufacturer. Develop an in-house training programme, using cascade training. See education.
Maximising capacity from the machines available	Undertake care pathway mapping to identify how delays can be reduced and procedures and staffing scheduled to maximise capacity.

Developing a business case

Cost savings

Some NHS trusts reported that using Spectra Optia for automated red cell exchange saved money through reduced use of iron chelation therapy and fewer emergency inpatient bed days.

NICE has published a resource impact report and template that can be used by NHS commissioners and providers to better understand the costs associated with adopting Spectra Optia for automated red cell exchange. The resource impact products can help guide commissioners and

providers in making the service financially viable. The national assumptions used in the template can be altered to reflect local circumstances.

Service commissioning

Sickle cell and thalassaemia services fall under the remit of the direct specialised services function of NHS England, specifically Cancer and Blood Programme of Care (B08 – Haemoglobinopathies).

The West Midlands Quality Review Service overview report 2012/13 for adults with haemoglobin disorders recommends that NHS England should ensure that commissioning of specialist haemoglobinopathy centres includes access to automated red blood cell exchange for at least routine care and, ideally, also emergency care.

NHS England commissions the specialised services in these case studies.

When considering the most appropriate commissioning model, services may wish to explore the therapeutic apheresis services offered by NHS Blood and Transplant.

Business case

Developing a business case should be a priority for the implementation team. Local arrangements for developing and approving business plans will vary from trust to trust, and each organisation is likely to have its own process in place.

The business case will need to consider the number of patients who could benefit from the treatment, potential savings from this treatment, optimal volumes of activity for capacity (number of machines needed and current availability of machines in the trust), costs and benefits of using the machine for other treatments and the financial viability of the service.

National drivers

When developing a business case, NHS trusts may find it useful to refer to table 2 below for details of publications at a national level which encourage implementing Spectra Optia for automated red cell exchange.

Table 2: National drivers related to Spectra Optia for automated red cell exchange

Driver	Significance or measure

British Committee for Standards in Haematology guideline on the clinical use of apheresis procedures for the treatment of patients and collection of cellular therapy products.	Provides healthcare professionals with clear guidance on the use of clinical apheresis.
West Midlands Quality Review Service, Services for Adults with Haemoglobin Disorders. Peer Review Programme 2012-13 Overview Report.	Summarises the findings of visits to services for adults with haemoglobin disorders in England.
NHS screening programmes Sickle Cell and Thalassaemia Sickle cell disease in childhood: standards and guidelines for clinical care.	Sets out standards and guidelines for clinical care and recommendations for how care for children with sickle cell disease should be delivered.
NICE guideline on the management of an acute painful sickle cell episode in hospital.	Addresses the management of an acute painful sickle cell episode in patients presenting to hospital until discharge.
National service framework for children, young people and maternity services: Children and young people who are ill.	Sets out the government's quality standards for children, young people and maternity standards.

Education

Vascular access

Because of difficulties in vascular access for patients with sickle cell disease and Spectra Optia's need for a high blood flow, it is important that practitioners inserting the venous access (peripheral and femoral) have the skills and experience to gain access quickly, minimising damage to veins and patient discomfort.

When sites first adopted Spectra Optia for red cell exchange, most venous access was via femoral line. Training small specialist teams to do this involved:

- femoral line-insertion policies for patients with sickle cell disease
- in-house training, including anatomy and physiology, from experts
- observation, supervision and completion of competencies.

All sites aimed to increase access through peripheral lines in a large arm vein (sited using ultrasound). Training programmes were devised for nurses using Spectra Optia who already had phlebotomy and cannulation skills. These programmes involved peer training both from within the trust and from external practitioners using the technique in other automated red cell exchange services, and support from the ultrasound manufacturer. Cascade training was then delivered to other nurses along with frequent opportunities to practice.

Sites had a number of current models for vascular access. The following healthcare professionals were responsible for femoral line insertion at the different sites:

- haematology and oncology vascular access nursing team (booked slots)
- sickle cell nurse specialists, apheresis nurse specialists or day senior day unit nurses
- hospital's vascular access team
- dedicated day-unit doctors.

The following healthcare professionals were responsible for peripheral line insertion under ultrasound guidance at the different sites

- haematology and oncology vascular access nursing team (booked slots)
- nurses responsible for using the Spectra Optia machines.

Using Spectra Optia

Governance of this procedure is important therefore training and experience so that users can competently set up, programme individual patient requirements and troubleshoot the machine is essential. Training involves:

- the manufacturer's 'Essentials' training package, comprising on-site training and a workbook on how to work the machine (not including managing a patient having the procedure)
- taking account of in-house skills for Spectra Optia
- completion of in-house developed competencies and sign-off by a senior nurse experienced in apheresis at the trust
- a session about the treatment purpose with an in-house expert
- a system of observing and supervision.

The cover needed to maintain the service and existing staff skills should guide the number of nurses trained to use the machine.

Developing local documentation

Sites have developed individualised patient records to be used as the patient's prescription and accessible from the day unit (either in paper or digital format). These records are updated regularly following team monitoring review meetings (see measuring success) and consist of:

- indications for treatment
- physical measurements (height, weight)
- current medications
- a prescription for red cell exchange (calculations for that procedure)
- frequency of treatments (how frequently consented)
- target levels (haemoglobin, haematocrit and haemoglobin 'S' percentage after the procedure)
- blood results before and after previous procedures
- specific transfusion instructions or requirements, sites of access
- documentation of incidences.

The following are examples from the sites that can be used to inform the development of local documentation.

- Homerton University Hospital NHS Foundation Trust – automated red cell exchange transfusion protocol template: a real-world example
- St Georges NHS Foundation trust – apheresis referral form for red blood cell exchange transfusion: a real-world example

7 The technology

The NICE medical technology guidance MTG28 contains full details.

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9 About this resource

This resource accompanies NICE medical technologies guidance on Spectra Optia Apheresis System for automated red blood cell exchange in patients with sickle cell disease. It was developed using the NICE adoption and impact programme: process guide for adoption support resources for health technologies. It is an implementation tool and discusses and summarises the experiences reported by NHS sites which have adopted this technology and shares the learning that took place.

It is the responsibility of local commissioners and providers to implement the guidance at a local level, being mindful of their duty to advance equality of opportunity and foster good relations. Nothing in this document should be interpreted in a way that would be inconsistent with this.

Click here for more information about the adoption and impact programme.

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