NICE National Institute for Health and Care Excellence

Adoption support resource – insights from the NHS

Implementation support

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1 Introduction

Published date: March 2016 **Last updated:** September 2020. See update information for a summary of the changes.

This resource has been developed to provide practical information and advice relating to NICE medical technologies guidance on Spectra Optia for automatic red blood cell exchange in people 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.

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 NICE guidance on Spectra Optia for more information.

NICE's Adoption and Impact programme worked with contributors in NHS organisations (referred to as 'sites' in this resource) to share their learning and experiences of using the Spectra Optia system for automated red blood cell exchange in people with sickle cell disease.

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 for people with sickle cell disease.

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 use of less iron chelation therapy and fewer 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 hospital admissions in people having automated exchange for recurrent painful crisis
- high levels of reported satisfaction associated with better management of symptoms; this includes better quality of life for carers.

2 Current practice

NICE medical technologies guidance on Spectra Optia for automatic red blood cell exchange in people 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 2015 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 people with severe disease who cannot have hydroxycarbamide.

3 Tips for adopting Spectra Optia

- Identify how the service and people's 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).
- Learn from other sites who are already offering automated red cell exchange services.
- Ensure that staff have structured training on the use, troubleshooting and quality assurance of the technology (see education).
- Ensure staff skilled in inserting femoral lines are available at the right time, and consider a departmental peripheral line insertion (under ultrasound) training programme (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.

4 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's into practice guide 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:

- Who will lead the service? Most contributing sites were led by a consultant haematologist with the support of nurse specialists in apheresis or sickle cell disease.
- Who will deliver the service? In all sites appropriately trained nurses were responsible for doing the procedure. Some of these nurses were not dedicated to the apheresis service and had other roles.
- Where will the service be delivered? This was commonly on the medical or haematology day case unit on weekdays. At one site apheresis nurses worked an on-call rota enabling emergency apheresis 24 hours a day.
- Which people will be offered automated red cell exchange and from what geographical area? See patient selection.
- Are there enough eligible people to warrant development of the service? See developing a business case.
- How many machines will be needed to run an efficient and effective service? This varied between sites. See maximising capacity.
- Are there Spectra Optia machines already in use within the organisation and do they have spare capacity? Where more than one machine was available, sites used this for other procedures including therapeutic plasma exchange, emergency leukapheresis, and peripheral blood stem cell collection (auto collection and off donor collection). See maximising capacity.
- Will new governance protocols and procedures be required or is there existing documentation within the organisation? See developing local documentation.

- How will the necessary education (using the device and venous access) be provided? See education.
- How will timely venous access be achieved? See maximising capacity.
- How will the project be funded? See developing a business case.
- How will local metrics be identified and measured? See measuring success.
- Who will be responsible for collecting clinical data? See measuring success.
- What are the criteria for starting, continuing and stopping treatment? See care pathway mapping.
- Are there any obvious challenges and how can these be overcome? See reported implementation challenges.
- What can we learn from other sites who have adopted automated red cell exchange for people with sickle cell disease?
- Are there opportunities to work with local haemoglobinopathy networks to offer a network-wide service?

Care pathway mapping

Patient selection

The sites reported offering regular (every 4 weeks to 8 weeks) automated red cell exchange to people in line with the BSCH guideline (2015) and including people at high risk of stroke or with history of stroke and people 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.

Some sites developed patient information resources to explain the benefits of automated red cell exchange for people who are eligible, to support engagement in the intervention.

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.
- Addressing sources of delays:
  - Considering ways to ensure people arrive on time.
  - Ensuring pre-procedure blood tests and cross-match samples are taken early enough (up to 1 week before) 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. Gaining vascular access in paediatric people requires planning on a case by case basis to increase success and minimise distress.
  - Ensuring staff can effectively troubleshoot the machine.
  - Reducing the impact of delays from other areas of the day unit.
- Planning staffing:
  - Staggering procedure starts to maintain constant activity.
  - Planning nurse cover for the busiest times and if a procedure is delayed.
  - Explore how healthcare assistants can help, for example by preparing machines.
- Monitoring and regularly reviewing all people's response to treatment. Protocols and criteria should be in place for optimising individual regiments and to guide stopping decisions if treatment is not beneficial. This important process commonly involves weekly multidisciplinary team meetings about the people and the development of local documentation, which can also be used to measure success of the service.

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.

Sites developed local documentation to support data collection. Suggested measures from the sites involved in developing this resource include:

- demographics
- indications for starting treatment and related outcomes
- unplanned admission rates (days in hospital)
- iron levels and requirement for iron chelation therapy
- previous transfusions
- 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
- people's experience and quality of life.

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

Overcoming implementation challenges

Table 1 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

Sites 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.

Service commissioning

Sickle cell and thalassaemia services fall under the remit of the direct specialised services function of NHS England, specifically Specialised haemoglobinopathy services (F05 – Haemoglobinopathies).

When considering the most appropriate commissioning model, services may wish to

explore the NHS Blood and Transplant therapeutic apheresis services.

Business case

Developing a business case should be a priority for the implementation team. It should consider the number of people 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. Some sites incorporated the case for adoption of automated red cell exchange in an overall apheresis or haematology business case, to support a whole service approach to business planning. Real-world data from sites already offering the service can be used to support the case for adoption.

Education

Vascular access

Because of difficulties in vascular access for people 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 the person's 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 people 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 initially 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 extended to other nurses which included creating frequent opportunities to practice.

Sites had a number of 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
- at the paediatric site, femoral lines were inserted under general anaesthetic.

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
- advanced nurse practitioners at the paediatric site; to minimise distress, if possible the same nurse practitioner inserts the person's peripheral line for each procedure.

Using Spectra Optia

Governance of this procedure is important, therefore users must be able to competently set up, programme, and troubleshoot the machine. Training involves:

- the manufacturer's 'Essentials' training package, comprising onsite training and a workbook on how to work the machine (not including managing someone 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. Training and achieving competence in using Spectra Optia independently was reported to take between 6 weeks and 3 months. Some sites developed care pathways that explain the checks and steps needed before the procedure starts, to support learning.

Developing local documentation

Sites have developed individualised patient records, which are accessible from the day unit (either in paper or digital format) to be used as the person's prescription. These records are updated regularly following clinical 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 examples from NHS sites can be used to inform the development of local documentation and can be accessed from tools and resources for the Spectra Optia guidance.

- Homerton University Hospital NHS Foundation Trust - automated red cell exchange transfusion protocol template: a real-world example
- Homerton University Hospital NHS Foundation Trust - data sheet for automated red cell exchange transfusion: a real-world example

- St Georges NHS Foundation Trust - apheresis referral form for red blood cell exchange transfusion: a real-world example.

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6 About this resource

This resource accompanies NICE medical technologies guidance on Spectra Optia for automatic red blood cell exchange in people with sickle cell disease. 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.

Update information

September 2020: This adoption resource was reformatted to bring together the learning from contributors into sections 3 and 4. Dated references and broken links were amended or removed.

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