1. Population Needs

1.1 National/local context and evidence base

The National Artificial Eye Service (NAES) holds a database of over 48,000 patients within England, who attend any of 65 clinic locations in England.

This is a single national provider of the service offering a service to patients from a number of sites across England. All referrals are made to the service based in Blackpool and hosted by Blackpool Teaching Hospitals NHS Foundation Trust.

There are up to 1000 new referrals per year to the NAES (880 in 2009, 957 in 2010, 934 in 2011).

Over 90% of these are new referrals for patients following trauma, surgery, cancer or congenital illnesses of the eye.

Loss of an eye(s) is a life-long condition but it should be recognised that sight loss can be managed effectively through specialised rehabilitation services and re-ablement support and can provide the individual patient with improvements in quality of life and independence.

Evidence base

The service has been in operation since 1915 under various titles. No other providers have been identified in the UK, that work in the same way as the NAES with separate staff groups manufacturing and fitting eyes. In light of this, the service has no defined
evidence base that relates entirely to the way it manages patient care. However, the service regularly carry out literature reviews from providers in other countries and have links with bodies such as British Oculoplastic Surgery Society (BOPPS).

Regular review of practice via international comparisons as proposed in the NHS Outcomes Framework 2012/13 will provide a more detailed benchmark for the Service.

The evidence base for the design and manufacture of artificial eye prostheses, as required by the Medicines and Healthcare Products Regulatory Agency (MHRA) for Medical Device Directive purposes, is accepted as appropriate due to many years of experience and monitoring. This has allowed the Service to build its own evidence base regarding manufacturing and fitting practice with regard to artificial eye prostheses. There is also recognition of a standard manufacturing model across the sector; using the same production processes and materials that are accepted as appropriate by the dental manufacturing industry and check the service methods against these on an ongoing basis.

The service also purchases regular assessments of finished products by external assessors to ensure product safety in terms of processing and curing methods.

National Service Framework for long-term conditions

The service provides full training for Orbital Prosthetists in the UK and other countries, as requested.

2. Scope

This service is for patients of any age requiring any type of artificial eye prosthesis, in order to improve the aesthetic appearance of a missing, damaged or disfigured eye; supporting the socket to maintain optimum cosmesis. The conditions this group encompass include cancer, trauma, congenital eye diseases.

2.1 Aims and objectives of service

The aim of the National Artificial Eye Service (NAES) is to provide patient centred specialist care to all eligible patients requiring artificial eye prosthetics (by nature of the service need is lifelong)

To achieve this aim, the NAES will:
- provide continuous, lifelong care for all NHS patients requiring ocular prostheses by offering high-quality, proactive treatments
- receive and process all appropriate referrals in order to treat patients in a timely manner.
- provide timely and appropriate interventions for every patient, specific to their individual needs
- provide smooth and managed lifelong care from the cradle to the grave
- support patients, parents and carers to manage the ongoing care of artificial eye
prostheses
- provide a personal service, encouraging the involvement of all service users in their care and the ongoing development of the Service.

2.2 Service description/care pathway

The NAES covers the whole of England, with the manufacturing, administration and headquarters at Bristol Avenue, Blackpool. There is also a main base treatment facility provided at the HQ. In addition, outpatient contact is provided at 15 other main bases and a further 49 locations visited as outreach. Staff are employed by the NAES, although some are based in various locations around the country. A range of services are provided to deliver:
- information for patients and carers
- specialised assessment and review
- prescription, provision and maintenance of bespoke ocular prostheses

The service will provide the appropriate level of support for education and workforce development for the current workforce and trainee workforce. Training and support is also offered to NHS colleagues in the United Kingdom.

Pregnancy or Operational Delivery Networks

Referral is via GP or secondary care, with lifelong care following this:
- Referral from GP or secondary care
- Initial Consultation appointment with Orbital Prosthetist
- Review Outpatient Appointment – decision regarding further treatment, CarePlan developed
- Provision of referral and appointment management service
- Manufacture of bespoke ocular prosthesis
- Regular Review for routine maintenance and regular replacement of ocular prosthesis as required (design life of standard ocular prosthesis approximately eight years)

Close links with referring services, e.g. ophthalmic surgery and General Practice services are critical for optimal patient outcomes. The service works closely with colleagues at various locations, taking part in joint clinics with Consultant Ophthalmologist teams in some areas. This area of provision is currently being expanded as much as time and resources allow. Orbital Prosthetists in the field also work with Specialist Nurse teams to educate and support practice, particularly in the pre-operative phase, to introduce patients to the Service and the practicalities of prosthesis provision and care.

The service works closely with a small number of charitable organisations, to provide education and support to individual patients. For example, the service sends delegates to Family Days run by the Childhood Eye Cancer Trust (CHECT) to act as expert advisers to patients and parents/carers.

Models of Service Delivery:

Pre-operative - Consultation can be arranged with appropriate members of the NAES
team.

**New patients** - New patients will have appropriate access to the service in their own locality.

**Established patients** - These patients will require input from the service in order to review and maintain their prosthetic provision as there will be minimal input from Primary and Secondary care.

**Changing needs** - Children, young adults and other patients with more complex problems require a more flexible model of care which provides more frequent appointments and prosthetic replacement.

**Non Prosthetic Eye Users** – These patients may access the service at any time for advice.

A basic routine patient pathway is as follows:

- following referral post surgery, the patient is seen for an initial 90 minute appointment. The socket is checked for healing and if deemed ready, a half-sphere prosthesis is cut, shaped and fitted
- approximately 3 months following surgery, if all swelling has reduced and the socket is ready, the patient attends a longer appointment (between 2 and 2 ½ hours) to have a mould taken of the socket and colour match the iris to the remaining eye. The order is sent to the Manufacturing Laboratory in Blackpool where the bespoke artificial eye is made. Once returned to the clinic, the eye is fitted at a further 30 minute appointment
- Following fitting (and excluding occasional additional visits for newer patients), the patient is seen approximately every 18 months for a check-up and the prosthesis may be polished.

The appointments are completed in clinics as near to the clients home as possible.

**General Paediatric care**

When treating children, the service will additionally follow the standards and criteria outlined in the Specification for Children’s Services (attached as Annex 1 to this specification).

**2.3 Population covered**

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

* Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a General Practitioner (GP) Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.
2.4 Any acceptance and exclusion criteria

Acceptance criteria

The service will accept inward referrals from primary or secondary care doctors. Patients will generally be under the care of a Consultant Ophthalmologist or Oculoplastic Surgeon.

The service will accept referrals for all eligible patients requiring ocular prosthetic treatment.

All referrals are managed by NAES Blackpool HQ and allocated to a clinic according to the patient’s individual geographic location or specific request.

Exclusions

There are no exclusions to access the service.
(Funding for veterans with service attributable injury may be sought from the veteran’s prosthetic panel under current arrangements. Treatment for serving military personnel may be sought from the Ministry of Defence under current guidelines).

2.5 Interdependencies with other services

There are no co-located services for the NAES. There are no interdependent services for the NAES.

Related services include

- The ophthalmic departments of referring hospitals
- General Practitioners
- Charitable organisations, as mentioned previously

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

Specific equipment needed is for the manufacture of ocular prostheses within the Service’s Laboratory (full list can be supplied if required).

Patient information is key; examples of patient information leaflets are available. These are reviewed and updated regularly. An external website is in place which meets full accessibility standards. A Telephone Helpline is run and managed from NAES HQ in Blackpool and is available Monday to Friday (9am to 5pm), excluding Bank Holidays.

As manufacturers of Medical Devices, the NAES must maintain certification to the ISO
There are a number of provisions within the 9001:2008 standard which must be managed, including the necessity to have an ongoing internal audit schedule (carried out by an internal audit team) and various patient satisfaction measures. The service is also required to monitor various manufacturing processes to ensure ongoing safety and traceability of all items produced.

In addition, the service is audited by the British Standards Institute to ensure continued compliance with the Standard.

The NAES holds a Patients Forum in Blackpool, Birmingham and Exeter and is working to develop groups in other areas of the country.

**Professional guidelines**

Equity and excellence: Liberating the NHS: section 3 Putting the patients and the public first, Department of Health, London, 2010

**4. Key Service Outcomes**

This specialised service seeks to empower patients, providing them with relevant information about their treatment pathway(s). The ability to return to normal life and work is a key service outcome thereby improving the individual’s quality of life.

The Key Service Outcomes for the NAES relate directly to domains 2, 4 and 5 of the NHS Outcomes Framework 2011/12.

**Domain 2:**

- By enhancing the quality of life for patients with long term conditions by the provision of high quality, bespoke ocular prosthetic services

**Domain 4:**

- Quality of patient experience by monitoring and review of Patient Experience Surveys

**Domain 5:**

- Improving safety by reporting any Untoward Incidents and monitoring staff training and development

This is achieved by providing services that take into account:

**Person (Patient) centred service:**

**Informed Patient Choice**

**Information:**

- The patient or advocates are provided access to all the information
Choice:

- The patient works with the Orbital Prosthetist to choose the management of their treatment based on information, advice and personal circumstance within the frame work of the practical and financial limitations of the service.

Timing of treatment:

- Appointments are as flexible as possible and include priority to certain patients (e.g. children). Urgent appointments are provided for replacement of lost prostheses or if a patient is experiencing problems with their current prosthesis.

Service provider outcomes

All patients offered prosthetic rehabilitation services and re-ablement support:

- Improved access
- Improved outcomes related to patient centred choice

Increased patient satisfaction:

- Monitored by regularly audited Patient Experience Surveys to new and established patients using prepaid envelopes.
ANNEX 1 TO SERVICE SPECIFICATION: PROVISION OF SERVICES TO CHILDREN

Aims and objectives of service

This specification annex applies to all children’s services and outlines generic standards and outcomes that would fundamental to all services.

The generic aspects of care:
The Care of Children in Hospital (HSC 1998/238) requires that:
• Children are admitted to hospital only if the care they require cannot be as well provided at home, in a day clinic or on a day basis in hospital.
• Children requiring admission to hospital are provided with a high standard of medical, nursing and therapeutic care to facilitate speedy recovery and minimize complications and mortality.
• Families with children have easy access to hospital facilities for children without needing to travel significantly further than to other similar amenities.
• Children are discharged from hospital as soon as socially and clinically appropriate and full support provided for subsequent home or day care.
• Good child health care is shared with parents/carers and they are closely involved in the care of their children at all times unless, exceptionally, this is not in the best interest of the child; Accommodation is provided for them to remain with their children overnight if they so wish.

Service description/care pathway

• All paediatric specialised services have a component of primary, secondary, tertiary and even quaternary elements.
• The efficient and effective delivery of services requires children to receive their care as close to home as possible dependent on the phase of their disease.
• Services should therefore be organised and delivered through “integrated pathways of care” (National Service Framework for children, young people and maternity services (Department of Health & Department for Education and Skills, London 2004)

Interdependencies with other services

All services will comply with Commissioning Safe and Sustainable Specialised Paediatric Services: A Framework of Critical Inter-Dependencies – Department of Health

Imaging

• All services will be supported by a 3 tier imaging network (‘Delivering quality imaging services for children’ Department of Health 13732 March 2010). Within the network:
  • It will be clearly defined which imaging test or interventional procedure can be
performed and reported at each site

- Robust procedures will be in place for image transfer for review by
- a specialist radiologist, these will be supported by appropriate contractual and information governance arrangements
- Robust arrangements will be in place for patient transfer if more complex imaging or intervention is required
- Common standards, protocols and governance procedures will exist throughout the network.
- All radiologists, and radiographers will have appropriate training, supervision and access to continuing professional development
- All equipment will be optimised for paediatric use and use specific paediatric software

**Specialist Paediatric Anaesthesia**

Wherever and whenever children undergo anaesthesia and surgery, their particular needs must be recognised and they should be managed in separate facilities, and looked after by staff with appropriate experience and training. All UK anaesthetists undergo training which provides them with the competencies to care for older babies and children with relatively straightforward surgical conditions and without major co-morbidity. However those working in specialist centres must have undergone additional (specialist) training and should maintain the competencies so acquired. These competencies include the care of very young/premature babies, the care of babies and children undergoing complex surgery and/or those with major/complex co-morbidity (including those already requiring intensive care support).

As well as providing an essential co-dependent service for surgery, specialist anaesthesia and sedation services may be required to facilitate radiological procedures and interventions (for example MRI scans and percutaneous nephrostomy) and medical interventions (for example joint injection and intrathecal chemotherapy), and for assistance with vascular access in babies and children with complex needs such as intravenous feeding.

Specialist acute pain services for babies and children are organised within existing departments of paediatric anaesthesia and include the provision of agreed (hospital wide) guidance for acute pain, the safe administration of complex analgesia regimes including epidural analgesia, and the daily input of specialist anaesthetists and acute pain nurses with expertise in paediatrics.

*The Safe and Sustainable reviews of paediatric cardiac and neuro-sciences in England have noted the need for additional training and maintenance of competencies by specialist anaesthetists in both fields of practice.

**References**

- Guidelines for the Provision of Anaesthetic Services (GPAS) Paediatric anaesthetic services. Royal College of Anaesthetists (RCoA) 2010  www.rcoa.ac.uk
- Certificate of Completion of Training (CCT) in Anaesthesia 2010
- CPD matrix level 3
Specialised Child and Adolescent Mental Health Services (CAMHS)

The age profile of children and young people admitted to specialised CAMHS day/in-patient settings is different to the age profile for paediatric units in that it is predominantly adolescents who are admitted to specialised CAMHS in-patient settings, including over-16s. The average length of stay is longer for admissions to mental health units. Children and young people in specialised CAMHS day/in-patient settings generally participate in a structured programme of education and therapeutic activities during their admission.

Taking account of the differences in patient profiles the principles and standards set out in this specification apply with modifications to the recommendations regarding the following:

- Facilities and environment – essential Quality Network for In-patient CAMHS (QNIC) standards should apply (http://www.rcpsych.ac.uk/quality/quality.accreditationaudit/qnic1.aspx)
- Staffing profiles and training - essential QNIC standards should apply.
- The child/young person’s family are allowed to visit at any time of day taking account of the child / young persons need to participate in therapeutic activities and education as well as any safeguarding concerns.
- Children and young people are offered appropriate education from the point of admission.
- Parents/carers are involved in the child/young persons care except where this is not in the best interests of the child / young person and in the case of young people who have the capacity to make their own decisions is subject to their consent.
- Parents/carers who wish to stay overnight are provided with accessible accommodation unless there are safeguarding concerns or this is not in the best interests of the child/young person.

Applicable national standards e.g. National Institute for Health and Clinical Excellence (NICE), Royal College

Children and young people must receive care, treatment and support by staff registered by the Nursing and Midwifery Council on the parts of their register that permit a nurse to work with children (Outcome 14h Essential Standards of Quality and Safety, Care Quality Commission, London 2010)

- There must be at least two Registered Children’s Nurses (RCNs) on duty 24 hours a day in all hospital children’s departments and wards.
- There must be an Registered Children’s Nurse available 24 hours a day to advise on the nursing of children in other departments (this post is included in the staff establishment of 2RCNs in total).

Accommodation, facilities and staffing must be appropriate to the needs of children and separate from those provided for adults. All facilities for children and young people must comply with the Hospital Build Notes HBN 23 Hospital Accommodation for Children and Young People NHS Estates, The Stationary Office 2004.

All staff who work with children and young people must be appropriately trained to
provide care, treatment and support for children, including Children's Workforce Development Council Induction standards (Outcome 14b Essential Standards of Quality and Safety, Care Quality Commission, London 2010).

Each hospital who admits inpatients must have appropriate medical cover at all times taking account of guidance from relevant expert or professional bodies (National Minimum Standards for Providers of Independent Healthcare, Department of Health, London 2002). “Facing the Future” Standards, Royal College of Paediatrics and Child Health.

Staff must carry out sufficient levels of activity to maintain their competence in caring for children and young people, including in relation to specific anaesthetic and surgical procedures for children, taking account of guidance from relevant expert or professional bodies (Outcome 14g Essential Standards of Quality and Safety, Care Quality Commission, London 2010).

Providers must have systems in place to gain and review consent from people who use services, and act on them (Outcome 2a Essential Standards of Quality and Safety, Care Quality Commission, London 2010). These must include specific arrangements for seeking valid consent from children while respecting their human rights and confidentiality and ensure that where the person using the service lacks capacity, best interest meetings are held with people who know and understand the person using the service. Staff should be able to show that they know how to take appropriate consent from children, young people and those with learning disabilities (Outcome 2b) (Seeking Consent: working with children Department of Health, London 2001).

Children and young people must only receive a service from a provider who takes steps to prevent abuse and does not tolerate any abusive practice should it occur (Outcome 7 Essential Standards of Quality and Safety, Care Quality Commission, London 2010 defines the standards and evidence required from providers in this regard). Providers minimise the risk and likelihood of abuse occurring by:

- Ensuring that staff and people who use services understand the aspects of the safeguarding processes that are relevant to them.
- Ensuring that staff understand the signs of abuse and raise this with the right person when those signs are noticed.
- Ensuring that people who use services are aware of how to raise concerns of abuse.
- Having effective means to monitor and review incidents, concerns and complaints that have the potential to become an abuse or safeguarding concern.
- Having effective means of receiving and acting upon feedback from people who use services and any other person.
- Taking action immediately to ensure that any abuse identified is stopped.
- and suspected abuse is addressed by:
  - having clear procedures followed in practice, monitored and reviewed that take account of relevant legislation and guidance for the management of alleged abuse.
  - separating the alleged abuser from the person who uses services and others
who may be at risk or managing the risk by removing the opportunity for abuse to occur, where this is within the control of the provider.

- reporting the alleged abuse to the appropriate authority.
- reviewing the person’s plan of care to ensure that they are properly supported following the alleged abuse incident.
- Using information from safeguarding concerns to identify non-compliance, or any risk of non-compliance, with the regulations and to decide what will be done to return to compliance.
- Working collaboratively with other services, teams, individuals and agencies in relation to all safeguarding matters and has safeguarding policies that link with local authority policies.
- Participates in local safeguarding children boards where required and understand their responsibilities and the responsibilities of others in line with the Children Act 2004.
- Having clear procedures followed in practice, monitored and reviewed in place about the use of restraint and safeguarding.
- Taking into account relevant guidance set out in the Care Quality Commission’s Schedule of Applicable Publications.
- Ensuring that those working with children must wait for a full CRB disclosure before starting work.
- Training and supervising staff in safeguarding to ensure they can demonstrate the competences listed in Outcome 7E of the Essential Standards of Quality and Safety, Care Quality Commission, London 2010.
- All children and young people who use services must be
  - Fully informed of their care, treatment and support.
  - Able to take part in decision making to the fullest extent that is possible.
  - Asked if they agree for their parents or guardians to be involved in decisions they need to make.

(Outcome 4I Essential Standards of Quality and Safety, Care Quality Commission, London 2010).

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**Key Service Outcomes**

Evidence is increasing that implementation of the national Quality Criteria for Young People Friendly Services (Department of Health, London 2011) have the potential to greatly improve patient experience, leading to better health outcomes for young people and increasing socially responsible life-long use of the NHS. Implementation is also expected to contribute to improvements in health inequalities and public health outcomes e.g. reduced teenage pregnancy and Sexually Transmitted Infections (STIs), and increased smoking cessation. All providers delivering services to young people should be implementing the good practice guidance which delivers compliance with the quality criteria.

Poorly planned transition from young people’s to adult-oriented health services can be associated with increased risk of non adherence to treatment and loss to follow-up, which can have serious consequences. There are measurable adverse
consequences in terms of morbidity and mortality as well as in social and educational outcomes. When children and young people who use paediatric services are moving to access adult services (for example, during transition for those with long term conditions), these should be organised so that:

- All those involved in the care, treatment and support cooperate with the planning and provision to ensure that the services provided continue to be appropriate to the age and needs of the person who uses services.

The National Minimum Standards for Providers of Independent Healthcare, (Department of Health, London 2002) require the following standards:

- A16.1 Children are seen in a separate out-patient area, or where the hospital does not have a separate outpatient area for children, they are seen promptly.
- A16.3 Toys and/or books suitable to the child’s age are provided.
- A16.8 There are segregated areas for the reception of children and adolescents into theatre and for recovery, to screen the children and adolescents from adult patients; the segregated areas contain all necessary equipment for the care of children.
- A16.9 A parent is to be actively encouraged to stay at all times, with accommodation made available for the adult in the child’s room or close by.
- A16.10 The child’s family is allowed to visit him/her at any time of the day, except where safeguarding procedures do not allow this
- A16.13 When a child is in hospital for more than five days, play is managed and supervised by a qualified Hospital Play Specialist.
- A16.14 Children are required to receive education when in hospital for more than five days; the Local Education Authority has an obligation to meet this need and are contacted if necessary.
- A18.10 There are written procedures for the assessment of pain in children and the provision of appropriate control.

All hospital settings should meet the Standards for the Care of Critically Ill Children (Paediatric Intensive Care Society, London 2010).

There should be age specific arrangements for meeting Regulation 14 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. These require:

- A choice of suitable and nutritious food and hydration, in sufficient quantities to meet service users’ needs;
- Food and hydration that meet any reasonable requirements arising from a service user’s religious or cultural background
- Support, where necessary, for the purposes of enabling service users to eat and drink sufficient amounts for their needs.
- For the purposes of this regulation, “food and hydration” includes, where applicable, parenteral nutrition and the administration of dietary supplements where prescribed.
- Providers must have access to facilities for infant feeding, including facilities to support breastfeeding (Outcome 5E, of the Essential Standards of Quality and Safety, Care Quality Commission, London 2010)

All paediatric patients should have access to appropriately trained paediatric trained dieticians, physiotherapists, occupational therapists, speech and language therapy,
psychology, social work and CAMHS services within nationally defined access standards.

All children and young people should have access to a professional who can undertake an assessment using the Common Assessment Framework and access support from social care, housing, education and other agencies as appropriate

All registered providers must ensure safe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines (Outcome 9 Essential Standards of Quality and Safety, Care Quality Commission, London 2010). For children, these should include specific arrangements that:

- ensure the medicines given are appropriate and person-centred by taking account of their age, weight and any learning disability
  - ensure that staff handling medicines have the competency and skills needed for children and young people’s medicines management
  - ensure the medicines given are appropriate and person-centred by taking account of their age, weight and any learning disability
  - ensure that staff handling medicines have the competency and skills needed for children and young people’s medicines management
  - ensure that wherever possible, age specific information is available for people about the medicines they are taking, including the risks, including information about the use of unlicensed medicine in paediatrics.

Many children with long term illnesses have a learning or physical disability. Providers should ensure that:

- They are supported to have a health action plan
- Facilities meet the appropriate requirements of the Disability Discrimination Act 1995
- They meet the standards set out in Transition: getting it right for young people. Improving the transition of young people with long-term conditions from children’s to adult health services. Department of Health, 2006, London