

Public Document Pack

Supplementary information for Scrutiny Board (Health and Well-being and Adult Social Care) on 28 March 2014

Pages 1-270: Agenda item 7 – Proposed changes to the 14 specialised service areas

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SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	A06/S/a
Service	In centre haemodialysis (ICHD): main and satellite units
Commissioner Lead	
Provider Lead	<i>The name of the individual leading on the service for the provider</i>
Period	<i>12 months</i>
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

End stage renal failure (ESRF), also known as established renal failure (ERF), is an irreversible, long-term condition as a result of chronic kidney disease for which regular dialysis treatment or transplantation is required if the individual is to survive. If the kidneys fail, the body is unable to excrete certain waste products, excess water, acid and salts resulting in increasing symptoms and eventually death. When ESRF is reached, renal replacement therapy (RRT), in the form of dialysis or transplantation, is required as a life-saving and life-sustaining measure. In 2011, 108 patients per million (ppm) population in the UK started renal replacement therapy (RRT) for established renal failure but the UK Renal Registry showed significant variation in the crude acceptance rate from 50 to 226 ppm. Some of this variation is explained by ethnicity and socioeconomic deprivation both of which influence the prevalence of kidney disease.

This specification focuses on haemodialysis which takes place in main or satellite dialysis units (adults) and forms just one part of a wider portfolio of detailed specifications for RRT. In recent years there has been a growing recognition that, in patients who are not transplanted, self-care in the home or in a community centre by either peritoneal or haemodialysis should be encouraged wherever possible to enhance health and quality of life prospects. Where these treatments are inappropriate or difficult to establish and whenever patients choose it, in-centre

haemodialysis (ICHD) is the mainstay of treatment. . The prevalence rate for patients receiving ICHD was 365 pmp in England in 2011. In England in 2011 82.2% of patient being treated with chronic dialysis received that as ICHD.

All 52 renal referral centres in England have an integral haemodialysis unit. These are referred to as Main Renal Units (MRUs). In addition to providing an essential support function for in-patient renal care including new and unstable patients they typically also provide routine ICHD for patients who live near to the main hospital. In 2011, 43% of ICHD patients in England were treated in MRUs.

In 2011 57% ICHD patients in England were treated in satellite units. At the time of writing 46 of the 52 renal referral centres have 'satellites' around them, some over five, the majority less than 3. Satellite renal units may be located in district general hospitals, or in other healthcare facilities (eg GP practice). Others are 'freestanding', often in industrial locations in towns and cities. Those in hospitals have the advantages of convenient access to other healthcare services and investigations, the latter having the advantage of 'locality', easy access and parking. Some years ago it was shown that there was little difference in the case-mix of patients managed in satellites or MRUs (Roderick et al). This is reflected in uniformity of tariff for ICHD patients, irrespective of dialysis location.

While the majority of ICHD units are managed by the NHS a number are managed by the independent sector. This includes a small number of MRUs. Over 30% of patients are thought to be treated by the independent sector, mainly in satellite units, and this proportion has increased year on year. While independent sector provider typically provides the building and equipment and employs the nursing staff other models exists in which the independent provider provides the non-clinical aspects of the service and the nurses remain in the NHS, accountable to the senior NHS nurse manager in the MRU. In all cases hitherto, the doctor who assumes the responsibility of continuity of care of the patient, remains an NHS employee of the Trust of the MRU. Similarly, access to other members of the multi-professional renal team most often are directly employed by the local NHS MRU but not exclusively so.

ICHD is a specialised service commissioned by NHS England, but there are currently different models whereby satellite ICHD, be it NHS or independent sector, is commissioned either directly from the centre or it is subcontracted from the local MRU which receives the tariff payment.

Haemodialysis patients are dependent on the maintenance of 'vascular access' to allow repeated connection to the HD machine. The need to maintain a satisfactory vascular access coupled with a high susceptibility to cardiovascular disease, dialysis patients present some of the most serious challenges encountered by vascular surgeons and interventional radiologists. A significant proportion of these interventions are required to be delivered urgently or as an emergency. The safety of dialysis patients while hospitalised with vascular complications of their disease requires special consideration in the commissioning of dialysis services.

1.2. Evidence Base

The National Service Framework (NSF) for Renal Services (Department of Health, 2004/5)

NHS Estates Health Building Notes 07-01 Satellite Dialysis Unit and 07-02 Main Renal Unit. 2009

European Best Practice Guidelines Expert Group on Haemodialysis. Nephrology Dial Transplant 2007; 22: (Suppl 2) S1–S120.

Clinical Practice Guidelines for Haemodialysis: UK Renal Association, 5th Edition, April 2010

Roderick P et al: An evaluation of the costs, effectiveness and quality of RRT provision in renal satellite units in England and Wales. Health Technol. Assess 2005; 9(24)

The Renal Team: A multi-professional renal workforce plan for adults and children with Renal Disease. Recommendations of the National Workforce Planning Group. British Renal Society: 2002

UK Renal Registry. Nephron. Clin. Prac. Vol. 120, Suppl. 1, 2012. 14th Annual Report of the Renal Association.

A Home Dialysis Manifesto. Findings of the 2013 Home Dialysis Summit. National Kidney Federation (NKF). Ed control: All-Party Parliamentary Kidney Group.

Nice Guidance CG73: Chronic kidney disease (2008)

Nice Guidance CG114: Anaemia management in people with chronic kidney disease (2011).

End of Life Care in Advanced Kidney Disease: A framework for implementation. NHS Kidney Care, National End of Life Care Programme, 2011.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	√
Domain 2	Enhancing quality of life for people with long-	√

	term conditions	
Domain 3	Helping people to recover from episodes of ill-health or following injury	√
Domain 4	Ensuring people have a positive experience of care	√
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	√

Patient Reported Outcome and Experience Measures should be prioritised and should be the principal barometer of. Improved quality of life and experience for both patients and carers should be sought.

The ICHD service aims to deliver the following outcomes:

- Patient centred and integrated care (domain 4)
- Improved patient life expectancy and the prevention of avoidable death from kidney disease or its complications (domain 1)
- Improved clinical outcomes (domain3)
- Improved quality of life and experience of care for people with end stage kidney disease and their family/carers (domain 2)
- Provision of care in a harm-free environment (domain 5)
- Provision of cost-effective services
- Care delivered at the appropriate time and place.(domain 3)
- Equity of service provision (domain 4)
- Innovation in service delivery

To provide a safe, cost effective, high quality specialist service for people with end stage kidney disease treated with ICHD to improve both life expectancy and quality of life by (domain 2, 5):

- Providing a personal service, sensitive to the physical, psychological and emotional needs of the patients and their families/carers
- Ensuring equity of access to services for those with kidney disease taking into account a patient's choice of RRT modality, location and the distance they travel
- Ensuring the opportunity for patients to share (contribute) to their care by education to enable them to participate in the tasks relating to haemodialysis treatments
- Facilitating autonomy and transition to adult care by additional support. Such support is to be patient centred and enabling patient choice. Consideration will be given to the particular educational and employment needs of these patients.
- Facilitating transition to conservative and end of life kidney care
- Ensuring effective communication and support between patients, families/carers and the service providers

National Renal Dataset

The provider will ensure that the required patient, activity and outcomes data is

provided in accordance with the requirements of the National Renal Dataset. The National Renal Dataset has been approved as a Full Operational Information Standard by the Information Standards Board for Health and Social Care. The dataset is mandated for collection by the Department of Health, <http://www.ic.nhs.uk/services/datasets/dataset-list/renal>

Renal Registry

The provider will ensure that the required patient, activity and outcomes data is provided in accordance with the requirements of the UK Renal Registry: <http://www.renalreg.com/>

Renal Patient View System

The provider will ensure that patient health records and any other personal data relating to a patient's treatment are returned to the national Renal Patient View System for those patients who wish to participate in this system.

3. Scope

3.1 Aims and objectives of service

Key objectives of renal replacement therapy (RRT) are to extend life quality and expectancy for those with advanced kidney failure who are likely to benefit.

Services will be patient-centred, and offer safe, effective, evidence-based therapies in appropriate care settings.

Patients will be supported to make informed choices regarding their treatment options and in managing their condition to achieve their goals and their best possible quality of life.

3.2 Service description/care pathway

The provider will deliver ICHD Services that:

Infrastructure:

Are provided in a safe and secure environment in a facility which complies with NHS Estates Building Notes and which meets all the technical standards detailed in the Renal Association Guidelines.

Access to entertainment including free to air television should be provided, internet access is desirable.

That the design of the centre meets the requirement to isolate patients using a dedicated dialysis machine when returning from dialysing in areas with high risk of blood borne virus transmission.

The provider will ensure that all equipment used in the delivery and monitoring of haemodialysis is CE marked and approved to ensure compliance with the relevant safety standards BS EN 60601-1:2006 'General safety standards for electrical equipment in clinical use' 2010) and BS EN 60601-2-16:2008 'Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment' and Renal Association guidelines (2009).

Water treatment standards must comply with all Renal Association guidelines.

Providers will offer Renal Patient View (RPV) to every patient treated in MRUs and Satellite haemodialysis units. Patients will be encouraged to advise their GP if they register with RPV.

Providers should have in place electronic download of all information required by the UK Renal Registry. The provider must ensure 100% of the data-set required is communicated to the UKRR including individual primary diagnosis and co-morbidity profile.

In the event that the provider is unable to provide sufficient equipment for treating patients at any time, or in the event of technical difficulties, or other emergencies, the provider shall have contingency systems in place. These should include the ability to provide or procure alternative dialysis sessions at other facilities.

Clinical Management:

Provide a specific support for those patients who start dialysis as late presenters or unplanned from within the kidney service to ensure that they receive appropriate information. These patients should be offered the same range of choices regarding their RRT modality.

Providers must offer education about access to self care training for patients interested in contributing to their management by participating in the tasks relating to haemodialysis treatment. In particular, this should include the opportunities for health gain offered by self-care either in the dialysis facility itself or by carrying out more frequent haemodialysis/peritoneal dialysis treatment in the home.

Ensure clear arrangements are in place for continuity of care which requires identifying the nephrologist responsible for each patient's management. There are arrangements whereby all patients have access to a multi-professional renal team for regular review and for also for ad-hoc input into their care.

In some patients who have retained some of their natural renal function, twice weekly sessions may be possible for a period. Similarly less frequent dialysis is sometimes prescribed as part of a package of palliative care. These variations are determined by the nephrologist and they should be fully discussed with the patient and their carer and the reasons clearly recorded in the patient's record.

A number of haemodialysis patients cannot maintain adequate fluid and blood pressure control on the normal dialysis prescription of thrice weekly sessions, often because of co-existing cardiac dysfunction. Higher frequency haemodialysis can control this condition. Patients in whom a greater frequency of treatment than three times a week is clinically indicated would normally be considering home haemodialysis.

For those patients where this is impractical the provider must be able to accommodate requests from consultants for frequent haemodialysis in either an MRU or satellite facility.

The provider shall ensure that it adheres to all national policies and guidelines relating to infection control and decontamination. The provider will take all steps required to reduce the risk of the spread of any infections to patients. This will include the provision of information to patients and carers regarding infection control processes.

The provider will have in place a protocol for ensuring vaccination against hepatitis B virus, delivered in primary care.

The provider will ensure that all patients in MRUs, and satellite units, should be included in the clinical governance (CG) processes of the MRU. By embedding CG within day to day operations there should be a commitment to monitoring clinical quality and outcomes. Delivery of care must be safe, timely, effective, efficient, equitable, patient centred and sustainable.

As ICHD is only one component in the continuum of the renal patient pathway. The monthly MDT review should review the on-going suitability of this dialysis modality. This is the appropriate place to update care plans. In particular, the opportunities for health gain offered by self-care either in the dialysis facility itself or by carrying out more frequent haemodialysis/peritoneal dialysis treatment in the home.

The Monthly MDT review will review suitability for transplant listing for all patients not on the transplant list and the suitability for patients so listed to remain on the waiting list.

Staffing structure:

The provider will ensure that the haemodialysis station-capacity and staffing is sufficient to enable patients to access haemodialysis as frequently as clinically prescribed and with sufficient flexibility of timings to allow patients minimal interruption to their work and family commitments.

The provider will ensure that the nurse staffing levels in haemodialysis units are adequate to manage the delivery of care. That the level of nurse staffing in all renal units is adjusted for the dependency of the patient group and in main renal units has capacity to treat with haemodialysis those patients (who usually dialysis in satellite units) during periods of in-patient care.

Providers of ICHD should have clear referral pathways for vascular surgery and interventional radiology in order to establish new fistulae and for fistula salvage and maintenance. Where tunnelled venous catheters (TVCs) are the only option (or the patient's choice) then providers must have strategies and protocols in place to minimise the risk and manage the complications of this type of vascular access, including infection and traumatic damage of blood vessels. These pathways should include pathways for urgent interventions.

In patient care for ICHD patients

Providers shall ensure that haemodialysis patients are managed in a safe environment when hospitalised. There should be 24/7 and urgent on-site cover available from

vascular surgeons, interventional radiologists, nephrologists and acute dialysis team. Patients should not be transported to another hospital for their regular maintenance dialysis or for 'acute' dialysis during a period of hospitalisation unless under exceptional circumstances, such as admission is for another treatment by another specialised service that is not co-located within a hospital with a renal unit.

The provider will ensure that clear protocols are in place for the urgent transfer of patients for in-patient care in the event of intercurrent medical emergencies. In the case of satellite units these include 'blue-light' transfer to the nearest A&E department, or urgent transfer to the MRU. Receiving departments must be fully appraised of and in agreement with the protocols.

Adolescent transition

Specialist support, that is patient centred and enables patient choice, will be provided for young adults (age 18-25). This will include those who are in the process of transferring from paediatrics, those who have transferred from paediatrics or those who have come straight into adult services at a young age. Transition will involve a period of joint care from paediatric and adult services and it is important for multi-disciplinary teams (MDTs) to be aware that this group may have additional developmental needs, including educational and employment.

Withdrawal of dialysis treatment

For those patients who wish to withdraw from treatment the provider will ensure that they will receive coordinated support and care in accordance with the best principles of end-of-life management.

The Multi-Professional Renal Team

End stage renal failure is often a devastating life changing event which impacts on physical and mental health, employment and on relationships. Care of the dialysis patient entails far more than simply the execution of the dialytic process by specialised haemodialysis nursing staff. The following inputs are required.

Nutrition and dietetic services

The provider will provide access to a dietetic service for patients. Patients will be seen by the dietician as required. In addition, patients will have access to telephone advice and literature as clinically required.

The provider will ensure services are in situ which allow an average provision for renal dietetic assessment on a quarterly basis in patients with unstable diet related electrolytes, or a consistent trend in flesh weight change. The frequency of monitoring may need to increase to monthly in a proportion of patients who have a very poor appetite and a significant weight loss. Those stable on dialysis (stable weight and stable diet related electrolytes) may only need 6 monthly reviews. The prioritisation and frequency of review to be decided by the patient's renal dietician.

Providers will supply patients during a ICHD session with a drink and an appropriate snack directed by dietetic advice.

Pharmacy services

The provider will ensure that medications required during ICHD are prescribed and dispensed. This will include intra-venous fluids and medications as well as anticoagulants.

The provider will prescribe and dispense erythrocyte stimulating agents (ESAs) and cinacalcet.

Pharmacy advice, support and stock drugs will be provided via an agreement between providers if appropriate.

Medicines management

The provider is expected to have in place a medicines management procedure.

The provider shall comply with the higher standards of (i) National Minimum Standards and (ii) the highest available Clinical Negligence Scheme for Trusts (CNST) Standard in relation to medicines management as updated from time to time. Patients should receive a regular scheduled formal medicines management review and this should be done routinely whenever a patient changes clinical locations for their care.

In line with national guidance, intravenous iron will be delivered in an environment with access to medical equipment that is able to deal with potential side effects and proportionate to the risk of such side effects.

Social work support

The provider will offer patients access to social work advice as required.

Patients receiving dialysis have complex medical, emotional and social needs. Access to a broad range of professionals is essential for delivering renal replacement dialysis therapy. The provider shall have sufficient clinical and support staff to ensure a multi-disciplinary approach to provision of services in respect of, and at all times in accordance with, good clinical practice.

Psychology services

The provider will offer patients access to psychology services as required. Applied psychologists include clinical psychologists, counselling psychologists and health psychologists. Psychologists offer evidence based psychological assessment and intervention for patients, their carers and families as well as clinical supervision for direct care staff, training on aspects of psychological care, input to service development and clinical governance and consultation as well as conducting research, audit and service evaluations

Recommended staffing levels for the above groups (Nursing, Dietetics, Pharmacy, Social Work, Psychology) have been declared by The British Renal Society

Patient Support Groups

The provider will ensure that patients and carers are provided with information about local and national support groups and how to access them, including such groups' involvement in patient education sessions organised by the provider as it is recognised that these are a vital source of peer support, advice and information for patients. Signposting information will be displayed within the provider's facilities.

Transport, Travel and Waiting Times

The provider should have robust and responsive relationships with the Patient Transport Service, ambulance service and local taxi firms.

The provider will ensure in conjunction with the transport provider compliance with Renal Association recommendations on patient travel time subject to geographical location. The provider should seek to provide haemodialysis services as close to the patients' home as possible.

After arrival at the unit the time of treatment initiation should be within the timeframe of that recommended in the Renal Association guidelines.

Self-transporting ICHD patients **should not be charged** for parking and any such charges will be reimbursed to the patient.

Dialysis Away From Base (DAFB)

The provider will facilitate arrangements for patients who wish to, or need to travel on a temporary basis, to other parts of the UK and those wishing to travel outside the UK in accordance with national agreements on the management of dialysis away from base. **National policy is currently being developed.**

Training to become self-supervised on mobile haemodialysis machines should be offered so that patients can travel freely in the UK, Europe and overseas.

End of Life Care: Withdrawal from Dialysis

For those patients who express a desire to withdraw from treatment, the provider must have clear protocols for the management of the situation which will involve liaison with a palliative care team experienced in the management of withdrawal.

Liaison with primary care services is also essential.

Withdrawal from dialysis may form part of an agreed palliative care treatment plan developed jointly between the clinician, the patient and their carers.

Information System (IT)

The provider will utilise information systems which both meet the requirement to submit data to the UK Renal Registry of the Renal Association and UK Transplant (UKT) for comparative audit purposes, and the additional information requirements outlined in the Renal National Service Framework and any other local requirements set out by the commissioner of the service. Clinical audit information should be made available to patients in an accessible format.

Where the provider operates multiple units, they will ensure that the same information system is installed with real time data transfer. Failing this, the provider will ensure that the systems employed interface with the provider's main clinical and management systems (including PAS), seamlessly, fully and without delay. The provider's renal information system for best should access to patient letters, discharge summaries and details of inter-current events taking place.

The electronic record in the renal information systems may include:

- Records of individual haemodialysis treatment including treatment time and clinical observations (blood pressure, temperature etc.);
- Haemodialysis orders;
- Drug prescriptions;
- Pathology results;
- Major events; and
- Record of nursing care;
- Renal Patient View.

3.3 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 GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England

3.4 Any acceptance and exclusion criteria and thresholds

ICHD should be offered to any patient reaching or presenting with established renal failure if it is deemed by the clinician in charge that the patient will benefit from treatment.

This specification refers to adults over the age of 18 years. Some young people aged less than 18 years may be best treated in an adult service, by mutual consent.

Satellite units, whether NHS or independent sector should have the same acceptance criteria as the MRU. Exclusions should not be on the basis of age (advancing age or adolescence), co-morbidity, frailty or type of vascular access.

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)

3.5 Interdependencies with other services/providers

Medical cover for emergencies

Pathology

Surgical and Intervention radiology procedures

Acute Admissions Wards

Accident and Emergency

Intensive Care

Psycho-social support

Pharmacy services

Vascular access

Nutrition and dietetic services

Anaemia management

Hepatitis B vaccination

Social care & work advice, including that relating to benefits

Related Services

General Practitioners and community services

General Practitioners with Special Interests

Secondary provider clinicians and specialist nurses

Specialist transplant providers

Patient transport services

Medical Physics renal technical teams

NHS estates staff

Environmental waste service

Many people with CKD also have other medical conditions, particularly diabetes, depression and cardiac conditions. It is therefore essential that strong clinical linkages are made with other services, preferably with care provided from a multi-disciplinary team setting.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

The provider is expected to comply with the legislative provisions of renal replacement therapy and the Care Standards Act (2000), and to provide services in accordance with regulations as defined by, but not limited to, the following authorities and organisations which may change over time:

3.1 Regulatory bodies and legislation

Care Quality Commission and any successor organisations; and

All applicable law on Health and Safety at work

Anti-discrimination and equal opportunities legislation

General Medical Council

3.2 Professional bodies with an interest and national guidance

Renal Association Clinical Practice Guideline for Haemodialysis 2010

UK Renal Registry

British Renal Society

British Transplantation Society including all relevant clinical practice guidelines

National and local health service bodies and relevant local government authorities

Strategic Clinical Networks

NICE guideline Anaemia management in people with chronic kidney disease 2011.

NHS Employment Check Standards

CNST General Clinical Risk management standard appropriate to the service being delivered;

National Service Framework for Renal Services

Royal College of Physicians Clinical Standards for Renal Services

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

6. Location of Provider Premises

The Provider's Premises are located at:

Appendix 1

Quality standards specific to the service using the following template

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
To reduce the incidence of MRSA and MSSA bacteraemia related to vascular access	No more than one bacteraemia per 25 patient years of receiving treatment	Number of bacteraemia per 100 patient years receiving treatment. Annual audit.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 2: Enhancing the quality of life of people with long-term conditions			
Monthly MDT review to assess on-going suitability of ICHD for the patients. To include a review of suitability for transplant listing. To increase the number of patients accessing	Benchmark followed by action plans for improvements if proportion of patients active on the transplant list/receiving home dialysis is in lower quartile of national performance	% of patients active on the transplant list as a % of all ICHD patients. Numbers of patients who change to home dialysis. Annual audit	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
transplant and home dialysis.			
Domain 3: Helping people to recover from episodes of ill-health or following injury			
To ensure patients are informed and involved in their care.	Benchmark followed by action plans for improvement.	<p>% of patients who are able to undertake a minimum of 5 tasks related to their haemodialysis treatment independently.</p> <p>Annual Audit.</p>	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 4: Ensuring that people have a positive experience of care			
To ensure informed patient choice and to be involved in shared decision making	Benchmark to be followed by evidence of improvement.	<p>Annual Audit: Patients and carers survey on quality of service together with satisfaction with choice of RRT and patient reported health related quality of life.</p> <p>2. Number and % of patients with access and instruction in the use of Renal Patient View.</p>	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
		3. Number and % of patients utilising shared decision making aids/actively involved in shared decision making.	
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
To increase the number of patients receiving ICHD with permanent access.	85%	% of patients with a fistula/graft of all haemodialysis patients. Annual audit.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan

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 be fundamental to all services.

- The generic aspects of care:
The Care of Children in Hospital (Health Service Circular (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 (DOH) & 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 – DOH

Imaging

- All services will be supported by a 3 tier imaging network ('Delivering quality imaging services for children' DOH 13732 March2010). 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 (CPD)
 - 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.¹ 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) training² and should maintain the competencies so acquired³ *. 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**

1. Guidelines on the Provision of Anaesthetic Services (GPAS) Paediatric anaesthetic services. Royal College of Anaesthetists (RCOA) 2010 www.rcoa.ac.uk
2. Certificate of Completion of Training (CCT) in Anaesthesia 2010
3. 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. 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*, 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)
Care Quality Commission, London 2010

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 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:
 - Ensures the medicines given are appropriate and person-centred by taking account of their age, weight and any learning disability
 - ensuring that staff handling medicines have the competency and skills needed for children and young people's medicines management
 - Ensures 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 Publications, 2006, London

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	A06/S/b
Service	Haemodialysis to treat established renal failure performed in a patients home
Commissioner Lead	
Provider Lead	<i>The name of the individual leading on the service for the provider</i>
Period	<i>12 months</i>
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

End stage renal failure (ESRF) also known as established renal failure (ERF), is an irreversible, long-term condition as a result of chronic kidney disease for which regular dialysis treatment or transplantation is required if the individual is to survive. If the kidneys fail, the body is unable to excrete certain waste products, excess water, acid and salts resulting in increasing symptoms and eventually death. When ESRF is reached, renal replacement therapy (RRT), in the form of dialysis or transplantation, is required or the person will die within weeks or months.

In 2011, 108 patients per million (ppm) population in the UK started renal replacement therapy (RRT) for established renal failure but the UK Renal Registry showed significant variation in the crude acceptance rate in England from 50 to 226 ppm. Some of this variation is explained by ethnicity and socioeconomic deprivation both of which influence the prevalence of kidney disease. The purpose of a RRT service is to offer people approaching end stage renal failure a choice of treatment modalities depending on their individual health and circumstances, delivered close to or in the home, providing education and support to achieve the best possible quality of life. Preparation and choice for this patient group are central principles that underpin the RRT service.

The number of patients receiving home HD (in UK) increased by 23% from 736 patients in 2010 to 905 patients in 2011. The prevalent rate of patients receiving RRT in England in 2011 was 843 pmp. (UK Renal Registry)

There is good evidence that home dialysis therapies (both peritoneal and haemodialysis) offer advantages for suitable patients. The limitations of thrice weekly standard in-centre haemodialysis have been recognised in recent years, in particular, the increased risk of hospitalisation or death after the 'two-day break' (Foley R. N Engl J Med 2011; 365). Although it is very difficult to separate the effect of different case mix the most up to date and comprehensive data does not show a survival difference between patients who received more frequent versus thrice weekly (standard regimen) haemodialysis (Kid Int 2011, 80(10): 1080-91). The advantage of self-care haemodialysis includes not only those related to control and convenience but also the opportunity to conduct more frequent or longer sessions to optimise health prospects. Improvements in the cardiovascular risk profile of patients on 'daily' treatment have been demonstrated (Frequent Haemodialysis Network, NEJM, Nov 2010). The introduction of smaller more portable haemodialysis machines also provides opportunity for travel for employment or holidays. Furthermore, these therapies are cost effective in the UK when compared with hospital treatments and have been demonstrated to be safe.

The National Institute of Care Excellence (NICE) technology guideline No 48 (2002) stated that "making the assumption that 10 to 15% of dialysis patients, given the choice, would opt for home haemodialysis, expansion of the services to support home haemodialysis will be required". Approximately 4% of those patients treated by haemodialysis receive that treatment at home. This is equivalent to a prevalence rate of approximately 14 per million population in England.

In 2011 the percentage of dialysis patients receiving home haemodialysis in England varied from 0% in 6 centres, to greater than 5% in 10 centres in England with one centre achieving 11.5% (UK Renal Registry)

The principle should be that home haemodialysis should always be an option for patients and that solutions should be sought to overcoming barriers that might prevent this.

Decisions should be made on an individual basis but in general, patients suitable for home haemodialysis will be those who - (NICE Technology Appraisal guidance No 48, Sept 2002):

- have the ability and motivation to learn to carry out the process and the commitment to maintain treatment
- are stable on dialysis
- are free of complications and significant concomitant disease that would render home haemodialysis unsuitable or unsafe
- have good functioning vascular access
- have a carer who has (or carers who have) also made an informed decision to assist with the haemodialysis unless the individual is able to manage on his or her own
- have suitable space and facilities or an area that could be adapted within their home environment.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

The following are expected outcomes of the home haemodialysis service:-

Patients (domains 2 & 4)

Patients are able to make an informed choice and shared decision making about treatment options, including home haemodialysis.

Education given to patients is evidence based and timely outlining benefits and disadvantages.

Patients currently accessing dialysis therapies are assessed and informed of treatment options annually.

Education and training programmes are against time frames and supported by competencies.

Evidence of flexible dialysis treatments – overnight etc.

Clear consistent national guidelines for the capital costs of home adaption, remote tele-monitoring and on- going funding for electricity, water and telephone costs due to dialysis treatment need to be put in place to ensure equity.

Patients and their carers are able to give formal annual feedback on the quality of the service **Patient reported outcome and experience measures should be prioritised, and should be the principle barometer of success. Improved quality of life and experience for both patients and carers should be sought.**

Specialist Renal Unit (domains 2 4 & 5)

An agreed eligibility criteria.

An educated workforce to support training for home haemodialysis (HHD) and self-care competencies.

A clinical champion to promote HHD and set targets for improvement.

Home therapies education and preparation to be appropriately timed; early discussions are essential as well as revisiting options.

A self-care area within main centre and/or satellite units.

An audit programme.

Technical support.

Home adaptation policy.

Electrical and water and telephone funding support.

An accelerated pathway option to accommodate non-planned starters.

Review of home therapies option with patients established on hospital or satellite centre haemodialysis during regular clinical reviews in outpatients or on the dialysis unit.

Capacity to accommodate home therapies.

Capacity for home visits and review of home circumstances.

High quality education to be delivered according to best practice.

Patient to have a named nurse/contact for queries.

Patients to have the opportunity to revisit education at regular intervals or have further education if necessary.

For all home therapies options relevant support services need to be involved at an early stage.

Culture (domains 2 3 4 &5)

A culture of shared-care for haemodialysis treatment.

A culture to provide home haemodialysis to all patients who choose this option when it is clinically appropriate, practical and cost-effective.

A culture of shared decision making is to be promoted

Home therapies are to be included in the training of all renal clinical professions

Create culture of environmental sustainability in kidney care – raising awareness amongst staff and patients.

3. Scope

3.1 Aims and objectives of service

The aims of this service are:

- to improve the wellbeing and quality of life for patients receiving renal replacement therapy.
- to provide home haemodialysis to all patients who choose this option when it is clinically appropriate, practical and cost-effective.

The objectives of this service are:

- to provide an emphasis on patients being involved in their own care as much as possible.
- to achieve equity in patient access to all treatment modalities acknowledging the limitations listed above.
- to seek solutions to overcoming barriers that might prevent treatment choice.
- to ensure that information and training for home haemodialysis are given in a timely manner.
- to make home dialysis services responsive to patient and carer's feedback.
- to maximise the value gained from NHS resources.
- to introduce new technologies and service innovations in a timely way including remote monitoring when supported by appropriate funding.
- to audit the quality of the service, including patient and carer feedback, on a regular basis.

3.2 Service description/care pathway

The provider will manage referrals in line with any relevant national or local guidelines or recommendations, and in accordance with the agreed response times. All patients will be managed by a multi professional team. Shared decision making principles and access to tools will be part of the standard operating policy.

The model of a Consultant with a particular focus on a group of patients treated by home haemodialysis, who are reviewed both in an out-patient environment with access to in-patient care and monitoring via a multi-disciplinary team (MDT) will be common to all units. The number of staff required and the detail of the frequency of clinics and MDT meetings will be determined by the scale of each service.

The provider will either provide home haemodialysis services or will arrange onward referral to another unit that offers:

- Assessment of suitability for home haemodialysis including a risk assessment and decision by the MDT on a patient's suitability to dialyse at home alone.
- Capacity to offer timely training for home haemodialysis
- Expertise and capacity to assess suitability of home for dialysis instillation.
- Capacity to carry out adaptations to patient's home.
- Surgical and interventional radiology procedures related to the establishment and maintenance of dialysis including procedures for establishing new fistulae, fistula salvage and peritoneal access.
- MDT review typically at monthly intervals for stable patients
- As home haemodialysis is only one component in the continuum of the renal patient pathway, the monthly MDT review should review the on-going suitability of the dialysis modality. This is the appropriate place to update care plans. The monthly MDT review will review suitability for transplant listing for all patients not on the transplant list and the suitability for patients so listed to remain on the waiting list.
- Medical cover for emergencies.
- Ongoing assessment and support in the home by a member of the multidisciplinary team.
- Technical support provided before the next dialysis is scheduled when problems are encountered.
- The ability to accommodate patients for respite care when home support is interrupted or through loss of confidence or the need for additional training.

Other services including:

- Patient /carer information
- Psycho-social support
- Nutrition and dietetic services
- Anaemia management, including intravenous iron (self-administered and provided at home). In line with national guidance, intravenous iron will be delivered in an environment with access to medical equipment that is able to deal with potential side effects and proportionate to the risk of such side effects.

- Blood transfusion and erythropoietin stimulating agents (ESAs) prescribing.
- Access to Renal Patient View (RPV). For those who register with RPV they will be encouraged to advise their GP.
- Hepatitis B immunisation in primary care.

Goals

The service provided should be seamless and enable patients to make informed choices about the care they receive.

Full choice of home therapies offered where clinically appropriate.

Facilitate shared decision-making, offering genuine choice for all treatment options.

Initiation of Treatment

Confirmation of modality decision:

HHD should be initiated in a controlled manner with the patient having received appropriate education and support. The decision to commence HHD should be based upon a holistic assessment of the patient, including physical signs and symptoms and competency-based education and should be made by a multi-disciplinary team.

Home Assessments and Adaptations:

Every potential home haemodialysis patient is required to have a home assessment. This is to determine the suitability of the patient's home to accommodate the requirements of home haemodialysis including physical space, plumbing and electricity, and should be a joint decision made between the patient and the healthcare team. Tariff payment for home haemodialysis will need to cover the cost of home conversion, remote tele-monitoring where appropriate and decommissioning when no longer required.

Preferred options in priority order are:

- Use of the tray system.
- Adaption of an existing spare room or other suitable space within the patients home.
- Where the above are not practical, then consideration may in exceptional circumstances be given to building adaptations.
- Training on a mobile machine may be considered.
- Adaptations such as conservatories or large extensions should be funded only in exceptional circumstances.

- A close working relationship with estates departments or a local electrician/ plumber at the provider Trusts must be developed to ensure that the most cost effective option is identified.
- Funding for the home adaptations is limited to allow installation of equipment only and for the removal of installed equipment and plumbing services when no longer required.
- Reimbursement should be provided for the excess costs of electricity and water to run the dialysis machine and excess costs for heating and telephone. These should be estimated and agreed between provider and individual patient.
- In some circumstance it may be helpful for clarity if the patient and the renal centre have a written agreement making clear the specific responsibilities and obligations of each party in regard to the installation and removal of equipment.

3.3 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 GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

3.4 Any acceptance and exclusion criteria and thresholds

This specification refers to adults over the age of 18 years. Some young people aged less than 18 years may be best treated in an adult service, by mutual consent. All patients with end-stage kidney disease should be considered for home haemodialysis.

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)

There are no absolute exclusion criteria for assessment except as implied by the NICE Guidance eligibility criteria.

3.5 Interdependencies with other services/providers

Co-located services

Co-located at training site for home haemodialysis

Interdependent Services

Medical cover for emergencies
Support at home by the MDT
Pathology
Surgical and Intervention radiology procedures
Psycho-social support
Pharmacy services
Vascular access
Nutrition and dietetic services
Anaemia management
Hepatitis B vaccination
Technical support for machine breakdown/problems

Related Services

General Practitioners and community services
General Practitioners with Special Interests
Secondary provider clinicians and specialist nurses
Specialist transplant providers
Patient transport services
Medical Physics renal technical teams
NHS estates staff
Water Boards
Environmental waste service

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

A number of documents provide relevant information in relation to home dialysis therapies and should be read in conjunction with this paper.

‘Improving choice for HHD’ 3

‘Five steps toolkit’ 4

National Service Framework for Renal Services 6

‘Achieving excellence in Kidney Care’7

The National Institute for Health and Clinical Excellence (NICE) technical

guidance (TA48) - Home versus Hospital Haemodialysis 8

NICE guideline Anaemia management in people with chronic kidney disease 2011

'Your Health, Your Way: A guide to long term condition & self-care' 9

Renal Association Working Party reports on HHD10 and PD11

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

6. Location of Provider Premises

The Provider's Premises are located at:

Appendix 1

Quality standards specific to the service using the following template

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
For all suitable patients to have	Benchmark with action plans for	% of patients receiving home haemodialysis as a % of all	As per Standard NHS Contract

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
option of having home haemodialysis	improvement to follow if proportion of home haemodialysis patients is in lower quartile of national performance	dialysis patients. Annual audit.	General Conditions Clause 9 (GC9) Remedial Action Plan

Domain 2: Enhancing the quality of life of people with long-term conditions

To increase the number of patients accessing home haemodialysis.	Benchmark followed by action plans for improvements if proportion of home haemodialysis patients is in lower quartile of national performance	% of patients receiving home haemodialysis as a % of all dialysis RRT patients. Annual audit	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
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Domain 3: Helping people to recover from episodes of ill-health or following injury

To ensure patients are informed and involved in their	Benchmark followed by action plans for	% of patients who complete education/training programme including repeat	As per Standard NHS Contract General Conditions Clause
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Quality Requirement	Threshold	Method of Measurement	Consequence of breach
care.	improvement.	<p>sessions/further education.</p> <p>Evidence of outcomes from education sessions.</p> <p>Annual Audit.</p>	9 (GC9) Remedial Action Plan

Domain 4: Ensuring that people have a positive experience of care

To ensure informed patient choice and to be involved in shared decision making	Benchmark to be followed by evidence of improvement.	<p>Annual Audit:</p> <p>Patients and carers survey on quality of service together with satisfaction with choice of RRT and patient reported health related quality of life.</p> <p>2. Number and % of patients with access and instruction in the use of Renal Patient View.</p> <p>3. Number and % of patients utilising shared decision making aids/actively involved in shared decision making.</p>	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
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Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm

To have relevant MDT and services available to support and ensure the safety of the patient at home.	In place for all units with home haemodialysis patients	<p>Evidence of MDT and service available, including arrangements for 24/7 cover.</p> <p>Evidence of access to respite care, available at short notice</p>	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
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Quality Requirement	Threshold	Method of Measurement	Consequence of breach
		if necessary. Annual audit.	

DRAFT

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 be fundamental to all services.

- The generic aspects of care:
The Care of Children in Hospital (Health Service Circular (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 (DOH) & 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 – DOH

Imaging

- All services will be supported by a 3 tier imaging network ('Delivering quality imaging services for children' DOH 13732 March2010). 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 (CPD)
 - 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.¹ 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) training² and should maintain the competencies so acquired³ *.
- 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**

1. Guidelines on the Provision of Anaesthetic Services (GPAS) Paediatric anaesthetic services. Royal College of Anaesthetists (RCoA) 2010 www.rcoa.ac.uk
2. Certificate of Completion of Training (CCT) in Anaesthesia 2010
3. 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. 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*, 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 41 *Essential Standards of Quality and Safety*, Care Quality Commission, London 2010)

Care Quality Commission, London 2010

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 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:
 - Ensures the medicines given are appropriate and person-centred by taking account of their age, weight and any learning disability
 - ensuring that staff handling medicines have the competency and skills needed for children and young people's medicines management
 - Ensures 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 Publications, 2006, London

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SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	A06/S/C
Service	Peritoneal Dialysis to treat established renal failure
Commissioner Lead	
Provider Lead	<i>The name of the individual leading on the service for the provider</i>
Period	<i>12 months</i>
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

End stage renal failure (ESRF), also known as established renal failure (ERF), is an irreversible, long-term condition as a result of chronic kidney disease for which regular dialysis treatment or transplantation is required if the individual is to survive. If the kidneys fail, the body is unable to excrete certain waste products, excess water, acid and salts resulting in increasing symptoms and eventually death. When ESRF is reached, renal replacement therapy (RRT), in the form of dialysis or transplantation, is required or the person may die within weeks or months. In 2011, 108 patients per million (ppm) population in the UK started RRT for established renal failure but the UK Renal Registry showed significant variation in the crude acceptance rate in England from 50 to 226 ppm. Although some of this variation is explained by ethnicity and socioeconomic deprivation both of which influence the prevalence of kidney disease.

To perform peritoneal dialysis the patient is taught to introduce fluid into their peritoneal cavity through a flexible pipe that has been implanted under local or general anaesthetic. This fluid absorbs “toxins” and is then drained away and discarded to be replaced by fresh fluid.

Peritoneal dialysis (PD) is long established as a major option for renal replacement therapy in patients with end stage renal disease. It is an important part of an integrated service for renal replacement therapy that is frequently selected by patients as their

preferred initial mode of therapy, and is a therapeutic option for patients wishing or needing to swap from haemodialysis (HD) and after renal transplant failure. At the point of commencing renal replacement therapy the incident rate of patients receiving peritoneal dialysis is approximately 20 per million population (pmp) (per year) in England (2011). The prevalence rate of peritoneal dialysis was 62 pmp in England in 2011.

The strong presence of Peritoneal Dialysis (PD) in the UK has fallen in the last decade, (first modality PD reduced from 40% to 21%¹). National Institute for Health and Care Excellence (NICE) clinical guidance (CG) 125 notes published evidence supporting the use of PD as first modality, with a suggested uptake if used as first choice for patients with residual renal function or those without significant co-morbidity at 39%. There is wide variation around the country, both in the number of patients on PD, and the types of PD available. Up to 50% of patients, given free choice, will choose PD². Despite this the percentage of prevalent dialysis patients treated with PD at ninety days ranged from 0% to 27% in England in 2011¹. At the same time, a population that is increasingly elderly and frail may be restricted to a choice between hospital haemodialysis (HD) and conservative care, when assisted PD, (standard therapy in several countries^{3,4}, but currently in its infancy in the UK) might be more appropriate. There is also evidence that older people may find PD less intrusive with an improved quality of life in comparison to haemodialysis.⁵

¹ NEPHRON CLINICAL PRACTICE 123/S1/13, UK Renal Registry, 15th Annual Report of the Renal Association, UK Renal Registry 2012.

² Jager K J, Kosevaar J C, Dekker F W, Krediet R T, Boeschoten E W, NECOSAD Study Group. The effect of contraindications and patient preference on dialysis modality selection in ESRD patients in the Netherlands. *American Journal of Kidney Disease* 2004; **43**: 891-899

³ Oliver M J, Quinn R R, Richardson E P, Kiss A J, Lamping D L, Manns B J. Home care assistance and the utilisation of peritoneal dialysis. *Kidney International* 2007; **71**: 673-678

⁴ Couchoud C, Moranne O, Frimat L, Labeeuw M, Allot V, Stengel B. Associations between comorbidities, treatment choice and outcome in the elderly with end stage renal disease. *Nephrology Dialysis Transplantation* 2007; **22**: 3246-3254

⁵ Edwina A. Brown, Lina Johansson, Ken Farrington, Hugh Gallagher, Tom Sensky, Fabiana Gordon, Maria Da Silva-Gane, Nigel Beckett and Mary Hickson Broadening Options for Long Term Dialysis in the Elderly (BOLDE) 2010; *Nephrol Dial Transplant* 25: 3755–3763

Evidence base

The National service Framework (NSF) for Renal Services (Department of Health 2004/5)

Peritoneal Dialysis. NICE Clinical Guideline 125 (July 2011)

Peritoneal Dialysis in CKD. UK Renal Association Clinical Guidelines for Peritoneal Dialysis. UK Renal Association (July 2010)

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	√
Domain 2	Enhancing quality of life for people with long-term conditions	√
Domain 3	Helping people to recover from episodes of ill-health or following injury	√
Domain 4	Ensuring people have a positive experience of care	√
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	√

A peritoneal dialysis service aims to deliver the following:

- Patient reported outcome and experience measures should be prioritised, and should be the principle barometer of success. Improved quality of life and experience for both patients and carers should be sought (domain 2)
- Patient-centred and integrated care with equitable provision of service (domain 4)
- Timely delivery of care in the right place to improve clinical outcomes (domain 3)
- Improved life expectancy and the prevention of avoidable death from kidney disease (domain 1) in a harm-free environment (domain 5)
- The pursuit of innovation and value in care offered

A service should provide:

- Personalised care, sensitive to the physical, psychological and emotional needs of patients and their families/carers
- Equity of access and the promotion of patient choice
- Facilitated autonomy and independent care
- Where required facilitated transition to end of life care
- Effective communication and support

A service will:

- Contribute fully to the National Renal Dataset (<http://www.ic.nhs.uk/services/datasets/dataset-list/renal>)
- Submit fully to the UK Renal Registry
- Make Renal Patient View (RPV) available to those who wish to and are able to participate. For those who register with RPV they will be encouraged to advise

their GP.

Below are listed a number of potential key performance indicators

Area	National/Local Guidance	Quality Indicator	Measurable Output
Preparation	Renal National Service Framework (NSF)	Meet NSF Clinical Guideline	Percentage of patients known to service for 90 days starting dialysis with planned access
	Renal Association Clinical Guidelines	Patient satisfaction survey	Percentage of patients choosing PD
	NICE PD guideline	Ensure informed patient choice	All units to have education protocols in place
Catheter Insertion	Renal Association/ International Society for PD Guidelines	Meet Renal Association clinical guideline	Percentage of patients with functioning catheter at 6 weeks ¹
		Patient satisfaction survey	Exit site infection rate ²
Patient Training	Renal Association Clinical Guidelines	Timely first time treatment	80% of planned PD patients start on PD
		Adequate training sign-off by 6 weeks	Number of patients with training sign-off at 6 weeks ³
		Peritonitis free by 6 weeks	Number of patients peritonitis free at 6 weeks ⁴
Maintenance	Renal NSF	PD peritonitis rate	<1 episode peritonitis in 18 patient months ⁵
	Renal Association		

	Clinical Guidelines	PD technique failure rate	Number of patients failing PD ⁶
	British Renal Society Workforce Planning Report	Facility to provide Assisted PD	Number of patients on Assisted PD ⁷

¹ A functioning catheter is defined as functioning from the first day after successful training is completed

² An exit site infection is defined according to the 2010 ISPD Guidelines as a 'purulent drainage from the exit site'

³ Training is defined as complete on the day after training has been successfully completed. Sign-off at six weeks confirms a patient as competent as trained to perform PD

⁴ Defined as six weeks from the day after training is successfully completed

⁵ As defined according to 2010 ISPD Guidelines

⁶ Where technique survival is defined as the per patient time on PD in months, censored for death, transplantation, transfer out or recovery of renal function

⁷ Assisted PD is where a paid (usually but not inevitably) unrelated trained carer is necessary to sustain a patient on PD as their chosen modality (and where hospital haemodialysis would otherwise be required)

3. Scope

3.1 Aims and objectives of service

The aim of the service is to offer all patients for whom it is clinically appropriate access to all PD treatment modalities. To ensure optimal utilisation of PD as a therapy for end-stage renal disease; to set standards for quality of care and outcomes; to maintain availability of the full range of PD products and services and to achieve national consistency across England.

The primary objectives will be:

Education of patients both in the "pre-dialysis care" and all those established on renal replacement therapy about the option of peritoneal dialysis to manage established renal failure.

Timely achievement of peritoneal dialysis access.

Patient training that is flexible around patients' needs.

Maintenance of service with clinical support staff with appropriate expertise.

Facilitation of patient support by patients.

Regular review of patients receiving renal replacement therapy to assess need for change of peritoneal dialysis prescription or need for modality change to haemodialysis and assessment and work up for renal transplantation.

Management of the option of withdrawal from dialysis.

3.2 Service description/care pathway

Peritoneal dialysis will be delivered in the context of a comprehensive and integrated specialist service for renal replacement therapies, including haemodialysis (with temporary back up facilities), transplantation and conservative care. Continuous ambulatory peritoneal dialysis (CAPD), automated peritoneal dialysis (APD) and assisted PD will be available.

The model of a consultant with a particular interest in peritoneal dialysis, supported by other specialists (defined as a competent middle-grade nephrologist with greater than 4 years' experience or a consultant) with nursing and other staff with primary focus on this group of patients, who are reviewed both in an out-patient environment with access to in patient care and monitoring via a multi-disciplinary team (MDT) will be common to all units.

Patients will approach peritoneal dialysis (PD) by various routes, including planned from Renal Clinic, from other parts of the Renal Unit or hospital, from primary care or as an unplanned presentation. Adequate preparation in an accessible setting, shared decision making and education is essential in each scenario, and all Renal units to have on-going analysis of their patient flow onto dialysis.

Specialist support, that is patient centred and enables patient choice, will be provided for young adults (age 18-25). This will include those who are in the process of transferring from paediatrics, those who have transferred from paediatrics or those who have come straight into adult services at a young age. Transition will involve a period of joint care from paediatric and adult services and it is important for multi-disciplinary teams (MDTs) to be aware that this group may have additional developmental needs, including educational and employment.

Structure

Dialysis preparation provided within an integrated specialised renal service, meeting the National Service Framework (NSF) target of education at least one year pre-dialysis, and ensure unbiased access to all treatment modalities.

Dedicated competent PD training team as part of an integrated PD service of a size adequate to the PD population, ideally in proximity to pre-dialysis, home haemodialysis and PD maintenance teams.

Patient training designed to provide well-educated patients who are able to care for themselves, trained in techniques to help reduce infection and prevent other PD related complications

Infrastructure able to offer all PD modalities (CAPD, APD, assisted APD).

A tailored pathway option to accommodate non-planned starters.

Capacity for home visits and review of home circumstances.

Ability to offer peer support by a patient buddy system.

Services will be sensitive to the needs of those from all cultures, and appropriate advocacy and translation made available.

Anaemia management, including intravenous iron therapy. In line with national guidance, intravenous iron will be delivered in an environment with access to medical equipment that is able to deal with potential side effects and proportionate to the risk of such side effects.

Blood transfusion and prescribing erythropoietin stimulating agents (ESAs).

People

PD to have a senior clinical champion.

PD clinicians (nursing, community PD staff, medical and allied health professionals) to work within an MDT to deliver co-ordinated best care.

Training for clinicians with an interest in PD against a specified training programme for trainees to gain the required skills to enable safe practice of PD.

Access to prompt surgical or radiological intervention for PD problems including need for catheter change, reposition and removal as necessary for access malfunction and infectious complications.

Defined links with Microbiology for management of infectious complications and development/modification of local protocols for preventing/managing PD-related infection.

Clinical/counselling psychologist and/or counsellor to be available on a case-by-case basis on referral from the MDT, or on request.

Training to be offered to patient, family, paid and unpaid carers.

Primary care to be informed in the planning process and involved where necessary.

Recognition of the unique needs of young people on renal replacement therapy might include peer support groups and/or counselling.

Technology

IT support, literature, websites and decision aids to reach a consistent standard for content when compared to peer providers. Renal Patient View to be offered to all patients.

Catheters, connectology and dialysis fluids chosen according to clinical need and value. There should be access to cycling machines where clinically indicated, and a minimum standard of ancillaries to be agreed,

Process

Confirm modality decision early to timely insertion of PD catheter^{7, 10} Catheter insertion to be available in appropriate settings, including operating theatre, radiology departments and clean areas on renal wards. Routine catheter insertion to be performed within two weeks and for an urgent catheter insertion within 24 hours. Catheter insertion should wherever possible be timed to avoid the need for temporary central venous access and haemodialysis.

Training to include training in CAPD, APD, assisted APD, post-infection technique reviews and retraining where required. Training to be tailored to all appropriate patient needs and delivered in hospital or at home where practicable.

Each patient to have a named carer or team, and an individual care plan – shared and available to all areas, including ward staff.

Out-patient care and monitoring should meet the RA guidelines⁹. To include regular review of markers of technique success and survival, regular clinical and nursing review.

Clinics to be available in centre or closer to home, with flexible times to suit working patients and access to the full MDT.

As peritoneal dialysis is only one component in the continuum of the renal patient pathway. The monthly MDT review should review the on-going suitability of this dialysis modality. This is the appropriate place to update care plans. The Monthly MDT review will review suitability for transplant listing for all patients not on the transplant list and the suitability for patients so listed to remain on the waiting list.

Assisted PD to be readily available to a patient choosing PD whose inability to perform the technique would otherwise require hospital haemodialysis. This to include access to paid carers (including family members) who are supported and regularly trained. Close liaison with local health agencies, hospices, primary care, social workers will be required. Regular review will also be required, as the required level of assistance may change.

Advance care planning to include recognition of changes in the patient and the suitability of PD as a modality. This will include increased social support, planned transfer to assisted APD or HD; planned end of life care, if necessary.

Dialysis away from home offered in line with a transparent local Unit policy pending the

completion of national guidance. Where possible, this should include supply to the patient's holiday destination within the UK. Allocation will vary on a patient to patient basis^{7, 13, 14}. Costings, which are agreed between renal unit and supplier, to be transparent.

Adequate 24/7 arrangements should be in place, with a standard service being available from 9am – 5pm Monday to Friday, and out of hours care available from appropriately trained clinical staff.

Prescribing should occur through use of the national formulary, or where no national guidance exists, the locally agreed formulary (including the 'traffic light' arrangement in respect of amber/red drugs) should be recognised.

National Specialist Surgery for Encapsulating Peritoneal Sclerosis

EPS is a rare but well-recognised complication of PD that occasionally requires specialist surgical management. Patients with suspected EPS should be considered for referral to specialist centres in Manchester and Cambridge. This should occur in a timely and co-ordinated fashion against agreed protocols

3.3 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 GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

Dialysis services form part of the NHS Commissioning Board's portfolio of described services and as such are directly commissioned through named local area teams. They would generally serve populations greater than 500,000.

3.4 Any acceptance and exclusion criteria and thresholds

This specification refers to adults over the age of 18 years. Some young people aged less than 18 years may also be best treated in an adult service, by mutual consent. All patients with end-stage kidney disease should be considered for PD. **Special arrangements will be required for young adults (age 18-25 years) to ensure their smooth transition from paediatric services or deal with the additional care needs, including employment and education, for patients newly presenting at this age. Additional support will be patient centred and enable patient choice.**

Reason for ineligibility should be recorded; this will include patient choice. Prior extensive lower abdominal surgery and morbid obesity, may also represent contraindications to this treatment. Where inappropriate housing is thought to preclude PD, the Renal Unit should consider liaison with the local authority/housing association to

encourage re-housing.

When treating children, the service will additionally follow the standards and criteria outlined in the Specification for Children's services (attached as Annex A to this specification)

3.5 Interdependencies with other services/providers

Co-located services

Co-located at training site for PD

Interdependent Services

Medical cover for emergencies

Pathology

Surgical and Intervention radiology procedures

Psycho-social support

Pharmacy services

Vascular access

Nutrition and dietetic services

Anaemia management

Hepatitis B vaccination

Social care & work advice, including that relating to benefits

Related Services

General Practitioners and community services

General Practitioners with Special Interests

Secondary provider clinicians and specialist nurses

Specialist transplant provider's

Patient transport services

Medical Physics renal technical teams

NHS estates staff

Environmental waste service

Many people with CKD also have other medical conditions, particularly diabetes, depression and cardiac conditions. It is therefore essential that strong clinical linkages are made with other services, preferably with care provided from a multi-disciplinary team setting.

The provider will work directly with, but not limited to, the following professionals to ensure a seamless service:

General Practitioners and community services
General Practitioners with Special Interest
Secondary provider clinicians and specialist nurses
Specialist transplant providers
Patient Transport Services

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

The provider is expected to comply with the legislative provisions of renal replacement therapy and the Care Standards Act (2000), and to provide services in accordance with regulations as defined by, but not limited to, the following authorities and organisations which may change over time:

Regulatory bodies and legislation

Care Quality Commission and any successor organisations; and

All applicable law on Health and Safety at work

Anti-discrimination and equal opportunities legislation

General Medical Council

Professional bodies with an interest and national guidance

Renal Association Clinical Practice Guideline for Peritoneal Dialysis 2011

Renal Association Clinical Practice Guideline for Peritoneal access January 2009

UK Renal Registry

British Renal Society

British Transplantation Society including all relevant clinical practice guidelines

National and local health service bodies and relevant local government authorities

Strategic Clinical Networks

NICE guideline: Peritoneal Dialysis. July 2011

NICE guideline Anaemia management in people with chronic kidney disease 2011.

NHS Employment Check Standards

CNST General Clinical Risk management standard appropriate to the service being delivered;

National Service Framework for Renal Services

Royal College of Physicians Clinical Standards for Renal Services

NICE guidance

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

6. Location of Provider Premises

The Provider's Premises are located at:

Appendix 1

Quality standards specific to the service using the following template

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
For all suitable patients to have option of having peritoneal dialysis	Benchmark followed by actions plans for improvement if proportion of peritoneal dialysis patients is in lower quartile of national performance	% of patients receiving peritoneal dialysis as a % of all dialysis patients. Annual audit.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 2: Enhancing the quality of life of people with long-term conditions			
To increase the number of patients accessing peritoneal dialysis.	Benchmark followed by actions plans for improvement if proportion of peritoneal dialysis patients is in lower quartile of national performance	% of patients receiving peritoneal dialysis as a % of all dialysis RRT patients Annual audit	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Access to assisted peritoneal dialysis	Benchmark followed by action plans for improvement if	% of assisted peritoneal patients as a % of all peritoneal patients.	

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
	proportion is in lower quartile of national performance	Annual audit	
Domain 3: Helping people to recover from episodes of ill-health or following injury			
To ensure patients are informed and involved in their care.	Benchmark followed by action plans for improvement.	<p>% of patients who complete education/training programme including repeat sessions/further education.</p> <p>Proportion of patients with training sign-off at 6 weeks.</p> <p>Annual Audit.</p>	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 4: Ensuring that people have a positive experience of care			
To ensure informed patient choice and to be involved in shared decision making	<p>Benchmark to be followed by evidence of improvement.</p> <p>80% of planned PD patients to start on PD.</p>	<p>Annual Audit:</p> <ol style="list-style-type: none"> 1. Patients and carers survey on quality of service together with satisfaction with choice of RRT and patient reported health related quality of life. 2. Number and % of patients with access and instruction in the use of Renal Patient View. 3. Number and % of patients utilising shared decision making aids/actively involved 	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
		<p>in shared decision making.</p> <p>4. evidence of education protocols within unit.</p>	
<p>Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm</p>			
<p>To have relevant MDT and services available to support and ensure the safety of the patient.</p>	<p><1 episode of peritonitis in 18 patient months of treatment.</p>	<p>Evidence of MDT and service available, including arrangements for 24/7 cover.</p> <p>% of patients with functioning catheter at 6 weeks.</p> <p>% of patients peritonitis free at 6 weeks.</p> <p>Number of peritonitis episodes.</p> <p>Exit site infection rate</p> <p>Annual audit.</p>	<p>As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan</p>

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 be fundamental to all services.

- The generic aspects of care:
The Care of Children in Hospital (Health Service Circular (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 (DOH) & 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 – DOH

Imaging

- All services will be supported by a 3 tier imaging network ('Delivering quality imaging services for children' DOH 13732 March2010). 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 (CPD)
 - 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.¹ 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) training² and should maintain the competencies so acquired³ * . 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**

1. Guidelines on the Provision of Anaesthetic Services (GPAS) Paediatric anaesthetic services. Royal College of Anaesthetists (RCOA) 2010 www.rcoa.ac.uk
2. Certificate of Completion of Training (CCT) in Anaesthesia 2010
3. 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. 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*, 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)
Care Quality Commission, London 2010

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 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:

- Ensures the medicines given are appropriate and person-centred by taking account of their age, weight and any learning disability
- ensuring that staff handling medicines have the competency and skills needed for children and young people's medicines management
- Ensures 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 Publications, 2006, London

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SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	A06/S/e
Service	Assessment and Preparation for Renal Replacement Therapy (including establishing dialysis access)
Commissioner Lead	
Provider Lead	<i>The name of the individual leading on the service for the provider</i>
Period	<i>12 months</i>
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

End stage renal failure (ESRF), also known as established renal failure (ERF), is an irreversible, long-term condition as a result of chronic kidney disease (CKD) (or less commonly acute kidney injury) for which regular dialysis treatment or transplantation is required if the individual is to survive. If the kidneys fail, the body is unable to excrete certain waste products, excess water, acid and salts resulting in increasing symptoms and eventually death. When ESRF is reached, renal replacement therapy (RRT), in the form of dialysis or transplantation, is required or the person may die within weeks or months. In 2011, 108 patients per million (ppm) population in the UK started renal replacement therapy (RRT) for established renal failure but the UK Renal Registry showed significant variation in the crude acceptance rate in England from 50 to 226 ppm. Some of this variation is explained by ethnicity and socioeconomic deprivation both of which influence the prevalence of kidney disease.

On average, 76% of incident RRT patients start treatment with haemodialysis, 18% peritoneal dialysis and 6% with a renal transplant but the percentage starting on each modality varies markedly between centres. The percentage of prevalent patients by dialysis modality (31/12/11) varies from 0 - 11.5% for home haemodialysis from 0 - 84% for satellite haemodialysis, 0 - 27% for continuous ambulatory peritoneal dialysis (CAPD) and 0 - 16% for automated peritoneal dialysis (APD) in England. The published (<http://www.rightcare.nhs.uk/index.php/atlas/kidneycare>) atlas of variation has shown that

the rate of pre-dialysis transplantation varies between 1 and 20 ppm in different parts of the UK.

Approximately 20% of patients start renal replacement therapy (by dialysis) without sufficient prior contact with renal services to allow optimal planning to take place. This may be because they present with an acute kidney problem (or acute on chronic kidney problem) and do not recover independent function or that the progression of their kidney problem is not recognised. Despite the introduction of chronic kidney disease registers in primary care, many patients are still not identified or the patients themselves may not be aware they have chronic kidney disease. These patients have poorer outcomes with increased hospitalisation and increased mortality. There is good evidence that patients who start RRT in a controlled manner with established vascular or peritoneal access have better outcomes. In addition, opportunities for pre-emptive transplantation or for patients to be able to choose not to have RRT are missed. Therefore an important part of the pathway of care for patients with chronic kidney disease is the planning of further treatment as renal function declines. This would include making a timely informed decision about treatment options and locations which covers renal transplantation, haemodialysis, peritoneal dialysis and **conservative** care.

The Renal National Service Framework (NSF) part 1 (2004) and clinical practice guidelines from the UK Renal Association

(<http://www.renal.org/Clinical/GuidelinesSection/RenalReplacementTherapy.aspx>)

emphasise the importance of counselling and education of patients with progressive chronic kidney disease to allow an informed choice about options for renal replacement therapy (including dialysis and transplantation) or, for some patients, **conservative** care.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	√
Domain 2	Enhancing quality of life for people with long-term conditions	√
Domain 3	Helping people to recover from episodes of ill-health or following injury	√
Domain 4	Ensuring people have a positive experience of care	√
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	√

The provider will have an IT system integrated into the hospital IT system for patients with

renal disease. This system will be able to provide information to the UK national Renal Registry.

The overall aim of the service is to prepare, educate and equip patients with ESRF in order to enable them to make an informed choice of their renal replacement therapy and to ensure that their therapy is started in a planned way.

Patient reported outcome and experience measures should be prioritised, and should be the principal barometer of success. Improved quality of life and experience for both patients and carers should be sought.

The following are outcomes expected.

Expected outcomes (Domain 1,2, 3, 4 and 5)

Outcome	Measurable output
<p>For the preparation of patients:- To ensure informed patient choice. For patients to be involved in shared decision making.</p>	<p>Patient survey including satisfaction with choice of RRT and patient reported health related quality of life. Percentage of patients starting dialysis known to the unit for >3 months who complete education programme Percentage of patients known for <3 months of starting dialysis Number and percentage of patients with access and instruction in use of Renal Patient View Number and percentage of patients utilising shared decision making aids/actively involved in decision making.</p>
<p>For the initiation of treatment:- For all suitable patients to have access to RRT. To increase the number of patients starting RRT electively with permanent access. To increase the number of patients starting RRT by transplantation.</p>	<p>Crude and corrected incidence rate of RRT (patients per million population). Percentage of patients on the electronic renal conservative care register, for who there is planned and collaborative care with palliative care specialists. Percentage of patients known > 3 months starting haemodialysis with a usable arteriovenous fistula/graft or peritoneal dialysis (target > 85%) Percentage of patients admitted to hospital to start RRT. Percentage of patients starting RRT who have pre-emptive transplants from living or deceased donors. eGFR at start of dialysis.</p>

<p>To ensure timely transplantation:- To meet the Renal Association guideline</p>	<p>Proportion of patients who have been assessed for suitability for transplantation or have a transplant status within a specified period.</p> <p>Proportion of patients starting RRT who receive a transplant prior to starting dialysis.</p>
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3. Scope

3.1 Aims and objectives of service

The aim of the service will be to prepare, educate and equip patients with end stage renal failure to enable them to choose their preferred form of renal replacement therapy and to commence this treatment in a planned manner through the delivery of a seamless and comprehensive out-patient service.

The primary objectives will be :-

- Education and counselling of patients about progressive chronic kidney disease (CKD)
- Education and counselling of patients regarding renal transplantation (where medically appropriate), all forms of dialysis in all settings (home/hospital/satellite/shared care) and conservative care
- Shared decision-making by patients and health care professionals about treatment for ERF using evidence based aids
- Education about what people with ERF can do for themselves ('self-management'), where appropriate
- Access to both living and deceased donor kidney transplantation prior to dialysis where possible
- Timely establishment of vascular or peritoneal access
- Timely initiation of dialysis either by peritoneal dialysis or haemodialysis in the setting chosen by patient
- Ensure patients vaccinated against hepatitis B virus, in primary care.

This specification sets out what is required of a clinically safe and effective organisation that is providing care for adults being prepared for renal replacement therapy. It describes the interventions and actions required along the patient pathway, as well as entry and exit points. It is based upon evidence-based care and treatment models.

3.2 Service description/care pathway

The initiation of renal replacement therapy is a well established patient pathway in specialist

renal centres. The pathway has been described by the National Institute for Health and Care Excellence (NICE).

Entry To The Pathway

Patients with progressive CKD will enter the pathway when it is clear that kidney function is declining and that without some form of renal support they will become increasingly symptomatic and kidney failure may become life limiting. This will include patients who may subsequently decide not to have RRT and have conservative care. Most patients will enter with an estimated glomerular filtration rate of less than 20 ml/min/1.73m² and evidence of a progressive decline. Although precise estimation of when RRT may be necessary is difficult, people approaching ERF within a year shall be referred to a multi-disciplinary team for education and advanced CKD management. For those patients who start dialysis without adequate prior contact with renal services, the provider will have an accelerated pathway to allow all options for renal replacement therapy to be discussed within 3 months of initiating dialysis.

Many patients will already be known to nephrology services and be managed in CKD clinics. However, others may be referred directly from other hospital departments, from hospitals that do not have nephrology services and from primary care.

Staffing

Patients with progressive CKD shall have access to a multidisciplinary team which will include:-

- Trained nephrologists
- Specialist renal nurses
- Specialist renal dieticians
- Renal pharmacist
- The provider shall also provide access to other support including (but not limited to) clinical psychology, counsellors and social workers/welfare officers with specific expertise in the problems encountered by patients with kidney disease
- Surgical teams (or other suitably trained operators) with expertise in creating vascular and peritoneal access
- Interventional radiology
- Transplant surgical teams and transplant co-ordinators
- Where these services are not available at the provider's facility, information should be provided about how, and/or arrangements made to, access them

Specialist support, that is patient centred and enables patient choice, will be provided for young adults (age 18-25). This will include those who are in the process of transferring from paediatrics, those who have transferred from paediatrics or those who have come straight into adult services at a young age. Transition will involve a period of joint care from paediatric and adult services and it is important for multi-disciplinary teams (MDTs) to be aware that this group may have additional developmental needs, including educational and employment.

Key Care deliverables

Preparation for renal replacement therapy will be based on Renal NSF part 1 standard 2

All adults approaching established renal failure are to receive timely preparation for renal replacement therapy so the complications and progression of their disease are minimised, and their choice of clinically appropriate treatment options is maximised.

Markers of good practice

Referral to a multi-skilled renal team, where possible at least one year before the anticipated start of dialysis treatment, for appropriate clinical and psychological preparation. This principle should also be followed for people with a failing transplant.

Accelerated process with intensive input from the renal team for those who present late to renal units or as acute uraemic emergencies.

People with ERF are provided with information about all forms of treatment so that an informed choice can be made.

Proportion of patients placed on the national transplant list within six months of their actual dialysis start date where clinically appropriate.

The provider will offer all patients, together with their families and carers, an appropriate education programme aimed at improving their knowledge and understanding of their condition, and of the options for treatment. This will include, where medically suitable, renal transplantation, all forms of dialysis including home dialysis and **conservative** care without dialysis. The education programme will be multidisciplinary, multifaceted and tailored to the needs of the individual. A variety of approaches will be available including individual conversations, group work, written materials, DVD/CDs and access to expert patients. This will be delivered in an appropriate setting and using lay language. Where necessary, interpreters and information in other languages will be provided to assure understanding. The process will be based on the principles of shared decision making with access to evidence based shared decision making aids. Providers shall make patients aware of local and national kidney patient support groups (e.g. local kidney patients' associations, National Kidney Federation, **British Kidney Patients Association**).

Patients will be enabled to change their initial treatment of choice over time (subject to clinical considerations) to reflect personal choice or change in personal circumstances.

Patients who present late or as uraemic emergencies will be able to access an accelerated pathway to provide the same information about treatment choices within 3 months of presentation to the provider. The provider will also ensure they liaise with referrers regarding late presentation to try to reduce this over time.

Establishing suitable access for dialysis will be based on Renal NSF part 1 standard 3

Adults with established renal failure are to have timely and appropriate surgery for permanent vascular or peritoneal dialysis access, which is monitored and maintained to achieve its maximum longevity.

Markers of good practice

Early referral for assessment and investigation for the best means of access, and timely surgery (current best practice being six months before haemodialysis, four weeks before peritoneal dialysis) which enables patients to begin dialysis with their vascular or peritoneal dialysis access established and functioning.

Monitoring and early intervention to minimise complications of the access.

Recording and regular auditing of the type of access in use at the start of dialysis, time from referral to surgery, and complication rates for each procedure.

Temporary access replaced by permanent access as early as possible.

Proper training for patients, carers and members of the renal team in the care of the access.

The provider will have a system to allow timely referral for vascular access surgery and should ensure there is adequate follow up and checking that vascular access has developed, remains patent and is suitable for use. The use of haemodialysis catheters should be discouraged to minimise the risk of health care associated infections.

The provider will have a system for peritoneal dialysis catheter insertion in appropriate settings, including operating theatre, radiology departments and clean areas on renal wards. There shall be sufficient flexibility in the provision to allow a routine catheter insertion to be performed within two weeks and for an urgent catheter insertion within **24** hours.

Work up for renal transplantation

Pre-emptive transplantation (i.e. transplantation before dialysis starts) is the optimal form of renal replacement therapy for medically suitable patients. It is associated with better outcomes compared to patients transplanted after starting dialysis.

The provider will have a structured system to ensure all medically suitable patients have explored all the options of living kidney donation (related/unrelated/paired exchange/blood group incompatible (ABOi) and antibody incompatible) and deceased donor transplant listing. The chance of a deceased donor renal transplant will be determined by the national allocation policy but patients should be activated on the transplant list where it is anticipated they will require RRT within six months.

Living donor transplantation should be explored for all medically suitable patients, where there is a potential live donor. The provider will plan to achieve renal transplantation before the need to initiate dialysis treatment with the process starting at least a year before RRT will be needed. If the provider does not have direct access to facilities for assessment of transplant recipients and donors, they must ensure they have a robust link and timely referral pathway with another provider to ensure equity of access to these treatments.

Initiation of Treatment

The decision to initiate RRT should be based on the guidelines laid out in section 5 of the

Renal Association clinical practice guideline on Planning, Initiating and Withdrawal of Renal Replacement Therapy (see below).

- Guideline 5.2 - RRT: Initiating renal replacement therapy
It is recommended that the decision to start RRT in patients with CKD stage 5 (estimated glomerular filtration rate (eGFR) < 15ml/min/1.73m²) should be based on a careful discussion with the patient of the risks and benefits of RRT taking into account the patient's symptoms and signs of renal failure, nutritional status, co-morbidity, functional status, and the physical, psychological and social consequences of starting dialysis in that individual
- Guideline 5.3 - RRT: Initiating renal replacement therapy
Serious consideration should be given to starting renal replacement therapy in patients with an eGFR <6ml/min/1.73m², even if the patient is asymptomatic
- Guideline 5.4 - RRT: Initiating renal replacement therapy
It is recommend that once a decision has been made to start dialysis in a patient with established access there should be no delay in starting treatment i.e. no waiting list to start dialysis
- Guideline 5.5 - RRT: Initiating renal replacement therapy
It is recommend that urgent dialysis via a haemodialysis catheter should only be initiated where there is a clear clinical indication
- Guideline 5.6 - RRT: Initiating renal replacement therapy
Where dialysis is started via an established access (vascular or peritoneal) which fails to work effectively urgent corrective action should be taken and dialysis via a haemodialysis catheter avoided if possible

Exit from the pathway

A proportion of patients being prepared for renal replacement therapy will die before renal replacement therapy is clinically indicated. The majority of patients will progress to renal replacement therapy at which point they come off this care pathway.

Patients opting for **conservative** care should receive similar medical treatment and support as those opting for dialysis with the exception of formation of vascular or peritoneal access. Links with local community health providers shall be established to provide comprehensive care. Their exit point would be when their symptom burden exceeds medical management (i.e. the point at which they would have started dialysis if they had chosen that option). At that time they would be referred on for 'End of Life' care. The provider will have an electronic renal **conservative** care register in place which includes all patients who have chosen not to start dialysis, those with a failing transplant who decide not to return to dialysis or those who are deteriorating despite dialysis and are thought to be in the last year of life. **This register to be shared with primary care and palliative care specialists to ensure co-ordinated care of the patient.**

Supporting Technology

The provider will have an IT system integrated into the hospital IT system for patients with renal disease. This system will be able to provide information to the UK National Renal

Registry and link with the national Renal Patient View (RPV) - a web based system which gives patients direct access their blood test results and, in many units, clinic letters. The IT system shall provide information for monitoring the quality of care for commissioners. All people with ERF (or their families/carers) shall be offered access to RPV **and encouraged to advise their GP if they register with RPV.**

3.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England or are otherwise the commissioning responsibility of the NHS in England (for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England).

Specifically this service is for adult patients (18 years and over) with progressive chronic kidney disease with an eGFR $<20\text{ml}/\text{min}/1.73\text{m}^2$ and evidence of declining renal function where it is anticipated that kidney failure will become increasingly symptomatic and/or life limiting. Special arrangements will be required for young adults (age 18-25 years) to ensure their smooth transition from paediatric services or deal with the additional care needs, **including employment and education**, for patients newly presenting at this age. **Additional support will be patient centred and enable patient choice.**

3.4 Any acceptance and exclusion criteria and thresholds

Acceptance criteria

This service will accept referrals from within nephrology departments, from other hospital departments, from hospitals that do not have nephrology services and from primary care.

The service will accept patients who meet one of the following criteria:-

- progressive chronic kidney disease with an eGFR $<20\text{ml}/\text{min}/1.73\text{m}^2$ and evidence of declining renal function where it is anticipated that kidney failure will become increasingly symptomatic and/or life limiting
- acute kidney injury where renal function does not recover (e.g. vasculitis, anti glomerular basement membrane disease)
- acute uraemic emergencies where it transpires that the patient had chronic kidney disease and remains on renal replacement therapy

Exclusions

This service specification excludes young people under the age of 18 years.

The general care of patients with CKD including management of blood pressure, fluid balance, anaemia, renal bone disease, acidosis and cardiovascular risk is not included in this specification. These aspects of care for patients approaching ESRF will be commissioned locally.

3.5 Interdependencies with other services/providers

The care of patients with progressive CKD is multidisciplinary and often involves interaction with other specialities. The members of the multidisciplinary team may vary but the minimum will as specified in section 3.2.

In addition the provider shall be able to provide rapid access to other specialities.

Co-located services

Surgical services

There will be timely access to surgical out patient review to assess for vascular and peritoneal access

There will be timely access to theatre time for vascular and peritoneal access surgery

There will be access to transplant surgical expertise for assessment of suitability for transplant listing.

Radiology

There will be access to ultrasound or other imaging for assessment of vascular access.

There will be access to interventional radiology to treat failed or sub-optimal peripheral vascular access.

There will be access to radiology investigations to allow assessment of both donors and recipients for renal transplantation (full details of this are given in the service specification for renal transplantation).

Anaesthetics/ITU

There will be access to specialist opinion, intensive care support for surgical interventions and to non-invasive tests for cardiac and respiratory reserve.

Interdependent services

Cardiology

There will be access to specialist opinion and investigations to assess suitability for transplantation given the high rate of cardiovascular morbidity in this group.

Related Services

- Renal Dieticians
- Specialist Pharmacy
- Clinical psychology
- Counsellors and social workers
- **Benefits advisors**
- Transplant services and transplant co-ordinators
- Primary care

All these services should be readily available and easily accessible but there is no absolute requirement for these to be on the same site.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

The following national guidelines, service frameworks and registries are applicable to this service specification.

Renal Association Clinical Practice Guidelines:

- Planning, Initiating and Withdrawal of Renal Replacement Therapy (<http://www.renal.org/Clinical/GuidelinesSection/RenalReplacementTherapy.aspx>)
- Assessment of the potential kidney transplant recipient
- Vascular access for haemodialysis
- Peritoneal access (<http://www.renal.org/Clinical/GuidelinesSection/PeritonealAccess.aspx>)

The National Service Framework for Renal Services. Part One: Dialysis and Transplantation 2004

NICE pathway on management of CKD stage 5

(<http://pathways.nice.org.uk/pathways/chronic-kidney-disease/management-of-stage-5-ckd>)

End of Life Care in Advanced Kidney Disease: A Framework for Implementation. NHS Kidney Care National End of Life Care Programme Jun 2009

(<http://www.endoflifecareforadults.nhs.uk/publications/eolcadvancedkidneydisease>)

Renal Registry (<http://www.renalreg.com/index.html>)

The provider shall ensure that data is recorded accurately on a local IT system and all required data is uploaded electronically to the national Renal Registry

Focus on: Preparing for End Stage Renal Disease. NHS Institute for Innovation and Improvement. Feb 2008

http://www.institute.nhs.uk/option,com_joomcart/Itemid,26/main_page,document_product_info/products_id,367.html)

Guidance on home compared with hospital haemodialysis for patients with end-stage renal failure. <http://publications.nice.org.uk/guidance-on-home-compared-with-hospital-haemodialysis-for-patients-with-end-stage-renal-failure-ta48>

Peritoneal dialysis: Peritoneal dialysis in the treatment of stage 5 chronic kidney disease.

<http://publications.nice.org.uk/peritoneal-dialysis-cg125>

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

6. Location of Provider Premises

The Provider's Premises are located at:

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Appendix 1

Quality standards specific to the service using the following template

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
For all suitable patients to have timely access to RRT	Service to comply with national standards. Less than 2% of patients admitted to hospital solely to allow start of RRT	Crude and corrected incidence rate of RRT (patients per million population). % of patients admitted to hospital to start RRT.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 2: Enhancing the quality of life of people with long-term conditions			
To increase the number of patients starting RRT by transplantation.	Benchmark followed by action plans for improvements. 5% more patients receive pre-emptive renal transplant compared to last	% of pre-emptive transplants. Annual audit	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
	twelve months. Exempt if already in top quartile of UK performance		

Domain 3: Helping people to recover from episodes of ill-health or following injury

To ensure patients are informed and involved in their care.	Benchmark followed by action plans for improvement.	Number and % of patients utilising shared decision making aids/actively involved in shared decision making.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
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Domain 4: Ensuring that people have a positive experience of care

To ensure informed patient choice and to be involved in shared decision making	Benchmark to be followed by evidence of improvement.	Annual Audit: 1. Patient survey including satisfaction with choice of RRT and patient reported health related quality of life. 2. Number and % of patients with access and instruction in the use of Renal Patient View.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
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Domain 5: Treating and caring for people in a safe environment and

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
protecting them from avoidable harm			
To increase the number of patients starting RRT electively with permanent access.	85%	% of patients known >3 months starting haemodialysis with a usable arteriovenous fistula/graft or peritoneal dialysis. Annual audit.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan

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SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	A06/S/d
Service	Renal dialysis – Intermittent Haemodialysis and Plasma Exchange to treat Acute Kidney Injury
Commissioner Lead	Nesta Hawker
Provider Lead	<i>The name of the individual leading on the service for the provider</i>
Period	<i>12 months</i>
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Acute Kidney Injury (AKI) requiring dialysis

This service specification is confined to patients receiving acute intermittent haemodialysis (HD) for AKI or rarely for other indications such as poisoning, and patients receiving plasma exchange (PEX) when delivered by a renal service. It excludes AKI not requiring renal replacement therapy (RRT) as AKI not requiring RRT is not centrally commissioned. It also excludes AKI treated by Continuous Veno-Venous Haemofiltration (CVVH) which is usually delivered by critical care services for severely ill, unstable patients with multi-organ failure. Delivery of CVVH does not require on-site renal services. Therefore, for the purpose of commissioning, CVVH is not part of this specification as it is now standard treatment in nearly all level 3 critical care units, and will be commissioned from critical care services. Peritoneal dialysis for AKI is also not included in this specification as this is only very rarely used in England as treatment for AKI.

The severity of AKI varies from a relatively trivial component of another illness, to a serious life threatening condition. This area is hampered by lack of consensus over the definition of AKI. In the NICE guidance (Acute Kidney Injury. Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy Clinical

Guide line 169, issued August 2013) it was stated that “In developed countries AKI is seen in 13-18% of all people admitted to hospital”. (, Kerr M, Insight Health Economics. Economics of acute kidney injury. Royal College of Physicians of Edinburgh Consensus Conference on AKI. 2012; November 2012. Pannu N, James M, Hemmelgarn BR, Dong J, Tonelli M, Klarenbach S et al. Modification of outcomes after acute kidney injury by the presence of CKD. *American Journal of Kidney Diseases*. 2011; 58(2):206-213. Uchino S, Bellomo R, Goldsmith D, Bates S, Ronco C. An assessment of the RIFLE criteria for acute renal failure in hospitalized patients. *Critical Care Medicine*. 2006; 34(7):1913-1917). Of those patients with AKI so severe that death would occur without RRT, approximately half are nursed in a level 3 unit and receive CVVH. The other half are most often nursed in a level 1 or level 2 bed and virtually always receive intermittent haemodialysis (HD). There is considerable overlap between critical care teams and renal teams in the management of AKI in level 2 or 3 beds, and patients may move between treatment modalities depending on the clinical situation. However, in situations where a prolonged period of RRT is required for AKI, patients will inevitably move from CVVH to intermittent HD delivered by a renal service

The precise incidence of AKI requiring intermittent HD is not known in England as most published data comes from single centres. As a consequence of this lack of data, the cost to the health service is not exactly known, but it has been estimated that treating all AKI costs the NHS between £434 and £620 (millions) per annum (*Health Service Journal Supplement*, 23/06/2011). The cost for dialysis will be a significant fraction of this estimated cost. It is envisaged that the Renal Registry is to collect data on the incidence of AKI in future.

AKI has a high morbidity and mortality. Where AKI occurs in conjunction with the failure of 2 or more organs in-hospital mortality is 50-70% in most published series. Single organ failure requiring RRT has an in-hospital mortality of about 10-20% in most series (*Uchino et al JAMA: 2005, 294(7)813: Bagshaw et al Crit Care 2005: 9(6) R700: Liano et al Kidney International: 1996, 50(3) 811*). A significant number of patients who develop AKI will either not recover function and require RRT for the rest of their lives, or develop CKD which may lead to ERF at some point in the future (*Lo et al, Kidney International 2009: 76, 893-899*).

Despite the severity and frequency of AKI, treatment is often less than good. The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) AKI enquiry, which was confined to patients who had died with AKI, highlighted that 20% of cases of AKI developing in hospital were predictable and avoidable, and that 50% of patients received care that was considered to be less than good (www.ncepod.org.uk/2009aki.htm). On a similar theme, The Acute Kidney Injury Capacity Survey -England and Wales (March 2011) was carried out on World Kidney Day 2011. This survey looked at the availability of renal and critical care beds. It highlights the challenges faced in managing AKI, including high levels of bed occupancy and significant numbers of patients awaiting transfer for specialist management. These 2 surveys highlight the need for a robust national policy with key quality indicators and outcomes for the treatment of AKI.

Therapeutic Plasma Exchange

Plasma exchange is a treatment which is occasionally performed by renal services in treating some forms of AKI (such as microscopic polyangiitis or anti-glomerular

basement disease) in an attempt to recover renal function or treat complications of the underlying disease (for example pulmonary haemorrhage).

Plasma exchange can also be used for conditions that do not cause AKI, but treatment is delivered by a renal service using a central venous dialysis catheter. These conditions are usually neurological or haematological. Patients with these conditions are usually managed jointly with other clinical teams, but the plasma exchange treatment and expertise may be delivered by the renal service depending on local arrangements which is why it is included in this specification.

There is no national dataset registering the number of plasma exchanges performed by renal units in England, but anecdotal evidence from individual renal units estimate the number to be in the region of 100-200 treatments per million population per year for combined AKI and non-AKI indications. This specification excludes plasma apheresis which is delivered by haematology services, usually without the need for a central venous catheterisation.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	√
Domain 2	Enhancing quality of life for people with long-term conditions	√
Domain 3	Helping people to recover from episodes of ill-health or following injury	√
Domain 4	Ensuring people have a positive experience of care	√
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	√

The overall aim of the service is to provide a clinically safe and effective service that will improve the outcomes for patients with AKI by providing timely access to therapies and to reduce the acute mortality and late morbidity of these patients.

It is expected that all renal units will have the capacity to record all episodes of AKI requiring HD or PEx. Renal units are to submit data to the Renal Registry and the data requirements particular to AKI and to capture data as per the outcomes below.

Patient reported outcome and experience measures should be prioritised, and should be the principle barometer of success. Improved quality of life and experience for both

patients and carers should be sought.

Expected outcomes (Domain 1,2, 3 and 5)

Outcome	Measurable output
To reduce any delays in transfer to a renal unit from another hospital for treatment of AKI requiring hd or PEx.	Measure of time between referral and arrival of patients requiring transfer to a renal centre.
To reduce the incidence of MRSA and MSSA bacteraemia related to vascular access	Number of bacteraemia per 100 patients with a dialysis catheter requiring HD or PEx for AKI
For patients to receive treatment in the most appropriate setting	Number of patients with AKI requiring escalation of care to level 2 or 3 within 24 hours of admission to a renal ward.
To improve patient outcome including incidence of acute mortality and late morbidity	Length of stay Hospital mortality 90 day mortality Incidence of surviving patients remaining independent of dialysis at 90 days

3. Scope

3.1 Aims and objectives of service

This specification sets out what is required of a clinically safe and effective organisation that is providing care for adults (18 years of age and older) requiring intermittent HD for AKI, or plasma exchange delivered by a renal service. It describes the interventions and actions required along the patient pathway, as well as entry and exit points. It is based upon evidence-based care and treatment models.

AKI requiring dialysis, and many of the diseases that require treatment with plasma exchange, have a high mortality rate and significant late morbidity. The aim of the service is to provide timely access to therapies, and to minimise both the acute mortality and late morbidity.

To provide an adequate dialysis service for AKI and plasma exchange service, the unit must provide the following:

- The service will encompass local referral guidelines
- Communication links between referring clinicians and renal units at both point of entry and exit
- Provision of intermittent haemodialysis for AKI

- Provision of plasma exchange via a central venous dialysis catheter for AKI or other non-AKI conditions that respond to plasma exchange
- Access to renal specialists and non-clinical expertise
- Provision of vascular access for haemodialysis or plasma exchange
- Access to diagnostic services (radiology, pathology and microbiology)
- Access to other medical specialties that may be involved in the management of patients with AKI or requiring plasma exchange (urology, haematology, interventional radiology, vascular and general surgery, cardiology, critical care services, clinical microbiology, diabetes services, cancer services, end of life services and obstetrics)
- Access to non-medical specialties involved in the management of patients with AKI or patients requiring plasma exchange (pharmacy services, physiotherapy and occupational therapy, dietetic services psychiatric and/or psychological services and social work services)
- Provision of adequate discharge planning including rehabilitation and follow up with an appropriate health care professional team

3.2 Service description/care pathway

Intermittent haemodialysis for patients with severe AKI is a well established treatment modality. It is always delivered as part of the portfolio of services delivered by a main renal unit. This integration into a comprehensive renal service allows for economies of scale and sharing of expertise, as often the delivery of intermittent haemodialysis for AKI uses the same equipment and staff used to deliver services for established renal failure.

Plasma exchange (PEx) to treat AKI is most often delivered as part of the portfolio of services delivered by a main renal unit. However this is not the situation in all renal units, as PEx is a much less common form of treatment than intermittent haemodialysis. In this situation, either referral to a unit which can deliver plasma exchange or on site delivery of plasma exchange by a different clinical team is required.

Entry To The Pathway

Primarily, patients will be identified with AKI either in a hospital with a comprehensive renal service or a hospital without an on site renal service. Frequently the identification will be made in primary care. The provision for transfer to a hospital with on-site renal services and emergency RRT should be available 24 hour, 7 days a week. It will include that referrers have the opportunity to discuss cases promptly with a suitably trained renal specialist (that is, a doctor with a certificate of completion of specialist training (CCST) in renal medicine, a non-consultant grade doctor with more than 4 years post registration experience, or a doctor in an approved Specialist Training post in renal medicine).

- **From other hospital departments**
Locally derived guidelines (for example, via abnormality flags on pathology results) should encourage timely referral into the in-hospital renal service.
- **From hospitals that do not have an on-site renal unit**
Renal units will have clear communication guidance to local hospitals to ensure prompt access to renal specialists to discuss cases; this will include

written criteria to ensure safe transfer.

- **From primary care** Renal units will have clear communication guidance with local primary care to ensure prompt access to renal specialists to discuss cases.

People

It is preferable that renal services will have a designated clinical lead to co-ordinate local policies; the multi-disciplinary team required managing patients with AKI; and AKI audit.

Renal units will be staffed so that there is access to medical clinical expertise from trained renal specialists on a daily basis, and doctors in training to provide resident cover.

Renal units will be staffed so that there is access to trained nurses able to deliver intermittent haemodialysis 24 hours a day 7 days a week, separate from the delivery of treatment to patients with established renal failure. Nurse to patient ratios for delivery of HD for AKI or PEx should be 1:1.

All staff prescribing (doctors) or delivering (nurses) intermittent haemodialysis or plasma exchange must be competent to prescribe or deliver such treatment, and will have satisfactorily completed a competency based training program.

Renal units will be staffed so that there is access to trained nurses to deliver plasma exchange seven days a week within 24 hours of a patient being identified as requiring PEx. For the condition of thrombotic thrombocytopenia purpura, PEx should ideally be delivered within 12 hours of presentation.

Renal units will be staffed so that there is access to dietetic, and pharmacy expertise five days a week within office hours.

Renal units will have access, within days, to physiotherapy, social work, and psychological and/or psychiatric support (for example, for patients developing AKI following a drug overdose).

Renal units providing plasma exchange should have access to nursing staff that can administer (non-cancer) chemotherapy as adjuvant treatment, where intravenous chemotherapy is indicated, 5 days a week during office hours, and will have the ability to schedule such adjuvant therapy in an appropriate and timely fashion.

Doctors in training will have sufficient exposure and training in the management of AKI to develop appropriate competencies. (As measured by satisfactory appraisal and review of their portfolio by their clinical supervisor)

Supporting Technology

All renal units will have sufficient IT facility to capture and record all episodes of AKI requiring HD or PEx. This is essential to capture all episodes for the purpose of commissioning, and also for the purpose of audit to measure outcomes such as

mortality rates.

Initiation of Treatment

The precise timing of the need to institute either intermittent haemodialysis or plasma exchange will be made by a renal specialist, as defined above, in a manner that minimises risks to patients.

Vascular Access

Dialysis access needs to be available in appropriate settings 24 hours a day. Appropriate settings include operating theatres, radiology departments and clean areas on renal wards.

Renal units will have access to central venous catheters designed for dialysis access.

All renal services will have the ability to place un-tunneled central venous dialysis catheters 24 hours a day 7 days a week.

All renal services will have the ability to place tunneled venous dialysis catheters 5 days a week within normal working hours as a minimum.

Renal units will have in place strategies to minimise the risk and also deal with the complications of dialysis access, such as health care associated infections and traumatic damage to blood vessels.

Technology

Haemodialysis machines as a minimum, will be capable of delivering bicarbonate buffered dialysis and ultrafiltration, and reach the standards for safety and water purity as set out by the Renal Association guidelines. All machines will reach European Conformity requirements (CE mark).

(<http://www.renal.org/Clinical/GuidelinesSection/Guidelines.aspx>)

Plasma exchange will be performed with any validated plasma exchange machine favoured by an individual unit and will be appropriately CE marked.

Exit from the pathway

The majority of patients who survive will recover renal function so that dialysis is no longer necessary. The renal unit will have handover documentation to allow the patient's prompt return to the referring service. The patient maybe re-referred back to another medical team in the same hospital; a medical team in a different referring hospital: rehabilitation services in the community: or the general practitioner if discharged home.

All patients will receive written documentation on discharge outlining the diagnosis, the care they received, an updated list of medication, and a plan for future management and monitoring. This will include appropriate rehabilitation if required.

For those patients who do not recover renal function they will transfer care to the unit's program for established renal failure and a suitable care plan for ERF will be initiated. Whether a patient is likely to recover function or not may not be immediately apparent: for those patients who are deemed to have irreversible AKI, counselling and preparation for long term RRT should be planned before discharge from hospital . These options for long term RRT include conservative care, peritoneal dialysis, long-term haemodialysis and transplantation.

3.3 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 GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

This service specification is confined to any adult patient, regardless of nationality, requiring life-saving intermittent dialysis for AKI, or organ / life -saving treatment requiring plasma exchange delivered by a renal service. This specification refers to adults over the age of 18 years. Some young people aged less than 18 years may be best treated in an adult service, by mutual consent. All patients with end-stage kidney disease should be considered for home haemodialysis.

When treating children, the service will additionally follow the standards and criteria outlined in the Specification for Children's services (attached as Appendix 2 to this specification)

3.4 Any acceptance and exclusion criteria and thresholds

This service specification excludes the treatment of children with AKI requiring dialysis: an adult is defined as any patient 18 years of age and over. It includes treatment of any adult, referred from any appropriately trained health care professional, where dialysis or plasma exchange is required as a life or organ saving treatment.

The geographical areas covered by the service include the catchment populations of all Clinical Commissioning Groups (CCGs) in England. Any patient presenting with AKI to renal services in England will receive lifesaving or organ saving treatment as soon as is clinically indicated from that renal service irrespective of the region or country that the patient originates from. Occasionally, patients will wish to receive treatment from a renal service outside the catchment area from which they presented: in such cases repatriation should take place at the earliest opportunity that does not jeopardise patient safety.

3.5 Interdependencies with other services/providers

Co-located services

Radiology

There will be access to renal ultrasound within 24 hours of presentation as a minimum.

When pyonephrosis is suspected renal ultrasound to be performed within 6 hours of assessment

There will be access to expertise to place nephrostomies within 12 hours of diagnosis

There will be access to fluoroscopy to place venous access catheters five days a week 09.00 to 17.00 as a minimum

Laboratory services

There will be access to routine biochemistry, haematology and blood transfusion services 24 hours a day.

Renal units will have urgent access to blood products, including plasma and plasma products, 24 hours a day 7 days a week.

There will be access to process specialised tests, such as immunology and specialty biochemistry, five days a week.

There will be access to allow processing of renal biopsies five days a week.

Interdependent Services

There will be access to the following medical specialties 24 hours a day: urology, critical care, general and vascular surgery, cardiology, haematology and obstetrics.

There will be available access to level 2 and 3 beds 24 hours a day

There will be access to interventional radiology and clinical microbiology 7 days a week

There will be access to diabetes services and blood and solid organ cancer services 5 days a week.

Related Services

There will be access to dieticians, physiotherapy, occupational therapy, social work, psychiatric and/or psychological services and pharmacy support five days a week, 09.00 to 17.00.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

Renal National Service Frameworks Parts 1 and 2

Renal Association Clinical Practice Guidelines

<http://www.renal.org/Clinical/GuidelinesSection/Guidelines.aspx>

KDIGO AKI guidelines 2012

http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-AKI-Suppl-Appendices-A-F_March2012.pdf

Acute Kidney Injury Protocols and Guidelines Adapted with permission from the North Central London AKI Network Version 1.0 September 2011 <http://www.londonaki.net/>

Acute Kidney Injury: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy
Clinical Guideline 169 August 2013. [Guidance.nice.org.uk/cg169](http://www.nice.org.uk/cg169)

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

6. Location of Provider Premises

The Provider's Premises are located at:

Appendix 1

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
To reduce the incidence of MRSA and MSSA bacteraemia related to vascular access	No more than one bacteraemia per 25 patients treated with intermittent haemodialysis or plasma exchange for AKI. Service to comply with national standards.	Number of bacteraemia per 100 patients with a dialysis catheter requiring intermittent haemodialysis for AKI or plasma exchange. Annual audit.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 2: Enhancing the quality of life of people with long-term conditions			
To improve patient outcome including incidence of acute mortality and late morbidity	Benchmark and improvements in reported length of stay, hospital mortality, 90 day mortality and incidence of surviving patients.	Annual audit	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 3: Helping people to recover from episodes of ill-health or			

following injury

<p>To reduce any delays in transfer to a renal unit from another hospital for treatment of AKI requiring hd or PEx.</p>	<p>Transfer occurring more than 24 hours after referral</p>	<p>Interval between referral and arrival of patients requiring transfer to a renal centre. Annual Audit.</p>	<p>As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan</p>
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Domain 4: Ensuring that people have a positive experience of care

<p>Feedback from in-patient experience</p>	<p>>75% "recommend care" as defined in test</p>	<p>Global scores in friends and family test for renal wards where patients with AKI are nursed.</p>	<p>As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan</p>
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Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm

<p>For patients to receive treatment in the most appropriate setting</p>		<p>Number of patients with AKI requiring escalation of care to level 2 or 3 within 24 hours of admission. Annual audit.</p>	<p>For patients to receive treatment in the most appropriate setting</p>
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APPENDIX 2:

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 be fundamental to all services.

- The generic aspects of care:
The Care of Children in Hospital (Health Service Circular (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 (DOH) & 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 – DOH

Imaging

- All services will be supported by a 3 tier imaging network ('Delivering quality imaging services for children' DOH 13732 March2010). 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 (CPD)
 - 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.¹ 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) training² and should maintain the competencies so acquired³ *. 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**

1. Guidelines on the Provision of Anaesthetic Services (GPAS) Paediatric anaesthetic services. Royal College of Anaesthetists (RCoA) 2010
www.rcoa.ac.uk
2. Certificate of Completion of Training (CCT) in Anaesthesia 2010
3. 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. 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*, 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)
Care Quality Commission, London 2010

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 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:
 - Ensures the medicines given are appropriate and person-centred by taking account of their age, weight and any learning disability
 - ensuring that staff handling medicines have the competency and skills needed for children and young people's medicines management
 - Ensures 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 Publications, 2006, London

DRAFT

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	<i>A10/S/a</i>
Service	CARDIAC SURGERY – ADULTS
Commissioner Lead	<i>Daniel Keenan</i> <i>Nesta Hawker</i>
Provider Lead	
Period	<i>12 months</i>
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Cardiac surgery is conveniently divided into that dealing with acquired heart disease and that with congenital disease. The group of adults with congenital disease is most conveniently dealt with alongside paediatric cardiac surgery.

Acquired heart disease that may be dealt with surgically falls into different categories. The largest single group relates to ischaemic heart disease and may lead to revascularisation of the heart following problems with its blood supply associated with narrowings and/or blockages in the coronary arteries. The next most common is related to malfunction of one of the valves in the heart. These ensure that there is a one-way flow of blood through the cardiac pumping chambers. There has been growth in this area of adult heart surgery. There is a smaller group of acquired conditions related to problems with the aorta as it leaves the heart and traverses the chest. These problems generally relate to enlargement of this vessel with the potential for rupture (or dissection) as the vessel enlarges. Finally there is an associated group of conditions such as surgery of cardiac arrhythmias and obstruction of the flow of blood through the heart due to cardiac muscle enlargement.

Overall over the last few years there has been a stabilisation in the numbers of patients being operated upon so that in 2011 the number of heart operations performed were 34760. It is likely that numbers will stabilise at this level, as there is growth in the elderly, a group that is steadily increasing. In addition there is a steady increase in the numbers of patients being operated on semi-urgently. Most units are experiencing pressures on their waiting

lists so there may be growth in the forthcoming years.

Ischaemic Heart Disease:

There is a variety of diseases that lead to abnormalities of the coronary arteries; the blood vessels that supply oxygen to heart muscles (coronary artery disease or CAD).

Revascularisation in patients with CAD can be performed surgically (Coronary Artery Bypass Grafting: 'CABG') or by percutaneous techniques (PCI).

There has been a reduction in CABG operations due to improvements in primary and secondary prevention and the emergence of PCI (17070 in 2011 and 18034 in 2010). In addition there has been a significant move from elective to urgent treatments.

The pattern in terms of isolated valve disease is somewhat different with a steady increase that appears to have reached a plateau. There has been a slow but steady growth in the number of patients requiring intervention for valve disease because of the changes in population demographics and because of the increasing numbers of patients with mitral regurgitation being diagnosed.

Valve Heart Disease

There has been a long history of surgery for abnormal heart valves.

Initially surgery started for congenital disease with surgery for rheumatic valve disease taking off simultaneously. Initially this comprised of closed mitral valvotomy which was a highly successful operation. As the post-war epidemic of rheumatic valve disease abated the incidence of degenerative aortic valve disease rose. This was seen particularly in the elderly who are particularly susceptible to this degenerative problem. As our population ages the requirements for this operation rises. This rise has been accompanied by improved prosthetic valves with increased survival of these prosthetic valves.

This has also been accompanied by improved diagnostic techniques, particularly echocardiography which is now widely available. These various factors have led to this unprecedented rise in this operation which is replacing surgery for ischaemic heart disease.

In addition there has been a slower rise in the diagnosis of patients with mitral regurgitation accompanied by improved expertise in the techniques in mitral valve repair procedures. Again improved access to echocardiography has added to this.

In the former group of patients with aortic valve disease, some of these elderly patients have important co-morbidities which contributes to their operative mortality. All patients for valve disease need careful assessment and usually need to be presented to an MDT to assess that surgery is the most appropriate treatment.

There has been the recent introduction of percutaneous transaortic valve implantation (TAVI). This is being extensively evaluated in trials involving patients turned down for conventional aortic valve replacement. All such patient need presented to a dedicated MDT so that the most optimal therapy (including no intervention) are considered.

It is likely that mitral valve repair procedures will move into an area covered by super-specialist surgeons who dedicate a lot of their time with these patients.

There is an important subgroup of patients with valve disease who have endocarditis. They need careful management with dedicated teams including non-invasive cardiologists, microbiologists and surgeons to ensure optimum treatment. Regions should develop such teams and these teams should be available to advise others who find such patients.

Aortic Vascular Disease:

There are a variety of diseases affecting the aorta. Cardiac surgeons deal with surgery of the ascending aorta, the arch of the aorta and the descending aorta in the thorax. The thoracic aorta is managed in a multidisciplinary way with involvement of stenting and vascular surgeons.

The criteria for operating on the aorta, in the elective setting, depends on size and symptoms. In the emergency setting, surgery is carried out at high risk.

The vascular surgical group will develop guidance for use in both elective and emergency settings.

This will likely involve a strong multidisciplinary meeting and might involve emergency rotas

Surgery for Arrhythmia.

There is a growing body of evidence that surgical ablation of arrhythmias leads to improved outcomes for patients.

While the original operations were performed as adjuncts to valvular surgery, there is evidence that surgical treatment of some arrhythmias might hold better outcomes for patients. The Clinical Reference Group (CRG) will look into this.

In 2010, 760 patients had their aortic valve disease treated by a trans-catheter approach (Transcatheter aortic valve implantation or TAVI). Many of these patients are patients who would not have been treated by open-heart surgery because of their obvious very high risk.

The evidence base for adult cardiac surgery is well documented in recent European Guidelines for both coronary and valvular heart disease and commissioning within the UK should be based around these guidelines. The sets of guidelines are:

European Society of Cardiology (ESC)/European Association of Cardio-thoracic Surgery (EACTS) Guidelines on myocardial revascularization

<http://eurheartj.oxfordjournals.org/content/early/2010/08/28/eurheartj.ehq277.full.pdf+html>

Guidelines on the management of valvular heart disease (version 2012)

<http://eurheartj.oxfordjournals.org/content/33/19/2451.full>

Nice guidelines Stable angina, 2011,

<http://www.nice.org.uk/nicemedia/live/13549/55657/55657.pdf>

The first two documents are available from: <http://eurheartj.oxfordjournals.org>

Guidelines on Myocardial revascularization. *European Heart Journal*, 2010;**31**:2501-2555.

Guidelines on the management of valvular heart disease (version 2012). *European Journal of cardio-Thoracic Surgery*, 2012;**42**:S1-S44.

Further evidence can be derived from the National Institute for Cardiovascular Outcomes Research (NICOR) report on adult cardiac surgery:

<http://bluebook.scts.org/>

Despite a steady increase in the risk profile of the patients treated (as reflected by an increase in the mean logistic Euroscore) there has been a steady reduction in hospital mortality

The numbers per million population should be expected to be in the region of:

- i) All cardiac surgery; circa 580/million
- ii) Isolated CABG; circa 300/million
- iii) Isolated valve surgery; 240/million

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	√
Domain 2	Enhancing quality of life for people with long-term conditions	√
Domain 3	Helping people to recover from episodes of ill-health or following injury	√
Domain 4	Ensuring people have a positive experience of care	√
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	√

All patients undergoing heart surgery will have their results entered into the National Adult Heart Surgery audit run through the National Institute for Cardiovascular Outcomes Research (NICOR). There is a data set which must be completed which includes demographics, clinical details and outcomes. This allows a risk prediction model to be used (modifications of Euroscore). All information being entered must be associated with an individual consultant and the information is entered against their GMC number. NICOR produce a report every year detailing the results for the procedures performed and giving unit and individual results.

Until recently it was optional whether the names surgeons results could be specified. From April 2014, under the Transparency Agenda, it will be mandatory for all results to be available on a named surgeon basis.

It is expected that the data will be used in a live way in each unit and will form the basis of

real time surveillance in each unit.

All these results are openly displayed. (<http://bluebook.scts.org/>) With the continued display and review of these results it is arguable that the results obtained in the United Kingdom are the best obtained in the World.

Domain 1

Many of the cardiac surgical procedures are done to prevent patients from dying prematurely. The majority of patients presenting for surgery are brought forward to reduce their symptoms or to prolong life. The evidence base for these extends back many years and is sound.

For elective patients requiring revascularisation, the evidence base was created in the 80's and has not changed over the years.

Revascularisation:

One of the hallmark studies in cardiac surgery was the coronary artery surgery study (CASS) study published in the late 80's. This showed that certain groups of patient had improved survival over medical therapy. The groups that had the most to benefit were those who presented, for surgery, at the highest risk. This specification concentrates of such patients. They are those shown to have a narrowing of the left main coronary artery and/or important narrowings of the three main coronary arteries, associated with some impairment of left ventricular function. For less than three-vessel disease the next most important narrowing is in the proximal portion of the left anterior descending coronary artery. This is frequently dealt with by percutaneous techniques although an arterial graft to this artery has been shown to neutralise on-going risk and confers important prognostic benefits in terms of survival (please see multi-disciplinary team (MDT) discussion).

Such patients would normally present with angina, breathlessness with or without a previous heart attack. There would be a small number who present through screening.

Semi urgent and urgent patients: Patients with an acute coronary syndrome (ACS) are those who present with less than an overt heart attack. The presence of an ACS would normally be thought of as patients at risk of an early acute heart attack. They are normally kept in hospital and investigated. Their situation is normally discussed at a MDT to decide on the best revascularisation strategy. The indications are similar to those who present electively although many of these patients will have important comorbidity and may have a more limited revascularisation performed percutaneous.

Surgery in all of these settings prevents people from dying prematurely.

The adult heart surgery audit will include all such patients.

The ACS group may also be included in the myocardial ischaemia national audit project (MINAP) audit and they may also be picked up using hospital episode statistics (HES) data.

There is a CQUIN target relating to the timely transfer for the ACS group for surgery following acceptance for surgery.

Valve Heart Surgery:

In relation to valvular heart disease the prognostic indication for surgery in the setting of aortic stenosis has changed and is sound. In the setting of symptoms, the indication is based upon the degree of obstruction produced by the valve and by the amount the left ventricle has enlarged. When the valves leak the indication is based upon the symptomatic state of the patient taken together with the degree of enlargement of the relevant pumping chamber.

Whilst not all valvular heart surgery is done for prognosis, the majority is. Generally this is because if a valve is malfunctioning and is left unchecked, the heart eventually fails and this leads to early death.

Results recorded in the Adult Cardiac Surgery Audit.

Aortic vascular disease:

When the aorta enlarges it can lead to untimely death from rupture or dissection. It can also cause important compression with adverse effects. Surgery neutralises this risk of death. The evidence base for this is strong, with slightly different size criteria for surgery, depending on which portion of the aorta has enlarged.

Results recorded in the Adult Cardiac Surgery Audit.

Domain 3

As is clear, there is a cross over between Domains 1 and 3. This is most clearly seen in patients presenting with ACS. These are patients presenting with a “minor” heart attack who are at risk of an important heart attack. For all the reasons given earlier, surgery in the context of an ACS would be regarded as helping people recover from an episode of ill health.

This will be covered by the Adult Heart Surgery Audit.

A large number of patients present with decompensated valve heart disease. Such patients may have had a valve problem for some time and suddenly decompensate. Others might present acutely. In addition patients present with endocarditis who need surgery to help them recover from this acute illness. All would be considered as having surgery to help them recover from an episode of ill health.

Covered by the Adult Heart Surgery Audit.

Domain 4

Many units are working on patient reported outcome measures (PROMS) and patient reported experience measures (PREMS). There are several examples of these but nothing uniform. The CRG is developing both of these for trial. It is hoped that this will be available in 2015/16.

Domain 5

All heart surgery takes place in environments where safety is monitored by the parent Trust. There are safety initiatives such as the Safety Thermometer and the Care bundles in the

Intensive Care Areas, which are equally applicable to cardiac patients as any others.

Similarly the drive to combat infection is at the forefront with our surgery.

The service is based on an accepted international and national evidence base.

The service will be sustainable, value for money and give equity of access to the service across the country.

The service will demonstrate continued high standards documented in previous reports.

The detailed specific service outcomes will be defined through and collected by the national data collection and analysis hosted by NICOR who will produce a National Report. These will include:

1. 30 day and/or in-hospital mortality,
2. Length of stay (LOS),
3. Post-operative infection rates,
4. Take back to theatre,
5. Stroke rate
6. Mortality at 1 year.

The CRG are working on a variety of additional measures distributed through the four main themes (revascularization, valve surgery, aortic vascular disease and arrhythmia), some of which may be generic and several specific. In addition with the introduction of a more comprehensive set of MDTs it is expected to have outcomes (probably process measures) related to these meetings. The CRG has been considering safety measures, which might be specific to cardiac surgery. In addition the CRG has been discussing PROMs and PREMS for future introduction.

In the future there are additional measures that the CRG would be interested in, such as mortality over one year, repeat or additional procedures within one year and a variety of measures that the Intensive care CRG might introduce such as length of time spent in Tiers 3,2 and 1, post operatively, time to extubation and reintubation rates.

3. Scope

3.1 Aims and objectives of service

Aims

The aim of the service is to ensure the whole population has equitable access to adult cardiac surgical services.

Objectives

The service will continue to deliver the high quality cardiac surgical service provided in the

UK.

It is expected that this service is delivered in an equitable manner to all those living in England. It encompasses an elective service and a semi urgent/urgent service. In relation to the former it is expected all cardiothoracic units to have well defined patient pathways which allow all patients presenting with cardiac disease, amenable to surgery, to have their condition investigated locally, have any invasive tests performed in a safe environment and to have a timely referral made to the relevant surgical unit. All such patients should be "processed" in an equitable manner so that there is no difference in the time it takes for a patient to have their procedure depending on where they start their journey. We would expect that all units have arrangements for elective patients to be discussed at a multidisciplinary meeting (MDT). There should be network wide agreement as to which patients are discussed (including patients who are going straight for angioplasty) and audits performed to assess if such agreements are working or if they need refashioning. It is expected that units will work with other colleagues in primary and secondary care so that there are consistent standards for diagnosing heart valve disease across the country.

In the surgical units there should be processes so that there is no imbalance in the waiting depending on the surgeon involved or the procedure to be performed. All patients should be seen by a consultant or surgeon with CCT and their procedure discussed and consent taken. The guidelines that exist for the taking of consent should be followed so that, irrespective of which clinician the patient meets, all interventional options and conservative ones are discussed and the patients and their families helped make the right decision suitable for them.

Patients presenting urgently are investigated locally depending on their presenting condition and transferred to their local cardiothoracic surgical centre without delay. This will vary depending on the particular condition:

- Acute ischaemia with decompensation will normally be dealt with by the tertiary cardiology team who may place an intra-aortic balloon pump (IABP) and perform percutaneous revascularisation. Occasionally such a patient may require urgent surgery (such as those with a rupture of the intraventricular septum as a consequence of a myocardial infarction).
- For patients with acute aortic dissection the diagnosis is frequently made by CT scan where ever the patient presents and the patient transferred, directly, urgently, for surgery.
- With acute cardiac decompensation due to valve disease, patients are generally seen by a cardiologist, locally, and may be transferred to the tertiary cardiology team or directly for surgery.

Local arrangements will usually exist for such patients. The principal will always be that such patients should experience no delay in their transfer depending on bed, ITU, surgeon or anaesthetic availability. All units providing cardiac surgery would have a surgeon available to perform surgery or offer telephone advice 24 hours a day. We would expect that all units providing NHS cardiac surgery would have written, working, audited arrangements to ensure that this is the case.

The larger group of patients are those who need semi urgent surgery. Such patients commonly present with a non-ST elevation myocardial infarction (NSTEMI) but can present with valve decompensation, valve endocarditis or a critical anatomical narrowing

of a coronary artery. There should be systems in place in all units so that there is cover available at all times. There needs to be pathways of care to allow the safe and quick processing of such patients, again, so that irrespective of where a patient presents, they will be transferred in, and have surgery within an agreed time frame. Commonly such patients will be discussed in a MDT so that the best modality of treatment is arrived at. Such MDTs should be organized so that the movement of the patient to definitive treatment is not delayed and so that there is an opportunity for the patient and their relative to have a say in the choice of therapy.

Semi-urgent patients, when accepted for surgery, should be seen by a surgeon with a CCT in cardiac surgery, and be consented for such surgery. There should be agreed network wide protocols for the safe management of their ongoing ischaemia so that antiplatelet drugs and other evidenced based therapies are continued to reduce risk to as low as possible while preparing for surgery. Variance in such protocols should be avoided and audit performed to ensure that this is the case. Such patients should be scheduled on the next list and not have to wait for any particular surgeons' availability depending on any geographical peculiarities related to elective referral patterns. There is a CQUIN related specifying the time from acceptance onto a surgical list, to surgery. This has not really given improvement and we would propose that a better CQUIN would be the time from diagnostic angiography (in the case of ischaemia) to surgery. In the case of patients with semi-urgent valve disease this would be the time from a cardiologist informing a surgeon of the need for surgery to surgery.

In the next year it is not anticipated that there will be major changes but looking forward would see many benefits in sub-dividing this specification into 4 divisions (revascularisation, valve disease, aortic vascular disease and surgery for arrhythmias). This will replicate what is already happening in cardiothoracic units with the development of more specialist surgeons.

It is the intention that there will always be a core set of procedures that all surgeons in the adult arena will perform. These would be those that a surgeon "on-call" would expect to encounter and deal with. These would encompass urgent coronary artery bypass grafting and surgery for acute valvular decompensation. It becomes more difficult when one included acute aortic dissection. The majority of such cases are dealt with by the "on-call" surgeon. It will be part of the remit of the Aortic Vascular Group to advise on how this area of acute surgery should be taken forward.

It is anticipated that there should be networks of surgeons crossing traditional geographical boundaries so that patients presenting with difficult or unusual problems could be discussed and, if need be, moved to a unit or surgeon with a particular expertise. There should also be systems of joint working so that surgeons might travel to work with others in their base hospital to ensure that expertise disseminates out and all learn from one surgeon's particular experience.

3.2 Service description/care pathway

All adult cardiac surgical units are appropriately configured to continue providing this service. The aforementioned National Institute for Care Excellence (NICE) and European guidelines for both coronary and valvular heart disease provide the basis for the care pathways that should be delivered by every cardiac centre. These standards

will apply also to any patients subcontracted to the independent sector and the governance will remain with the referring Trust.

There are many advantages in discussing many patients presenting for open heart surgery at multidisciplinary meetings. It is anticipated that the four divisions specified above would have their individual meetings. This is particularly important in the decision making when dealing with patients presenting with ischaemic heart disease. In this way the three strategies, medical therapy, angioplasty and surgery, can be discussed. When setting up these meetings it is the anticipation that the lessons learned from adopting the same approach for cancer are adopted. There should be all the members of the team as are necessary, there should be minutes, junior doctors and nurses should be active participants, the meetings should be audited and there should be systems so that patients and families understand the process and outcomes are conveyed to them in a timely manner.

There should be regular meeting whereby all cases that have not gone well, including those who have died, are discussed and reflected upon. These morbidity and mortality meetings should be formal with registers and minutes, and most importantly, action plans for improvement.

All patients should be offered cardiac rehabilitation. Phase 1 rehabilitation will be carried out during the inpatient stay. This will be undertaken by the High Dependency Unit (HDU) ward nurse/cardiac rehab nurse.

Upon discharge patients will be referred to the local district general hospital or general practitioner, as appropriate, for medical review and to the local cardiac rehabilitation service for cardiac rehabilitation unless this is to take place in the base hospital when a similar referral will be made.

All patients will have a clear follow-up plan at the time of discharge along with a discharge summary and plan to be given to the patient and the GP.

All patients to be discharged on the full battery of evidenced based medicines.

3.3 Population covered.

The service outlined in the 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 GP practice in Wales or Scotland, but INCLUDES patients resident in Wales or Scotland who are registered with a GP practice in England.

It is expected that the entire population of England would access cardiac surgical services in similar ways irrespective of geography, gender and race. Some units have developed

common waiting lists, particularly for CABG operations. Many units run such a system for semi urgent patients. To run such systems surgeons need to have agreed criteria to allow this to run smoothly.

3.4 Any acceptance and exclusion criteria and thresholds

This specification covers ALL adult cardiac surgery BUT does not include surgery for the following groups of patients who might require cardiac surgery:

- i) Transplantation with or without Ventricular Assisted Device implantation
- ii) Surgery for congenital cardiac problems
- iii) Non vascular thoracic surgery

3.5 Interdependencies with other services/providers

All open heart surgery should be undertaken in fully equipped and staffed operating theatres by specialist cardiac anaesthetists with immediate availability of transoesophageal echocardiography. Patients who have undergone such surgery are returned to an area capable of managing such patients including those who do not follow a straightforward path and might necessitate prolonged ventilation and inotropic support, an intra aortic balloon pump, haemofiltration and access to many additional specialists who should be available to attend at short notice. This should be available without a transfer of hospital.

Such a service will be delivered in a dedicated area with core staff dedicated to the delivery of postoperative care of patients recovering from open-heart surgery. Such staff would be fully trained in the post operative care of surgical patients, including their resuscitation. Similarly there should be dedicated intensivists who have experience and training in the management of the ill postoperative patient following open-heart surgery.

All cardiac surgical units must have detailed and robust working relationships with all other major branches of acute medicine and surgery, in particular; complex interventional cardiology, vascular services, renal, gastroenterological, general and plastic surgical, neurology and intensive care programmes. In addition, there must be close links with physiotherapy and rehabilitation services.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

All units must submit data pertaining to open heart surgery to the NICOR national audit into postoperative death. The data must be of satisfactory quality (i.e. 100% completion of age, gender, responsible consultant, operation type, discharge status and >97% completion of other risk fields, and >95% completion of non-mortality outcomes). The submission must contain all patients operated on. It is expected that such audits will be "live" audits in departments so that the data is used real time to improve outcomes for patients.

There needs to be a dedicated perfusion service, which is fully compliant with Department of Health guidance “A guide to good practice in clinical perfusion”¹. Monitoring during surgery needs to be compliant with the Surgical/Anaesthetic recommendations “Recommendations of standards for monitoring during cardiopulmonary bypass”², and that there be near patient testing available to both the theatres and recovery area.

To perform in accordance with the European Society of Cardiology/European Association of Cardio-Thoracic Surgery (ESC/EACTS) guidelines on both coronary and valvular heart disease.

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

6. Location of Provider Premises

The Provider’s Premises are located at:

All current active adult cardiac surgical centres

The Provider’s Premises are located at:

¹ <http://www.acta.org.uk/store/docs/guidelines/DH-Guide-to-good-practice-199-30-07-2009.pdf>

² <http://www.acta.org.uk/store/docs/publications/CPBRecommendations2007-298972-31-08-2011.pdf>

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
<p>Optimal quality of life and survival for patients post surgery</p> <ol style="list-style-type: none"> 1. In base hospital mortality for CABG (first time) and Cardiac Surgery (All) as specified by the Society of Cardiothoracic Surgeons NICOR audit 2. Post operative deep sternal infection rates, 3. Take back to theatre for bleeding/tamponade, 4. In first time CABG operations the rate of use of the internal mammary artery. 5. Mortality at 1 	<p>Risk adjusted threshold:</p> <ol style="list-style-type: none"> 1. First time CABG and Cardiac Surgery (All), mortality to be within 99% confidence limit as predicted by Logistic Euroscore. 2. Less than 2.5% 3. Less than 5% 4. Greater than 90% 5. 1st time CABG, 	<p>Figures from the annual NICOR audit together with ONS data for 5.</p>	<p>As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan</p>

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
year.	survival greater than 85%; First time AVR, greater than 85%		
Domain 2: Enhancing the quality of life of people with long-term conditions			
All patients with prostheses (valves and rings) have these recorded in NICOR data set to enable the late surveillance of such implants	95% completion of relevant fields	Completion of the data fields relating to prosthetic implants in NICOR. Annual audit.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Patients needing semi urgent Cardiac Surgery* to have the procedure within 7 days of acceptance to treat by cardiac surgeon.	20% reduction in patients waiting from baseline	Quarterly reports to commissioner	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 4: Ensuring that people have a positive experience of care			
Each provider will undertake a patient satisfaction questionnaire and	75%	Patient satisfaction questionnaire.	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
report results to commissioners.			Action Plan
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
<p>Provider to learn from and improve performance related to Never Events,</p> <p>SUIs, Safety Thermometer and critical care bundles.</p>	<p>Never Events. None tolerated.</p> <p>Benchmark and review of all in quality surveillance meetings.</p>	<p>Reporting through NRLS.</p> <p>Annual audit done by Trusts</p>	<p>As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan</p>

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Service Specification No.	D01/S/d
Service	Complex Disability Equipment – Prosthetic Specialised Services for People of All Ages with Limb Loss
Commissioner Lead	Carolyn Young
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

This specification will benefit the patient by improving health and well-being outcomes for persons of all ages with limb loss and any related condition(s) by offering personalised care, whilst supporting, facilitating and enabling patient choice and by putting them first. This will also support equity, equality and ease of access to the highest quality services. A prosthesis is an artificial device designed to emulate where possible a missing body part like a limb. Prosthetic rehabilitation is the clinical practice to use prostheses and appliances to restore function in people with limb loss following amputations or congenital limb deficiencies.

Limb loss and any related co-morbidities are life-long conditions and it is recognised that limb loss can be managed effectively through specialised rehabilitation services. This service specification places the patient at the heart of everything specialised rehabilitation service centres do. It focuses on maximising their independence, achievement of their individual goals and improving their quality of life. This service specification empowers and liberates clinicians to innovate, with the freedom to focus on improving healthcare services.

This service specification also honours the Cross Government guarantee to our Armed Forces, Veterans and their Families, as set out with the Murrison Report – A Better Deal for Military Amputees and so relates to the provision of enhanced prosthetic services to Veterans. This should also offer a benefit to all NHS patients with limb loss in the wider NHS. (**Appendix 1**).

The implementation and delivery of this service specification will reward quality, efficiency, innovation, best practice and support patient choice. It will also encourage the effective and efficient use of vital resources.

The total number of patients with an amputation or congenital limb deficiency attending specialist rehabilitation service centres in the UK is estimated at 55,000 - 60,000.

The rehabilitation and re-ablement of all patients is provided by a specialised Multi-Disciplinary Team (MDT) (**Appendix 2**) which should be consultant led. The needs of patients of all age groups are addressed including physical, psychological, social, emotional and spiritual with the emphasis on individual outcomes, independence and prevention keeping patients dexterous, mobile and safe. Secondary injuries should be minimised.

This specification recognises and supports NHS England's duty to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. It is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and

maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England and its service and equipment providers will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities.

This specification should be read in conjunction with National Statutory Requirements in relation to the supply of Services and Equipment by the NHS in England.

Advances in Technology: Evidence Base for Clinical Use

It is generally accepted that the evidence base for prosthetics services is limited due to low numbers of participants and difficulties with conducting randomised controlled trials.

Other relevant documents are included but are not limited to those shown in **Appendix 3**.

2. Outcomes

Service Provider Outcomes

All patients offered rehabilitation and re-ablement services

- Improved access, including flexible out of hours appointments if required, to all members of the MDT as required by the patient
- All persons with limb loss should have lifelong access to the service(s) and be offered an MDT review at least every 24 months.
- Improved individual outcomes related to patient centred service: informed patient choice
- Increased patient satisfaction
- Maintenance appointments as indicated by the prosthetics component manufacturers

Key Outcome Measurements

These will include where appropriate but are not limited to:

Impairment Measures:

- McGill Pain Scores which are well recognised for description of pain
- Numeral Rating Score or Visual Analogue Score for Pain which are widely used for scoring pain
- Socket Comfort Score is a validated numerical measure for comfort of prosthetic socket fit
- Stump Descriptors (e.g. ISO). These are the recognised descriptors for various levels of upper and lower limb amputations and congenital limb deficiencies

Mobility Disability/Activity Measures:

- Special Interest Group in Amputee Medicine Mobility (SIGAM) Grades. This is a recently validated disability measure for mobility and the measure recommended by the British Society of Rehabilitation Medicine (BSRM) for routine clinical practice. It is also validated for self-completion by the patient and for use over the telephone
- Locomotor Capabilities Index 5 (LCI-5). The LCI-5 is a 14 item sub scale within the Prosthetic Profile of the Amputee Questionnaire (PPA) scored according to whether an individual can perform a particular activity while wearing a prosthesis
- Timed Walking Tests. A simple objective measure that appears to correlate well to functional mobility in amputees
- Timed Up and Go. An objective measure that is a simple, quick test of basic functional mobility. It helps to assess balance and risk of falling and provides an objective means of following functional change over time
- Video recording of gait while performing tasks relevant to the agreed goals as a means to assess Gait Quality
- Canadian Occupational Performance Measure (COPM). A client centred tool which measures patient satisfaction with their occupational performance and enables the patient and Occupational Therapist to set achievable rehabilitation goals

Participation:

- Assessment of mutually agreed personalised care plans

- EuroQol - 5D, a Quality of Life Questionnaire that provides a simple descriptive profile and a single index value for health status
- Trinity Amputation and Prosthetic Scales (TAPES) is a multi- dimensional self-report instrument to better understand the experience of amputation and adjustment to a prosthesis and may be applied as a clinical and research tool where appropriate

Emotional:

- Hospital Anxiety and Depression Scale (HADS) or
- General Health Questionnaire (SF-12 Health Survey is a short and easily completed document that uses a small number of questions to measure functional health and well-being from the patient’s point of view)

The above should be used where clinically appropriate, or where they have been previously used as an outcome measurement tool for individual patients to ensure consistency.

2.1 NHS Outcomes Framework Domains & Indicators - See Appendix 6

Limb Loss Service Specific Outcome Measures:

Domain 1	Preventing people from dying prematurely •	X
Domain 2	Enhancing quality of life for people with long-term conditions •	X
Domain 3	Helping people to recover from episodes of ill-health or following injury •	X
Domain 4	Ensuring people have a positive experience of care •	X
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm •	X

3. Scope

3.1 Aims and objectives of this limb deficient/limb loss patient service

Aims

The service aims to maximise the mobility, independence and quality of life of the individual, working in collaboration with the patient as equal partners.

This aim is achieved by the provision of prostheses (artificial limbs) through a dedicated and specialised multidisciplinary team (**Appendix 2**).

These specialised services seek to empower patients, provide them with information about their condition(s) and offer individual choice(s) about where, how and by whom they are to be treated and allow for a collaboratively agreed prescription(s) to be provided. The ability to return to normal life and work are key service outcomes thereby improving the individual’s quality of life. The value of rehabilitation is highlighted by the fact that 66% of working age amputees return to employment and this is achieved by providing services that are focused on:

Person (Patient) Centred Service: Informed Patient Choice

- Patient Information Pack
- The patient or their advocates are provided access to all the information necessary to make informed and timely choices
- Collaboratively produced personalised care plans with the Patient/MDT including individual goal setting and improving and maintaining health and well-being
- The Patient working collaboratively with the MDT may exercise their patient choice to decide by whom they are seen and where they receive their treatment

Timing of Treatment

Appointments need to be agreed, flexible and include emergency appointments. There should be sufficient time allowed for clinicians to work with service users to achieve an optimal outcome at each appointment and over time.

The dynamic nature of rehabilitation means that as the patients goals change so does the rehabilitation and re-ablement programme.

Areas of Focus in order to Maximise Independence:

Education and Advice

- Pre-Amputation Consultation
- Advice to Surgical and Referring Teams
- Congenital Limb Deficiency including Antenatal
- Specialist education and general advice related to prosthetics and co-morbidities

Mobility and Stability

- Provision of appropriate artificial limbs (prosthetic limbs)
- Provision of enhanced prostheses to veterans including spare limbs as set out in **Appendix 1**
- Provision of appropriate specialised mobility training e.g. prosthetic rehabilitation and gait re-education with specialised physiotherapists and or wheelchair training with specialised therapists
- Provision of orthotics if linked to limb loss
- Liaison with and shared care with community services e.g. physiotherapy, occupational therapy, orthotics and social services

Activities of Daily Living

- Washing & dressing, food preparation and consumption, personal hygiene
- Provision of lower limb (leg) artificial limbs for mobility
- Provision of upper limb (arm/hand) artificial limbs for carrying out activities

Occupational/Vocational Management

- Assisting patients back to work or education
- Assisting patients in work to stay in work or education
- Support with maintaining and or improving existing levels of fitness

Recreation

- Prosthetic appliances and components to meet the clinical need(s) and rehabilitation goals of the individual e.g. terminal devices

Social and Psychological Wellbeing

- Counselling for any person with limb loss including management of Post-Traumatic Stress Disorder
- Provision of appropriate non weight bearing cosmetic limbs for use in a wheelchair
- Provision of a patient acceptable cosmetic finish taking account of the custom made silicone covers for prosthetic limbs and partial hand prosthesis policy where appropriate

Objectives

The core objectives include the active participation of the individual, returning the post amputation individual to their pre-amputation activity levels wherever possible, to decrease reliance on carers and or social services and to aim for maximising mobility, independence, inclusion and participation in society. This is achieved through pro-active multidisciplinary rehabilitation, regular review and patient and clinician education.

For patients with congenital limb deficiency the aim is to improve mobility and function from birth to a level that maximises mobility, independence, inclusion and participation in society. This is achieved by

supporting the patient and family, consultations including antenatal where appropriate, functional assessment, prescription of prostheses, surgical intervention when appropriate and lifelong follow-up (cradle to grave).

Patients of all ages accessing prosthetics services either have acquired limb loss or are individuals with congenital limb deficiency. Generally these individuals have more than one condition or complex needs, which are often in combination. NB: Complex will be determined as part of the MDT assessment.

The conditions this patient group encompass include co-morbidities such as diabetes, cardio-vascular disease, neurological and musculoskeletal conditions.

The service objectives include giving opinions and advice and training to other relevant specialties, such as general practitioners, surgeons, paediatricians and acute trust therapists, on matters relating to amputation and limb deficiencies.

3.2 Service Description/Care Pathway

Service Delivery

The service is expected to be provided through a National Network of Specialist Rehabilitation Service Centres to maximise highest quality of informed patient choice of service and provider encouraging innovation.

For military veterans in England the service aims to provide prosthetics, orthotics and associated services to meet the needs of veterans who have a service attributable injury (**Appendix 1**).

Key Priorities

The Service should be provided in specially designed and adapted facilities to meet the needs of patients with limb deficiency and limb loss.

The Service should have separate paediatric facilities and be responsive to the special needs of children with limb deficiency and limb loss (also see **Appendix 4**).

Each service should have in place an appointment system that allows for the allocation of sufficient time for the treatment of each user of the Service. All users attending the service should be allocated dedicated time with each appropriate member of the multi-disciplinary team, as required for that episode of care.

The Service Provider should be able to demonstrate on-going monitoring and review of:

- Effectiveness
 - the use of preventative best practices
 - enhancing the quality of life for the patients with limb deficiency and or limb loss
 - helping people to recover from episodes of ill health or following injury
- Patient Experience with the service
 - patient waiting times for appointments
 - outcome measures (in alphabetical order) including but not exclusively the following areas:
 - achievement of agreed rehabilitation goals
 - emotional issues including body image and prosthesis appearance issues
 - mobility and activity levels
 - positive experience of care
 - socket fit and comfort
- Complaints and plaudits (patients must have access to the NHS complaints procedure)
- Adverse incidents, accidents, near miss and never events

The Service Provider must ensure that patients' Privacy and Dignity is maintained and that Equality and

Diversity is observed at all times. It should be able to respond to requests for a patient's partner or carer to accompany them during their treatment and to requests for treatment by staff of the same gender where possible. Facilities must include the opportunity for patients to be treated in single treatment rooms when requested.

The Service Provider must supply suitable transport services for patients who are unable to make their own way to appointments due to medical reasons and should be able to demonstrate that the use of this service is monitored. Service providers must provide an appropriate number of disabled parking spaces close to the Centre to facilitate ease of access for patients.

The Service Provider must have or be able to demonstrate that they are working towards an integrated IT system which enables them to store and manage information and run operational systems. There should be evidence that the service provider is working towards electronic clinical records which will be maintained throughout the patient's contact with the service. Patients should be able to request access to information on all aspects of their care.

The Service Provider must be able to demonstrate that:

- Patients receive the most appropriate treatment to meet their needs
- Records are kept of audit activity in relation to clinical effectiveness
- All clinicians and healthcare professionals participate effectively in Clinical Governance/Audit and that they comply fully with Information Governance requirements
- Professional registration is routinely monitored
- They wholly support Continuing Professional Development, Research & Development and other education and mandatory training
- Patients and or Patient Stakeholders, User Groups and or Support Groups are involved in local service design and delivery

Amputee and limb loss rehabilitation service centres provide a range of services in order to deliver the outcomes highlighted and referred to in the Key Service Outcomes to Patients and Service Users Section. These include:

- Information for patients and carers
- Consultant led prosthetic and rehabilitation services that will offer support to other non-consultant-led service centres when required
- Specialised assessment and review
- Prescription, provision and maintenance of individualised prosthetic limbs including partial limbs whether upper or lower limbs or both
- Prescription of silicone cosmeses
- Specialised gait re-education
- Functional rehabilitation and education
- Pain management
- Psychological support
- Educational, vocational, leisure, mobility and driving advice

The service will be provided by a specialised multi-disciplinary rehabilitation team (**Appendix 2**) with training in the field of prosthetic rehabilitation.

When treating children, the service will additionally follow the standards and criteria outlined in the Specification for Children's Services (**Appendix 4**).

The service will provide the appropriate level of support for education and workforce development for the current and trainee workforce by:

- Enabling support for the future workforce through provision of sufficient high quality practice placements and learning environment
- Provision of preceptorship for newly qualified staff
- The workforce must be continually developed to enable contemporary practice, through systematic education and learning

- Promotion of widening access to education
- Provision of and/or access to mandatory training
- Promoting ethnicity and diversity in the workforce
- Enabling research and development and innovation
- Promoting educational governance, thus recognising the importance and value of education
- Supporting staff health and wellbeing
- Meeting workforce assurance requirements

The team will work in close liaison taking an interdisciplinary and holistic approach to individual patient outcomes. The service will be able to demonstrate how the specialised service interacts and liaises with local and community services to ensure patients receive the most appropriate care in the most appropriate location.

The team will develop close links with referring services, e.g. vascular surgery, orthopaedic surgery, plastic surgery, diabetic teams, paediatric teams, diagnostic imaging, obstetric and General Practice services. These form the entry point into the amputee and congenital limb deficiency service and are critical for optimal patient outcomes.

Preoperative consultation wherever possible with the consultant in rehabilitation medicine, senior prosthetist, specialist physiotherapist and occupational therapist is advisable to secure the best outcomes for the patient.

Care Pathway

Congenital limb absence or defects – this occurs when a portion or the entire upper or lower limb fails to form completely when the baby is developing in the uterus. The common congenital limb loss or limb defects can include but are not limited to:

- complete or partial absence of the limb (such as fibula hemimelia or congenital absence of the tibia)
- failure of the portion of the limb to separate (commonly seen in fingers or toes)
- duplication (commonly seen as extra fingers or toes)
- overgrowth (the limb is much larger than the normal limb)
- undergrowth (the limb is much smaller than the normal limb)

Consultation with the appropriate members of the MDT will be offered to parents on identification of an unborn or new-born child with congenital limb absence or defects.

Pre-amputation - Consultation will be arranged with appropriate members of the specialist rehabilitation service centre's multidisciplinary team. This is also applicable and will be offered to parents on identification of an unborn child with congenital limb absence

A Rehabilitation and re-ablement programme will commence pre-operatively if possible.

Primary patients - New patients with limb loss, including military personnel leaving the Defence Medical Rehabilitation Programme, will have appropriate access to all the disciplines available to the service as well as community and other services in their own locality.

The rehabilitation and re-ablement phase 'Patient' - This phase covers three main clinical situations where intensive rehabilitation is required:

1. New amputation surgery having been carried out:
 - Patient undergoing an amputation for the first time on that limb(s)
 - Revision of amputation to a higher level e.g. transtibial converted to transfemoral
 - Revision and or reconstruction to the residual limb
 - Referral into the service of a child or adult with congenital limb absence or defects
2. Patient with limb loss returning to the service:

- Patients who for whatever reason (e.g. bio psychosocial) were unable to participate in their original post-amputation rehabilitation
 - Patients medical status changes
3. Patients with limb loss transferring into a service from other NHS areas, or from the DMRP or from other qualifying countries:
- Full assessments should be undertaken and carried out by the Consultant/MDT
 - Limb provision may be inadequate or a prosthesis may not have previously been supplied

See **Appendix 5** for the Patient Pathway: Rehabilitation Phase.

Established Patients with Limb Loss - These patients have undergone a period of rehabilitation and re-ablement following congenital loss or amputation and achieved their maximum potential in terms of mobility, independence and participation. They will normally require input from part of the team in order to review and maintain their prosthetic provision but will not always require on-going medical monitoring or therapy.

The Established Patient 'User' - This phase starts when the first phase finishes when the patient meets the following criteria:

- The patient has been medically assessed and treatment provided with successful and stable outcome e.g. residual limb wound healed or phantom limb pain being managed
- The patient has been discharged from the initial episode of physiotherapy e.g. patients gait, mobility and function is optimised
- Agreed patient and multi-disciplinary team goals have been achieved
- The patient does not need any specialised amputee occupational therapy e.g. patient satisfied that they have achieved their optimal functional potential
- Primary limb is delivered and deemed 'fit for purpose, fits and is comfortable' by the patient and the specialised multi-disciplinary team
- Communication with the GP to state the patient has graduated to level of 'established user'

This 'User' phase allows for

- The on-going review of the patient/user, which is required because patients with prostheses may need socket adjustments, a different type of prosthesis to facilitate a new activity, monitoring of the sound limb or treatment for pain or other complications
- Children and young adults to be offered a review a minimum of twice a year. Consideration should be given to the rate of child development and the need for prompt and frequent delivery of prostheses. Associated waiting and response times should be prioritised accordingly.
- Established users to be able to bring their limbs back for preventive maintenance by individual arrangement dependent upon manufacturer's warranty, patient use or no later than 24 months
- Full access to the medical assessment e.g. assessments for medical issues such as sores, infections, swelling, bursa formation, sinus formation, veracious hyperplasia
- Full access to explore and assess for a prosthetic change as required e.g. sockets and suspension and component changes frequently, when the patient enters the established phase and can lead to significant increases in component cost
- Full access to therapeutic intervention e.g. provision of a different knee unit frequently requires prosthetic rehabilitation and gait re-education and provision of a different hand or elbow unit frequently requires occupational therapy intervention

Changing needs - Children, young adults, veterans and other patients require a flexible model of care which provides longer term involvement with the full MDT. This specification recognises that child growth is a recognised clinical need.

Non Prosthetic Limb Users – These patients will be encouraged to access the service at any time for advice, support and therapeutic intervention as required.

Communication

Service Providers should be actively involved in the on-going development of service delivery in collaboration with User Groups, Support Groups, Independent Providers, Professional Bodies and appropriate Charities.

The Service Provider should be able to demonstrate that patients have access to the following information at the Centre:

- Information about the Centre and the services provided including opening times, contact details and access
- Contact details of the named clinicians involved in their care
- Details of Patient User Groups, Patient Support Groups and or Support Systems, National Charities and Organisations in relation to limb deficiency and or limb loss

Resources

Services are provided through a national interactive network of Specialist Rehabilitation Service Centres, which allow and provide for the specialist range of rehabilitation skills and resources necessary to ensure ease of access to all aspects of service and equipment provision required by patient choice. These services will be delivered through a model which provides for increased specialisation and sustainability of service provision, thereby ensuring that the multi-professional team has the range and level of skills to deal with all complex cases. Centres should encourage innovation at all levels.

All patients should be provided with ease of access to the full range of services and specialist medical and rehabilitation skills, no matter which centre they may attend. Increased and improved collaboration is a prerequisite to service delivery to ensure accessibility for all. The service provided to all users will be accessible and available to all irrespective of their geographical location, ability to travel and any service and or equipment prescription(s).

Prosthetic and related Technical Services may be provided by appropriate providers contracted to the NHS, who need to be seen and practice as equal members of the Multi-Disciplinary Team and thereby be expected to support and sustain its high standards and foster collaboratively innovations both in technologies and in systems.

The Centres are described as follows:

N.B. It is important to note, that these descriptions DO NOT reflect the quality, standard of service or equipment to be provided to the patient, but are ONLY used to reflect the range of services made available at the centre so described.

1. Tertiary Centre

A Centre of expertise for ALL levels of amputation and limb loss (including upper limb, congenital and multiple limb loss), which is able to provide the full range of advice and prosthetic rehabilitation for all levels of upper and lower limb loss including paediatric services.

The multidisciplinary team (**Appendix 2**) must be led by a suitably experienced consultant in rehabilitation medicine who specialises in prosthetics and whose job is predominantly prosthetics, involving minimum of 5 or more weekly sessions in amputee rehabilitation. These centres should have access to socket manufacture and limb assembly on-site.

It is necessary to have close links and access to psychologist and counselling services, podiatry and orthotic services, or preferably to have them as part of the team. MDT members must have specialist experience and the appropriate training in the management of children with acquired or congenital limb loss, upper limb prosthetics and amputees with complex needs and or those requiring high specification, technologically advanced components. The centre should have access to inpatient rehabilitation beds for complex cases.

All services providing paediatric services are required to provide appropriate separate facilities.

The centres should hold combined clinics in conjunction with appropriate specialists, including but not limited to, Surgeons and Paediatricians etc. for:

- Congenital limb deficiency
- Pain management
- Limb Surgery including revision and reconstruction

Tertiary centres must be further developed to ensure specialist expertise in the future, both for rare and expensive conditions and for innovation, research and development. These centres also play a key co-ordinating and educating role whilst supporting standard centres ensuring high quality standards are maintained.

2. Standard Centre

These centres have a smaller multidisciplinary team and should have close links and access to a tertiary centre. The team should include an experienced rehabilitation consultant or other suitably qualified medical practitioner, prosthetists and specialist therapists. Other expertise including medical, psychological and engineering input can be provided through local services or a tertiary centre. These centres will provide all standard lower limb services and should have established links and referral pathways with a tertiary centre for complex cases and additional services.

Some standard upper limb amputees and congenital limb deficient patients may be managed provided there are appropriately trained and experienced staff. The standard centre will deliver the core services for most patients in the relevant local area with some expected variations depending upon local agreements. These centres should have the ability to respond, assess and where technically feasible deliver on the same day access to socket manufacture and limb assembly on-site.

3. Satellite

These centres have a smaller multidisciplinary team and should be affiliated to a tertiary or standard centre. The team includes experienced prosthetists and therapists. Other expertise including medical, psychological and engineering input can be provided through the affiliated tertiary or standard centre. These centres should have access to workshop facilities for minor adjustments and repairs.

NB: A Visiting Clinic is where a specialist team from a tertiary or standard centre visits an acute setting, to assess patients with limb loss together with the acute team and take over their rehabilitation programme. They generally do not have any access to workshop facilities.

Service Centre designation as Tertiary, Standard or Satellite will be reviewed by NHS England as part of the contracting process.

3.3 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, Scotland or Northern Ireland but INCLUDES patients resident in Wales, Scotland or Northern Ireland who are registered with a GP Practice in England.

This specification also relates to military veterans ordinarily resident in England. NOTE: It does not cover veterans in Scotland, Northern Ireland or Wales within which authorities are making their own arrangements for implementation of "A better deal for military amputees". Nor does it apply to crown dependencies such as the Isle of Man or the Channel Islands. A veteran is defined as any member of the armed forces who has served for one day or more with injuries that must be service attributable (Appendix 1).

Discharge planning

These patient groups have lifelong conditions and therefore have lifelong access to specialist service centres.

3.4 Any acceptance and exclusion criteria and thresholds

When treating children, the service will additionally follow the standards and criteria outlined in the Specification for Children's Services in **Appendix 4**.

For all eligible patients there are no exclusions to access of the service and clinical assessment.

All veterans will continue to have access to high quality prosthetics based on clinical need and as set out in the prescription guidelines in **Appendix 1**.

National policies' are being developed to support this service specification and include but are not limited to:

- Microprocessor Controlled Prosthetic Knees
- Custom Made Silicone Covers for Prosthetic Limbs and Partial Hand Prosthesis
- Multi-Grip Upper Limb Prostheses

3.5 Related Interdependencies with other services/providers

The prosthetics service will have a relationship with the following:

- The prosthetics learning and development network
- The regional vascular network (including MDT)
- The orthopaedic departments of referring hospital
- Regional pain management services
- Regional plastic surgery services
- Diabetic Units
- Paediatric Units – in hospital (including neo-natal units) and community
- Trauma Network
- Other complex rehabilitation services
- Primary & Secondary Care Services
- Special Educational Needs Co-ordinators
- Defence Medical Rehabilitation Programme
- Civilian Limb Loss Charities e.g. Limbless Association, STEPS and Reach
- Patient User and Support Groups
- Military Charities e.g. British Limbless Ex-Service Men's Association (BLESMA), Armed Forces Networks and Help for Heroes

4. Applicable Service Standards

4.1 Core Requirements

Core Requirement 1 - The provider can demonstrate the prosthetics service is provided by a specialised multi-disciplinary amputee rehabilitation team with training in the field of prosthetic rehabilitation appropriate to the level of service, which include the following:

- access to a consultant in rehabilitation medicine with a special interest in amputee rehabilitation
- MDT to include from the following: prosthetists; occupational therapists; physiotherapists; podiatrists; orthotists; clinical nurse specialists; dieticians; psychologists; counsellors; prosthetic technicians; rehabilitation engineers; healthcare assistants; social workers; clinical and administrative support staff and peer group volunteers.

Core Requirement 2 - The provider can demonstrate the prosthetics service has full access to a medical assessment e.g. assessments for medical issues such as sore, infections, swelling, bursa formation, sinus formation, veracious hyperplasia.

Core Requirement 3 - The provider can demonstrate the prosthetics service has full access to therapeutic intervention e.g. provision of a different knee unit frequently requires gait re-education and provision of a different hand or elbow unit frequently requires occupational therapy intervention

Core Requirement 4 - The provider can demonstrate the prosthetics service is provided in specially designed and adapted facilities to meet the needs of prosthetic patient. The Service has appropriate paediatric facilities and be responsive to the special needs of children with limb deficiency and limb loss.

Core Requirement 5 - The Service Provider can demonstrate that patients have access to the following information at the Centre:

- Information about the Centre and the services provided including opening times, contact details and access.
- Contact details of the named clinicians involved in their care.
- Details of Patient User Groups, Patient support systems, National Charities and Organisations in relation to limb loss

4.2 Applicable national standards e.g. NICE

To protect and promote the best interests of the patient, it is vital that all service providers comply with all Clinical Governance applicable national standards, which include but are not limited to:

All Service Centres must be in receipt of, or be able to evidence working towards, third party accreditation in respect of quality, service delivery and customer service standards e.g. ISO 9001-2008 & Customer Service Excellence.

The Service Provider must ensure that policies are in place to cover all aspects of Health and Safety and to demonstrate monitoring/action plans to resolve problems:

- Patient safety – Incident and accident reporting mechanisms and infection control
- Equipment Issues – Medicines and Healthcare Products Regulatory Agency reporting, reuse of components, Planned Preventative Maintenance

Service Providers must ensure that all Clinicians/Healthcare Professionals have:

- Annual performance reviews which should include appraisal of performance and objective setting
- Annual Development Plans to enable them to undertake any required training and to perform to their maximum potential
- Protected time for Continuing Professional Development, practice placement support and preceptorship for newly qualified staff
- To work to this specification and national supporting policies and any appropriate professional guidelines

In conjunction with this service specification Quality & Service should also take account of a provider's:

- Ability to meet/surpass this specification
- Capacity of service & confidence in ability to deliver quality outcomes
- Ability to provide adequate clinical and technical cover for patients
- Transition planning and sustainability
- Improvements in Patient Outcomes
- Quality, standards assurance, performance management, implementation
- Use of policies, guidance and user group views to shape services
- Experience & achievements, methods & tools
- Innovation & creativity

There is collective responsibility within the spirit co-production, participation and collaboration to improve and innovate service(s) locally, regionally and nationally.

National quality measures are being developed in Patient Related Outcome Measures (PROMS) and CQUINS and Quality Innovation Prevention and Productivity (QIPP). When available they should be used in conjunction with this specification.

Other relevant documents are included but are not limited to those shown in **Appendix 3**.

4.3 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

Specific equipment is needed for the fabrication of full artificial limb sockets and the production of artificial limbs. Each patient is an individual and it should be the expertise of the skilled healthcare professional that determines any prescription. This is a specialist bespoke service that cannot be prescribed in advance.

Professional guidelines are included but not limited to those shown in **Appendix 3**.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Appendix 6 Parts A-D)

5.2 Applicable CQUIN goals (See Appendix 6 Part E)

6. Location of Provider Premises that have been through the Formal Designation Process

Designated Provider's include but are not limited to premises located in the following areas:

Birmingham Community Healthcare NHS Trust; Royal Bournemouth & Christchurch Hospitals NHS Trust; Sussex Community NHS Trust; North Bristol NHS Trust; Cambridge University Hospitals NHS Foundation Trust; North Cumbria Acute Hospitals NHS Trust; South Tees Acute Hospitals NHS Trust; Colchester Hospitals University NHS Foundation Trust; South Derbyshire Acute Hospitals NHS Trust; Royal Devon & Exeter Healthcare NHS Trust; Kent and Medway NHS Social Care Partnership Trust; North East London NHS Foundation Trust; Hull and East Yorkshire Hospitals NHS Trust; Isle of Wight NHS trust; Leeds Teaching Hospitals NHS Trust; Leicester Specialist Mobility Centre; Aintree Hospitals NHS Trust; Hammersmith Hospitals NHS Trust; Guys and St Thomas' NHS Foundation Trust; St George's Healthcare NHS Trust; Royal National Orthopaedic Hospital; Luton & Dunstable NHS Foundation Trust; University Hospital of South NHS Foundation Trust; Newcastle upon Tyne Hospitals NHS Foundation Trust; Northampton General Hospital NHS Trust; Norfolk Community Health & Care NHS Trust; Nottingham University Hospitals NHS Trust; Oxford University Hospitals NHS Trust; Plymouth Community Healthcare NHS Trust; Portsmouth Hospital NHS Trust; Lancashire Teaching Hospitals NHS Foundation Trust; Sheffield Teaching Hospitals NHS Foundation Trust; Staffordshire and Stoke on Trent Partnership NHS Trust; Wirral University Teaching Hospital NHS Foundation Trust and The Royal Wolverhampton NHS Trust

7. Individual Service User Placement

Appendix 1 – Veteran Prosthetic Services

This appendix has been developed to support this specification in the commissioning of veterans' prosthetics services by NHS England and is focused on delivering the principal recommendation of the report "A better deal for military amputees", namely the delivery of nationally commissioned specialised prosthetics services for veterans.

In addition to the civilian numbers shown in the service specification, service centres will provide an enhanced service to veterans who have lost a limb in the service of their country.

New veterans will, generally speaking, be veterans of recent conflicts e.g. Iraq and Afghanistan. They have had prolonged periods of intensive intervention and rehabilitation at the Defence Medical Rehabilitation Centre Headley Court. So the purpose of this service for these veterans is to maintain the existing level of function. This will be achieved through maintenance of existing prostheses, replacement of these prostheses when required, upgrading of prosthetic components where appropriate, ensuring that excellent socket fit is achieved and maintained and regular MDT review to ensure optimum physical condition and independence as near to levels at discharge from Headley Court as possible. Other services e.g. psychological support may or may not be required, and this will need to be identified in the assessment and planning of individual's needs.

Both new and existing veterans of any conflict, who may well be established patients of an existing Tertiary, Standard or Satellite service centre (definitions of which are included within the specification), which may not be a centre with enhanced veteran care (EVC)¹, and who may be happy with their existing service, and may choose to continue to use that centre², transfer their care to another centre and or continue to use their existing service whilst accessing certain enhanced services e.g. MDT services, advanced socket technology, rapid access to pain management and psychology.

Serving personnel who have lost limbs will be reassured that should they leave the military that they will continue to receive high quality prosthetics and services in the NHS. Their amputation rehabilitation needs continue to be met and that independence gained during their rehabilitation at Defence Medical Rehabilitation Centre Headley Court continues.

Defence Rehabilitation Services

Eligible Service personnel leaving the armed forces who are making the transition into civilian life will be referred into NHS services through the Defence Medical Rehabilitation Programme.

The Defence Medical Rehabilitation Programme

All NHS prosthetics services will have some veteran patients. Some centres will have high densities of veterans because they are located close to areas where people settle after military service. Centres with higher densities of "post 9/11" veterans i.e. veterans of the conflicts in Iraq and Afghanistan, are required to have contacts with parts of the Defence Medical Rehabilitation Programme particularly Headley Court. The aim of the Defence Medical Rehabilitation Programme is to return those service personnel to operational levels of fitness as soon as possible – the "fitter quicker" principle – where this is not achievable the aim is to attain the maximal level of physical, psychological and social health. Enhanced prosthetics services for veterans in the NHS will be expected to achieve a similar aim.

Services for Military Veterans

¹ Centres with enhanced veteran care i.e. funding via the Murrison report funds will be called enhanced veteran care centres, within this operating model to differentiate them from tertiary and standard centres.

² Dr Daniel Poulter MP, Parliamentary Under Secretary of State for Health said that: "Veterans are free to choose the Centre from which they receive their care and NHS England will continue to agree funding requests for high specification prosthetics through the Veterans Prosthetics Panel regardless of which disablement service centre they attend." and "Veterans are free to choose which Centre they receive their care from and there is no requirement or expectation that any veteran will be asked to move to one of the nine centres."

Services for veterans will be incorporated within NHS prosthetic services and in complex cases are likely to take place in the EVC centres. All new veteran patients must be considered a primary referral for their first attendance.

Centres that provide services to veterans will have resources to support veterans as below:

- Identification of veterans
- Have a robust patient information management system
- Be able to identify veterans on this system
- Be able to identify if injuries are service attributable (for people injured after 2005 this is straightforward as Service Personnel and Veterans Agency have electronic records, before this the veterans' own records will need to be viewed by a clinician)
 - This information (and where possible a copy of the documentary evidence such as the War Pension letter or AFCS Award Notice) will need to be provided for each subsequent request for funding via the Veterans Prosthetics Panel. This information should therefore be recorded and maintained with the patient record.
- Be able to identify type of amputation, prosthetics, and history including socket types

Treatment of veterans:

- Centres will offer an upper and lower limb service to veterans
- All new veterans transitioning into the NHS from the Defence Medical Rehabilitation Programme should be seen at a tertiary centre by a consultant in rehabilitation medicine in the first instance, who will allocate their primary clinician subject to the veterans individual choices of centre, service provider and healthcare professional
- Subject to the veterans individual choices of centre, service provider and healthcare professional(s); veterans with complex stumps and/or multiple injuries should be managed at a tertiary centre by a consultant in rehabilitation medicine on an on-going basis, with full inputs from the Multi-Disciplinary Team where required. All veterans' will have an holistic assessment and treatment plan focusing on preservation of residual limb, excellent sockets, high quality prosthetics
- Any psychological health issues and any social issues should be assessed and identified and supported and treated accordingly
- All centres will have an identified pathway to an integrated wheelchair and special seating service, and orthotics provision
- There will be a clear pathway for veterans to access specialist pain management, and specialist plastic and vascular surgery
- Centres will offer enhanced prosthetics provision as outlined in the prescription guidelines shown below
- Intensive socket services e.g. multiple scans taken, multiple sockets developed until maximum comfort and utility is achieved
- Centres will offer advanced socket and scanning technology
- Centres will offer peer to peer and group support run by veterans for veterans
- Centres will offer access to or provision of specialist fitness, exercise and/or sports programmes for veterans

Support

Centres will offer access to a British Limbless Ex Service Men's Association support officer.

Outcomes data

Maintain or improve mobility, socket comfort, gait and satisfaction as measured by valid reliable, standardised outcome measures.

Relationships and transition

Tertiary services will link with standard and satellite centres and will offer consultation, advice and treatment to those veterans who choose not to use a tertiary centre on an on-going basis.

Tertiary centres will provide assertive in-reach to Defence Medical Rehabilitation Programme, particularly to Defence Medical Rehabilitation Centre Headley Court, to establish numbers of veterans likely to be medically discharged and likely dates. Tertiary centres will provide a 'Transition Service' in the assessment of all leaving service personnel and either retain them for treatment or refer them to an appropriate prosthetics centre. This will include ensuring that new veterans coming from the Defence Medical Rehabilitation Programme are normally identified 6 months prior to discharge.

Cost Data

Data collection on cost per case supplied to commissioners quarterly. Costs are broken down by each intervention and by each professional group to support the development of currencies.

Environment

The service will offer specialist veterans' clinics available outside normal working hours to ensure minimal disruption to working and home life, but to also ensure that other NHS patients are not disadvantaged.

Centres providing an enhanced service to veterans will be expected to demonstrate how they meet or exceed these standards. Services meeting most of the criteria will have access to the pool of "Murrison" funding available in 2012-15 to further enhance services.

Each centre will have a costed development plan showing the improvements to services for veterans that they wish to put in place over this period of time. All measures will be aggregated and Defence Medical Rehabilitation Centre and NHS Centres are required to liaise closely to ensure that they are aware of new veterans' making the transition to NHS services. This will be arranged well in advance of the discharge of the person concerned. An initial consultant-led MDT assessment will be carried out to ensure complete review on discharge from the armed forces. A joint document will be produced for the transfer of care.

Centres that wholly or substantially meet this service specification will offer enhanced services to veterans. These services will form a network of tertiary services across England. In addition to this, all enhanced services will support a number of standard and satellite centres in a "hub and spoke" model. This is to ensure that all existing veterans have access to specialist support and advanced socket technology should this be required. All centres will participate in a learning and development network that spans all prosthetic services, private sector providers (should they wish to participate) and the Defence Medical Rehabilitation Programme.

This specification also relates to military veterans ordinarily resident in England. It does not cover veterans in Scotland, Northern Ireland or Wales within which authorities are making their own arrangements for implementation of "A better deal for military amputees". Nor does it apply to crown dependencies such as the Isle of Man or the Channel Islands. A veteran is defined as any member of the armed forces who has served for one day or more.

Injuries must be service attributable.

Prosthetic devices for veterans are funded through the Veteran Prosthetic Panel. As part of the implementation of 'A better deal for military amputees' the Government has committed up to £15m over three years to fund prosthetics and to improve services for veterans. These prescription guidelines have been in use for veterans since April 2012 and are intended to reflect those used at Defence Medical Rehabilitation Programme Headley Court and to ensure that the commitment to a 'proper return for sacrifice' is met.

Prescription guidelines:

1. The veteran and their Multi-Disciplinary Team must demonstrate the benefit to the patient of any newly prescribed prosthetics. This will include evidence based measures of improved function, gait, mobility etc.
2. A trial period using a new prosthesis should be initiated
3. Provision of limbs will extend to:
 - a. Mobility and shower limbs including a spare that maintains function
 - b. Work related adaptations e.g. limbs with multiple grips
 - c. Basic recreation limbs for swimming or running
4. Funding will be available for the out of warranty maintenance of components provided by Headley Court as in 3 above
5. Updates and upgrades of components will also be funded. An update is a like-for-like replacement of a current component, and an upgrade would provide a component that offers increased functionality. Again, this is restricted to those categories mentioned above
6. High activity specialist or sporting limbs would not routinely be considered for funding, nor would funding provision be made for out of warranty maintenance of such specialist limbs
7. The following components would not routinely be considered:
 - a. Components not CE marked and passed standards for use in this country
 - b. High cost components
 - c. Components not routinely used in Headley Court
 - d. Components that are being used as part of a trial or to support a study.
8. Provision will be made for items that would provide ancillary mobility. Again benefit to the patient must be demonstrated via the application process and supported by evidence

Appendix 2 - Specialised Multi-Disciplinary Team

This team (with the possible exception of the dietician, podiatrist and social worker) would be based in the rehabilitation service centre and with in-reach to the wards, and is in no particular order.

Consultant in Rehabilitation Medicine (usually with a special interest in amputee rehabilitation)

The consultant should be responsible for the overall clinical care of the patient, although it is appropriate for other team members to lead on specific areas of care. In the current NHS structure, the consultant physician is generally considered to be the most appropriate team leader. The role of the Consultant in Rehabilitation Medicine is well described in the Royal College of Physicians' Report, Medical Rehabilitation for People with Physical and Complex Disabilities (2000) and the Clinical Governance Supplement of Clinical Rehabilitation. Supporting medical staff may include an Associate Specialised, Staff Grade doctor or a Clinical Assistant for service provision, and a Specialised Registrar in Rehabilitation Medicine undertaking training. The Consultant in Rehabilitation Medicine should have completed the accredited training for a Consultant in Rehabilitation Medicine (currently CCST in Rehabilitation Medicine includes 3 months mandatory training in Amputee Rehabilitation). However to specialise in this field will need an extra 12 months in the area. This equates to a total of 15 months full-time (3 months compulsory plus 12 months optional).

For an appointment at the nodal Referral specialised rehabilitation service centre the Consultant should have this extra training and experience particularly in the management of congenital limb deficiency, complex and multiple limb loss and more specialised prosthetic techniques.

Prosthetists

Prosthetists are all registered Allied Health Professionals with the Health and Care Professions Council and have undertaken degree education with a recognised UK or overseas University.

Prosthetists provide the best possible artificial limb for patients who have lost or were born without a limb. Prosthetists should be conversant with the guidelines published by the British Association of Prosthetists and Orthotists (BAPO, 2000) and available on their website (www.bapo.com). Within their HCPC registration all Prosthetist / Orthotists are able to assess, diagnose, and prescribe and provide appropriate prosthetic treatment.

Designated Prosthetists should manage or oversee the prosthetic care of patients with the rarer types of limb loss (e.g. congenital limb deficiency or upper or multiple limb loss) in order to develop and maintain the specialised experience necessary to meet the needs of these patients. This approach should be considered for all children and is supported by the Prosthetic Paediatric Consortium.

Prosthetic Technicians

Prosthetic technicians main role is to manufacture the various types of prosthetic devices (protheses) supplied by their specialist rehabilitation service centre. Prosthetics patients require protheses to replace missing limbs, or part of a limb in order to allow them to lead as independent a life as possible.

Technicians are supplied with a measurement sheet, body cast, body tracing or a job card by a prosthetist. The technician will then be required to use their skills to manufacture the required protheses, which can be manufactured using a wide range of materials, including plastics, metals, leather, carbon fibre, and composite materials. All of the protheses manufactured are bespoke - designed specifically for each patient. Frequently the technician will be involved in the design stage.

Physiotherapists

Specialist physiotherapists should be experienced in amputee management, including lower limb pre-prosthetic and prosthetic rehabilitation/gait re-education skills training, have a good understanding of prosthetics, be able to look after limb loss patients with complex problems, and be conversant with the evidence-based clinical guidelines produced by British Association of Chartered Physiotherapy in Amputee Rehabilitation (BACPAR). They should have skills in goal setting and use of outcome measures. They should be able to liaise with, advise and educate the physiotherapists and other multidisciplinary team members in the referring (acute) and rehabilitating hospitals. It is recommended

that at least one physiotherapist within each Centre⁸ has a relevant post-graduate accredited qualification in Amputee Rehabilitation and should be graded as a clinical specialist. In tertiary centres knowledge of paediatrics is recommended and experience of upper limb loss management and prosthetics is advantageous. N.B. Many centres utilise the specialist occupational therapy skills for upper limb patients.

Occupational Therapists

Occupational Therapists undertake prosthetic limb training for patients with upper limb amputation or congenital deficiency, including training in one-handed activities where relevant. They also undertake training for activities of daily living for both upper and lower limb amputees and arrange home or school visits in liaison with physiotherapists and community therapists. A suitably experienced occupational therapist should be a member of the core clinical team at all specialised rehabilitation service centres. Occupational Therapists should be conversant with the guidelines produced by the College of Occupational Therapists (Appendix 3) and be members of the Prosthetic Occupational Therapy (POT's) network.

Clinical Nurse Specialists

Clinical Nurse Specialists are nurses trained in the holistic care of amputees. They should have undertaken training in tissue viability and wound management and have a good understanding of prosthetics and Amputee Rehabilitation. Many will have undertaken counselling courses to enable them to assist patients to deal with the emotional effects of their amputation. The role of the CNS in rural areas incorporates the maintenance of close links between hospitals and the specialised rehabilitation service centres

Rehabilitation Engineers

A Rehabilitation Engineer should be available to advise on technical matters related to the quality, risk management, maintenance, assessment and prescription (e.g. gait analysis) procurement and disposal of prosthetic devices. Rehabilitation Engineers can be either Clinical Scientists or Clinical Technologists. The former are registered under the Health and Care Professions Council, the latter are registered on the Voluntary Register of Clinical Technologists, after completing training schemes with the Institute of Physics and Engineering in Medicine. Registrations are under review by the Academy of Healthcare Science.

Orthotists

Orthotists are all registered Allied Health Professionals with the Health and Care Professions Council and have undertaken accredited degree education with a recognised UK or overseas University.

Orthotists should be conversant with the guidelines published by the British Association of Prosthetists and Orthotists (BAPO, 2000) and available on their website (www.bapo.com). Within their HCPC registration they are qualified and able to assess, diagnose, prescribe, and provide appropriate orthotic treatment.

Assistant Practitioner

Assistant Practitioners act under the guidance of a qualified healthcare professional. The role can be very varied depending upon the area in which the person is employed.

Healthcare Assistants

Healthcare assistants act under the guidance of a qualified healthcare professional. The role can be very varied depending upon the area in which the person is employed. Their role includes: washing and dressing, feeding, helping people to mobilise, toileting, generally assisting with patients overall comfort, monitoring patients conditions by taking temperatures, pulse, respiration's and weight.

Podiatrists

A Podiatrist should be available, particularly to provide care for the remaining foot in unilateral lower limb diabetic or dysvascular amputees, or appropriate links with local podiatric services must be established.

Psychologists / Counsellors

A counselling service must be provided by Clinical counsellors who have experience of working in a Rehabilitation setting. Although basic counselling will indirectly be provided by many members of the specialised multi-disciplinary team, patients at all centres should have the option of seeing a qualified Clinical Counsellor. The counsellor should be available to see relatives or carers of the amputee.

A clinical Psychologist with experience in dealing with the particular problems of patients with physical disabilities should be readily available to see selected patients.

Dieticians

Provides counselling regarding nutrition issues to improve health, aid in optimal weight maintenance and healthy living.

Social Worker

A hospital Social Worker/Care Manager should be available to establish the appropriate links with Social Services; identify any continuing health care needs, give advice regarding benefits and other financial matters, and to be involved with plans for discharge from the acute hospital.

Peer Group Volunteers

Are available on part-time basis to talk to patients (who are interested) and help patients.

Appendix 3 – Relevant Documents

Government

- National Service Framework for long-term conditions (2005)
- Dr Andrew Murrison MD, MP 'A Better Deal for Military Amputees', 2011
- Department of Health (2010), Equity and excellence: Liberating the NHS: section 3 Putting the patients and the public first, Department of Health, London
- Audit Commission (2000), Fully equipped; The provision of equipment to older or disabled people by the NHS and social services in England and Wales, London <http://archive.audit-commission.gov.uk/auditcommission/nationalstudies/health/socialcare/pages/fullyequipped.aspx.html>
- Audit Commission (2002), Fully equipped: Assisting independence, London <http://archive.audit-commission.gov.uk/auditcommission/nationalstudies/health/socialcare/pages/fullyequipped2002.aspx.html>
- Audit Commission (2004), Guidance on the commissioning of prosthetics services, London, <http://archive.audit-commission.gov.uk/auditcommission/SiteCollectionDocuments/AuditCommissionReports/NationalStudies/olderpeopleprosthetics.pdf>

NICE

- NICE Guidelines: Prevention of Cardiovascular disease (June 2010)
- NICE Guidelines: Physical Activity Guidelines in the UK (May 2010)
- NICE Guidelines: Promoting Physical Activity for Children and Young People (Jan 2009)

Multi-Disciplinary Team

- Commissioning For Patients: Guidance on National Commissioning of Specialised Services for People of All Ages with Limb Loss (2011), National Patient and Professionals Stakeholders, London
- British Society of Rehabilitation Medicine (2003), Amputee and Prosthetic Rehabilitation – standards and guidelines (2nd edition) section 4.19, British Society of Rehabilitation Medicine, London
- National Prosthetic Centre Managers Group (2010), National Service Specification for Prosthetic and Amputee Rehabilitation Services, National Prosthetic Centre Managers Group, Preston
- Royal College of Physicians & British Society of Rehabilitation Medicine (2010), Medical rehabilitation in 2011 and beyond. A report of a working party (6.21), London
- British Association of Prosthetists and Orthotists (2005), Guidelines for best practice No 1: The Role of the Prosthetist/Orthotist (Issued 2000 and then re-issued in February 2005, British Association of Prosthetists and Orthotists, Paisley
- Clinical Guidelines for the Physiotherapy Management of Adults with Lower Limb Prosthesis – British Association of Chartered Physiotherapists in Amputee Rehabilitation Guidelines December 2012
- Occupational Therapy with People who have had lower limb amputations. Evidence based guidelines. College of Occupational Therapists (2011) College of Occupational Therapists Ltd. 106-114 Borough High St, London SE1 1LB www.cot.co.uk/sites/default/files/publications/public/Lower-Limb-Guidelines%5B1%5D.pdf
- Occupational Therapy with Adults who have had lower limb amputations. Fact sheet (2013) www.cot.co.uk/sites/default/files/commissioning_ot/public/Lower-Limb-Evidence-Fact-sheet.pdf
- Upper limb Prosthetic Rehabilitation – Guidance document. College of Occupational Therapists (2006) College of Occupational Therapists Ltd. 106-114 Borough High St, London SE1 1LB

Patient

- CES (2010), Patient-led Prosthetics Services Charter, emPOWER consortium of charities, London www.em-pow-er.org/resources/Prosthetics+Charter+emPOWER+v11+Jan+2013.pdf
- Gallop, S & McNeice, SR (2009), Pain Free Mobility and Dexterity with Pathfinder Prosthetists eBook, CES a division of limbPOWER a trading style of the emPOWER consortium of charities, London www.em-pow-er.org

Appendix 4 – Children’s Services

Aims and objectives of service

This specification annex applies to all children’s services and outlines generic standards and outcomes that would be 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 March2010). Within the network:

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

- It will be clearly defined which imaging test or interventional 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 (CPD)
- 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) training² and should maintain the competencies so acquired³ *. 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

1. Guidelines for the Provision of Anaesthetic Services (GPAS) Paediatric anaesthetic services. Royal College of Anaesthetists (RCoA) 2010 www.rcoa.ac.uk
2. Certificate of Completion of Training (CCT) in Anaesthesia 2010
3. 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. 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 permits 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)

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). These require:

- A choice of suitable and nutritious food and hydration, 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 medicine 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.

Appendix 5 - PATIENT PATHWAY: REHABILITATION PHASE

The following represent the pathways of referrals to the service. The most common form of referral is from the vascular surgeons, but this also carries for orthopaedic and plastic surgeons.

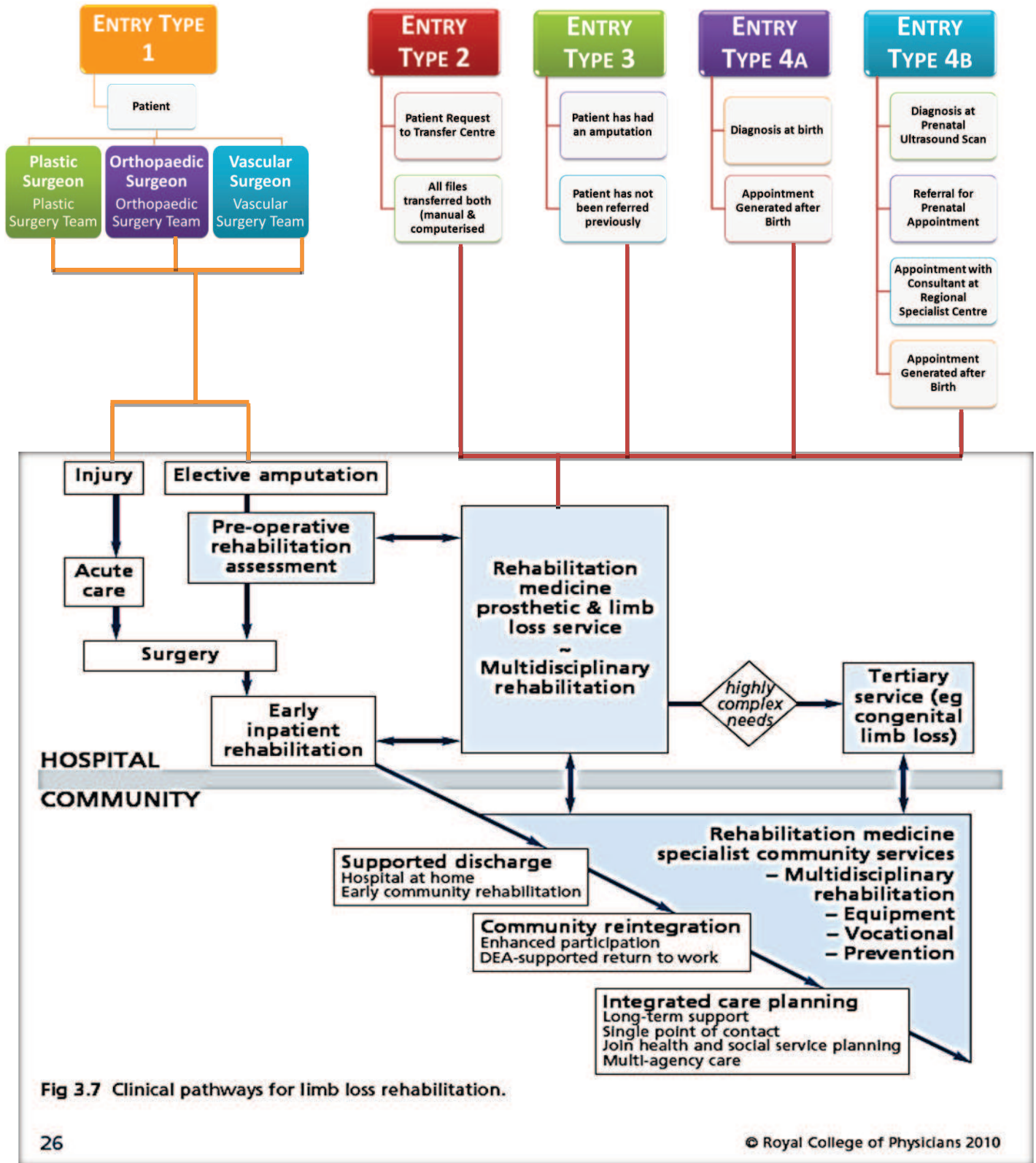


Fig 3.7 Clinical pathways for limb loss rehabilitation.

NOTE: This does not reflect the service for veterans

Appendix 6 - Quality standards specific to the service using the following template:

It is the intention in the future that patients would be able to access details and performance data of Quality Standards contained within this template or otherwise for their service provider.

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Maintaining and or improving existing levels of fitness	To be agreed with service provider	SIGAM & K levels Outcome measures	Noncompliance with contract
Diabetes Management including residual limb care and prevalence of further amputations	To be agreed with service provider	Patient review and Audit of numbers of surgical residual limb revisions and any further amputations	Noncompliance with contract
Domain 2: Enhancing the quality of life of people with long-term conditions			
Achievement of agreed individual patient goals	To be agreed with service provider	EuroQol-5D Outcome Measure	Noncompliance with contract
Agree collaboratively Personalised Care Plans with the Patient	To be agreed with service provider	Care Plan Audit	Noncompliance with contract
Promoting Physical Activity	To be agreed with service provider	SIGAM & K levels Outcome measures & Patient Questionnaire	Noncompliance with contract
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Agree collaboratively Personalised Care and Recovery Plans with the Patient	To be agreed with service provider	SF12 Health Survey	Noncompliance with contract
Domain 4: Ensuring that people have a positive experience of care			
Customer Service Excellence Award	To be agreed with service provider	Annual review of award & Patient satisfaction survey	Noncompliance with contract
Local Patient Satisfaction Survey	To be agreed with service provider	Local or Nationally designed questionnaire delivered through a variety of mediums	Noncompliance with contract
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
ISO 9001-2008 accreditation	To be achieved and maintained no later than 12 months from contract	Annual Audit	Noncompliance with contract
Completion of IR1s and	To be agreed with	Monthly Audits and Action Plans	Noncompliance with contract

Risk Assessments	service provider		
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SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	E07/S/a
Service	Level 3 - Paediatric Critical Care (PCC)
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Paediatric Critical Care (PCC) services look after children and young people whose conditions are life-threatening and need constant close monitoring and support from equipment and medication to restore and/or maintain normal body functions. The definitions of the full range of Paediatric Critical Care is provided below.

This specification specifically covers care provided in Level 3 Paediatric Critical Care (PCC) units previously known as PICUs, (Paediatric Intensive Care Units) which are usually located in tertiary centres or specialist hospitals which provide all 3 levels of PCC. However PCC level 3 units will care for patients across the whole range of PCC levels 1 – 3.

PCC level 3 units provide care for children requiring intensive care and monitoring, including medically unstable patients requiring intubation or ventilation, single or multi-organ support, and continuous or intensive medical or nursing supervision. PCC level 3 units also provides routine planned post-operative care for surgical procedures, or

during some planned medical admissions.

1.2.

The definitions of the full range of Paediatric Critical Care (PCC) are as follows:

- Level 1 paediatric Critical Care Units (PCCUs) will be located in all hospitals providing inpatient care to children and will deliver level 1 PCC care. (Provided in all District General Hospitals which have in-patient facilities and is not commissioned by NHS England).
- Level 2 PCCUs may be specialist or non-specialist and are provided in tertiary hospitals and a limited number of DGHs and will deliver level 1 & 2 care. These were formerly classified as HDUs. (Commissioned by NHS England)
- Level 3 PCCUs (PICUs) are usually located in tertiary centres or specialist hospitals and can provide all 3 levels of PCC.(Commissioned by NHS England)

The service model and standards outlined in this specification are congruent with the revised *Standards for the Care of Critically Ill Children* (4th Edition, 2010), produced by The Paediatric Intensive Care Society (see section 1.2 for link)

Case-mix and level of intervention performed varies substantially between units depending on the tertiary services supported and local provision of level 2 PCC services.

In England 1.4 children per 100,000 population are admitted to a PCC Level 3 unit.

Paediatric Critical Care Minimum Data Set (PCCMDS) data submitted to Paediatric Intensive Care Audit Network (PICANet) from PCC care providers in the UK and Ireland, presented in the Annual Report of PICANet, Jan 2008 to Dec 2010 for the 0–15 age group, indicate the following national averages:

- 40.9% of admissions (52,337 in total) to PIC level 3 are planned - 34.2% (17,891) following surgery, and 6.7% (3,513) for non-surgical reasons.
- 59.1% (30,933) of admissions are for unplanned emergency care.
- The top three indications for admission to a PCC level 3 unit are: cardiovascular (28.6%); respiratory (26.0%); and neurological (11.0%).
- 65.7% require invasive mechanical ventilation (i.e. via an endotracheal tube) during their stay; 14.9% will require non-invasive ventilation.
- These averages conceal substantial inter-unit variation, with the percentage of children on PCC requiring invasive ventilation varying from 6 to 85%.

<http://www.picanet.org.uk/ : Documents/General/Annual%20report%20published%202011/Annual report 02 12 11v2.pdf>

PCC should be planned on an annualised overall average occupancy of around 80%. However, there is considerable seasonal variation in demand, and PCC units are especially susceptible to “winter pressures” due to the increase in severe respiratory infections (especially bronchiolitis) during the winter months.

Providers need to make contingency plans to manage this pressure. A PCC unit must be able to plan to meet demand based on local/regional circumstances and historical activity patterns.

An important aspect of capacity planning is to ensure the ability to flex staffing to meet the demand for occupancy levels above normal levels where necessary, while maintaining a safe service. Close cooperation between the following partners is essential to maintain adequate capacity at times of peak demand:

1. PCC units and referring hospitals within networks
2. Adult and neonatal critical care networks
3. Transport services.

Level 3 PCC units need to co-operate, as part of a national system, with other units to deliver optimal flexibility during periods of peak demand.

1.3. Evidence Base

National reference documents relating to the service standards for paediatric critical care services, and referenced in this specification are:

- Department of Health (2008) Commissioning Safe and Sustainable Paediatric Services: A Framework of Critical Interdependencies
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_088068
- Department of Health (2006) Review of Commissioning Arrangements for Specialised Services (the Carter Review)
http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Managingyourorganisation/Commissioning/Commissioningspecialisedservices/DH_4135174
- Department of Health (2006) The acutely or critically sick or injured child in the district general hospital
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_062668
- Department of Health (2006) Critical Care Minimum Data Set (CCMDS)
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_116368
- Department of Health (2003) Getting the Right Start: National Service Framework for Children; Standards for Hospital Services
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006182
- Department of Health (1997) A Bridge to the Future: nursing standards, education, workforce and planning in paediatric intensive care
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005506
- Department of Health/Health Services Directorate (1997) Paediatric Intensive Care: "A Framework for the Future"
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005760
- Healthcare Commission (2007) Improving Services for Children in Hospital
http://caredirectory.cqc.org.uk/db/documents/Improving_services_for_children_in_hospital.pdf
- Paediatric Intensive Care Society (2010) Standards for the Care of Critically Ill Children (v.2, 4th ed.) http://www.ukpics.org.uk/documents/PICS_standards.pdf
- Royal College of Nursing (2011) Health care service standards in caring for

neonates, children and young people

http://www.rcn.org.uk/data/assets/pdf_file/0010/378091/003823.pdf

- Safeguarding children and young people-roles and competencies for health care staff. Intercollegiate document, September 2010.
<http://www.rcpch.ac.uk/safeguarding>
- Protecting children and young people: responsibilities of all doctors. GMC Sept 2012. www.gmc-uk.org/guidance.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

Key Outcomes:

1. Risk Adjusted Mortality – (Domain 1, 4, 5,)
2. Refused emergency admissions for the population served, resulting in an out of network transfer (Domain 1, 3, 4, 5,)
3. Cancelled elective surgical procedures due to lack of PIC bed (Domain 1, 3, 4, 5,)
4. Unplanned readmissions to PICU within 48 hours of a previous discharge / transfer from PICU (Domain 1, 3, 4,5,)
5. Patient deaths in PICU discussed at a multi-disciplinary review meeting (M&M) within 3 months of date of death, with written documentation of the findings and an action plan (Domain 1, 4, 5,)
6. Timely participation in PICANET (Domains 1, 3, 5)
7. Discharge letters to the next lead carer dispatched within 48 hours of discharge from PCC (Domain 3,4,)
8. Rate of accidental extubation of patients (Domain, 1,3,4,5,)

PCC level 3 providers are required to submit data to the SUS and PICANet. Furthermore there is a national quality dashboard in place for PIC level 3 services, and data submission is mandated via CQUIN.

3. Scope

3.1 Aims and objectives of service

The aim of the PCC level 3 service is to provide care for the critically ill or injured child, including those recovering from elective surgery and that care is delivered "within PCC level 3 units conforming to agreed guidelines and standards" (PIC Standards June 2010). These national standards set out the optimal requirements for the care of critically ill children and their families and identify specific medical, nursing, technical and emotional needs that are best provided by a specialist Paediatric Intensive Care multidisciplinary team in a PCC level 3 unit. .

The PCC level 3 service will deliver care in line with the national standards (PICS 2010).

Key Service Principles are:

- PCC level 3 is provided as part of a pathway of care and co-located with other specialist children's services and facilities.
- PCC level 3 will not normally be provided outside of a level 3 centre with the exception of short term care until the arrival of the PCC retrieval team. PCC level 3 care should only be provided in adult Intensive care units as part of a local agreement with the lead centre and in line with agreed network pathways.
- PCC level 3 units must provide or have access to a 24 hour Retrieval Service.
- PIC must be provided by appropriately trained staff in equipped facilities. Families should be able to participate fully in decisions about the care of their child and wherever possible, in giving this care.
- Appropriate support services to children and families during the child's critical illness and, if necessary, through bereavement must be provided.
- There must be active support to the care of critically ill children in referring hospitals, including through advice, training and audit delivered through a network.

3.2 Service description/care pathway

Children will access level 3 PCC through a number of routes including:

- Inpatient children's services within the same hospital
- Operating theatres
- Neonatal units and occasionally, labour wards.
- Emergency Department

PCC Transport Services (as per Service Specification E07/S/d) will facilitate many of

the admissions to from level 1 and 2 PCC units into level 3 PCC units and protocols for transfer will apply as per the PCC Transport Service Specification.

Level 3 PCC units must ensure that comprehensive referral pathways and mechanisms are in place, and that similar pathways are in place to support egress from the service.

Paediatric critical care services must be available and fully operational 24 hours per day, 365 days per year.

PCC Level 3 care is delivered in 3 types of hospital within a network model:

- Level 3 PCCUs, providing most of the PCC level 3 care needed in the area and supporting the whole service for the area through provision of advice and training.
- Major acute general hospitals with large adult intensive care units, which already provide a significant volume of paediatric intensive care.
- Specialist hospitals providing some PCC level 3 in support of specific specialties (e.g. cardiac surgery, neurosurgery, burn care).

3.2.1.

The level 3 PCC, working as part of a Network will be responsible for the development of appropriate referral and care pathways with other level 2 and 1 PCC providers within its catchment.

The level of complexity of patients will vary as described in the table below:

PCC level	Provided in:	Description	Nurse dependency level	Nurse: patient ratio
1	Level 1,2 & 3 PCCU	Children requiring monitoring or interventions defined by PCCMDS HRG 1	High dependency care (basic)	0.5:1 (1:1 if in a cubicle)
2	Level 2 & 3 PCCU	Children requiring monitoring or interventions defined by PCCMDS HRG 2	High dependency care (advanced)	
3	Level 3 PCCU	Children requiring ventilatory support or support of two or more organs systems. Children at level 3 are usually intubated to assist breathing. HRG 3&4	Intensive care	1:1
		Children undergoing complex monitoring and/or therapeutic procedures, including advanced respiratory support. HRG 5&6	Advanced Intensive care	1.5:1
	Level 3 PCCU which supports cardiac surgery	Children receiving treatment by extra-corporeal membrane oxygenation (ECMO) HRG 7	Specialised intensive care	2:1

Not all level 3 PCC units offer all levels of care. Some PICUs act as Lead Centres with a fuller range of paediatric intensive care services and capabilities whereas other units offer more limited levels of care in consultation with a Lead Centre.

Children may require cardiovascular or renal support, intracranial pressure monitoring or other advanced interventions, or may need to be nursed separately in a cubicle. The

complexity of nursing and medical support for these aspects of care necessitates a high staff to patient ratio follows:

In most cases, patients undertake a "step-down" pathway to level 2 or level 1 PCC and/or regular paediatric wards (often to a hospital closer to the patient's home) prior to discharge home. The standards and commissioning responsibilities for level 2 PCC services are outlined in a separate service specification. (Ref:E07/S/b)

Patients may require care in a PCCU if they are in the process of transitioning to alternative permanent long-term ventilation (LTV) facilities (possibly requiring home adaptations), or to palliative care placements. However, once a patient has been medically stable on LTV for 90 days, commissioning responsibility and charges pass to local Clinical Commissioning Group commissioners.

Further information on LTV services is available in the separate Long Term Ventilation service specification. (Ref: E07/S/C)

PCC units which are co-located with paediatric cardiac surgery centres are occasionally required to undertake ECMO.

Further information on cardiac ECMO services is available in the paediatric cardiac surgery specification. (E05/S/a)

There should be arrangements for the transfer of children requiring specialised intensive care (including for specialist burns care, respiratory ECMO, organ transplant etc.) not available at the admitting unit.

3.2.2 Multidisciplinary Team

Level 3 PCC units will need to maintain excellent working relationships and undertake frequent liaison with appropriate areas/bodies according to the needs of the child as per PICS standards.

Complex discharge planning may need to involve external agencies such as continuing health care teams, education and housing authorities and social services.

3.3 Population covered

Children up to the age of 16 are normally cared for in a Paediatric Critical Care environment, although the *National Service Framework for Children* (section 1.2 for link) states the age range for inclusion within paediatric care is 0-18 years (up to but not including the 19th birthday).

PCC services shall be available to all critically ill children from the point of discharge from maternity or a neonatal unit until their 16th birthday.

In addition, on rare occasions a PCC unit may be deemed to be the most clinically appropriate place to provide critical care to young adults between the ages of 16-24 years (up to but not including the 24th birthday) – for instance as part of a long-term pathway of care managed by a paediatric team or because of their stage of physical or emotional development. Young people who have not completed transition to adult services will usually be cared for in a PICU unless they, or their carers, express a different preference.

Therefore, any patient between the ages of 0-24 years cared for in a designated **level 3 PCC** or transferred to or from a level 3 PCC unit by a commissioned paediatric critical care transport service, will be considered to be accessing paediatric critical care.

Ensuring equity of access to any specialised service can present challenges, particularly in areas with a large geographical area and sparse population. There is a balance to be found in ensuring that a PCC unit has sufficient activity to maintain clinical competence and safety, but allowing access to as much of the population being served as possible within a limited travelling distance.

It is important that all level 3 PCC units are supported by **PCC Transport Services**, and that **level 3 PCC** units have systems in place to ensure that capacity is optimally managed with sufficient flex so that beds are available as required, both for emergency admissions and to support any complex elective or non-elective surgery. Further information on paediatric critical care transport services is available in the Paediatric Critical Care Transport specification.

Level 3 PCC units will agree region-wide policies with referring hospitals and paediatric critical care transport services for the management of time critical referrals, for example in the event of spinal or head injury trauma cases who may need to be transferred directly to a neurosurgical centre for emergency surgery.

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 GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

3.4 Any acceptance and exclusion criteria and thresholds

3.4.1. Acceptance criteria

Referral for admission to **level 3 PCC** is via secondary care (usually consultant) referral, and is possible from the following sources:

Internal sources (from within the same hospital)	<ul style="list-style-type: none"> • Planned booked admission following complex surgery • Emergency admission following surgery (following unexpected complications) • Paediatric ward • Paediatric HDU • Neonatal intensive care unit (NICU), Local Neonatal Unit (LNU) or Special Care Unit (SCU) • A&E
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External sources	<ul style="list-style-type: none"> • Paediatric Critical Care Transport services. • Occasionally, transfer by ambulance from another hospital using hospital staff.
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Referral from external sources is in the majority of cases via specialised paediatric Critical Care Transport, and must be the result of a consultant-to-consultant discussion.

Paediatric intensive care admission is mandatory for children likely to require advanced respiratory support (i.e. acute or medium term mechanical ventilation). Other children can be referred to level 3 PCC according to locally agreed pathways.

Patients will be transferred to a level 3 PCC unit if the expected length of intubation is more than 24 hours, unless a longer period has been explicitly agreed with the lead centre.

3.4.2. Exclusion criteria

Neonates that have not already been discharged home are not usually cared for in a PICU. However, arrangements may be agreed locally relating to the management of neonates requiring intensive care following surgery – for example, cardiac and gastrointestinal surgery. Any neonate cared for in a PICU will be classified as receiving paediatric critical care. When caring for neonates, care should be delivered in line with the DH Neonatal Toolkit. (2009).

Adult patients should not be treated in a paediatric critical care environment, though patients aged 16-18 years (or occasionally, up to 24 years) may be treated in a paediatric critical care environment if this is deemed to be the most appropriate location care based on individual needs (see section 2.3 above).

Children with a paediatric critical care stay of 4 hours or less will not be classified as having a chargeable PCC stay.

Only a limited number of centres nationally have the facilities to provide respiratory ECMO and other highly specialised paediatric intensive care, for example, Burns Care, though some PICUs providing Level 3 care have the ability to "step-up" their care level on a short-term basis.

This specification excludes respiratory ECMO.

3.5 Interdependencies with other services/providers

Paediatric Critical Care is a key interdependent service for a large number of specialised services, and also has several dependencies of its own, as detailed in *Commissioning Safe and Sustainable Paediatric Services: A Framework of Critical Interdependencies* (section 1.2 for link).

Paediatric Critical Care providers must comply with the co-location and adjacency requirements as set out in the interdependencies framework. Whilst links to adult

specialised services are important, the interdependencies between specialised children's services should take precedence.

Any failure to secure, or loss of, services identified with a red, amber 3 or amber 2 interdependency should provoke an immediate review by Area Team Commissioners, of the safety and sustainability of the delivery of paediatric intensive care.

Co-location in this context is defined as meaning either location:

- on the same hospital site or
- in other neighbouring hospitals if specialist opinion and intervention were available within the same parameters as if services were on the same site. These would be reinforced through formal links such as consultant job plans and on-call rotas.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

Not applicable

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

- Department of Health (1997) A Bridge to the Future: nursing standards, education, workforce and planning in paediatric intensive care http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005506
- Paediatric Intensive Care Society (2010) Standards for the Care of Critically Ill Children (v.2, 4th ed.) http://www.ukpics.org.uk/documents/PICS_standards.pdf
- Royal College of Nursing (2011) Health care service standards in caring for neonates, children and young people http://www.rcn.org.uk/_data/assets/pdf_file/0010/378091/003823.pdf

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

There are two PCC CQUINs on the national pick list which are as follows:

Prevention of Unplanned Readmissions to PICU within 48 hours
Transfers out of normal catchment/ network to PICU

There is a Quality Dashboard in Place for PCC the list of indicator reference numbers is provided below:

PIC01	Domain 1	Risk adjusted mortality
PIC02	Domain 5	Refusal Rate for Emergency Admissions
PIC03	Domain 4	Cancellation of Elective Paediatric Surgery
PIC04	Domain 5	Emergency Readmissions to PCC within 48 hours
PIC05a	Domain 5	Bed Occupancy
PIC05b	Domain 5	Bed Throughput Rates
PIC08	Domain 5	Rate of accidental extubation of patients
PIC09	Domain 5	% of death reviews conducted within 3 months
PIC10	Timeliness of PICANET Data submissions	% of data submissions within 3 months of discharge
PIC12	Effective Communication	% of handover letters to the next lead carer dispatched within 48 hours of discharge from PCC
PIC13	Retrieval Service Performance	% of refused requests for retrieval of a patient within define catchment
PIC14	Domain 1	Mobilisation of PIC retrieval team

6. Location of Provider Premises

The Provider's Premises are located at:

To be identified by Area Teams.

7.1 Individual Service User Placement

Not Applicable.

14/15 SPECIFICATION DRAFT - STAKEHOLDER TESTING STAGE

Appendix One

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Access to care within Network boundary , reducing transfer delays	<5% refused admissions	Quality Dashboard/PICANET	Non compliance with contract General Conditions 8 & 9
Standardised mortality	remain within 99.9% confidence limits	PICANET Data	Non compliance with contract General Conditions 8 & 9
Domain 2: Enhancing the quality of life of people with long-term conditions			
Effective and timely communication is supplied to receiving health care professionals following transfer / discharge from PICU	To be agreed	Quality Dashboard	Non compliance with contract General Conditions 8 & 9
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Cancellation of elective surgery due to bed unavailability	<5% elective surgery cancelled on the day of surgery owing to a lack of a PICU bed	Quality Dashboard	Non compliance with contract General Conditions 8 & 9
Domain 4: Ensuring that people have a positive experience of care			
Number in denominator where the team departs the transport base within 1 hour from the start of the referring call during period	To be agreed	Local collection	Non compliance with contract General Conditions 8 & 9
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
rate of accidental extubation, reduced number of unplanned extubation,	To be agreed	PICANET/Quality Dashboard	Non compliance with contract General Conditions 8 & 9

14/15 SPECIFICATION DRAFT - STAKEHOLDER TESTING STAGE

Appendix 3

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	E07/S/b
Service	Level 2 Paediatric Critical Care
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Paediatric Critical Care (PCC) is the provision of close observation, monitoring and therapies to children who are, or have a significant potential to be, physiologically unstable which is beyond the capability of a general paediatric ward.

Entry into PCC is governed by the degree of physiological instability as much as by diagnosis.

Three levels of PCC units are defined:

- Level 1 paediatric Critical Care Units (PCCUs) will be located in all hospitals providing inpatient care to children and will deliver level 1 PCC care. (provided in all district general hospitals which provide in-patient facilities and is not commissioned by NHS England)
- Level 2 PCCUs may be specialist or non-specialist and are provided in tertiary hospitals and a limited number of DGHs and will deliver level 1 & 2 care. These were formerly classified as HDUs. (commissioned by NHS England)
- Level 3 PCCUs (LEVEL 3 PCCUs) are usually located in tertiary centres or specialist

hospitals and can provide all 3 levels of PCC.(commissioned by NHS England)

This specification describes level 2 PCCUs

Children exit from Level 2 PCC either once their physiological condition stabilises to the point where they can be cared for on a general ward or their condition deteriorates and they require care on a Level 3 PCCU.

- Paediatric Critical Care is provided in an identified Paediatric CC setting: i.e. it is not provided on a general Paediatric Ward or an Adult HDU.

Level 2 PCC occurs in a number of locations:

- Within or alongside level 3 PCCUs, either as the highest level of care attained by some admissions or else as “step-up” or “step-down” care from an episode of Level 3 care.
- In defined Level 2 PCCUs, associated with other specialist services such as cardiology, burns or specialist surgery, usually in tertiary centres.
- In defined Level 2 PCCUs that are not associated with specialist services, usually outside tertiary centres.

Level 2 PCC will be provided in a manner in which it is under the clinical governance oversight arrangements of a designated Level 3 PCCU or through formal clinical network arrangements.

The Level 3 PCC service is under particular stress during the bronchiolitis season, which occurs November to January. During this period demand often exceeds capacity with the result that children are transferred long distances to access care. Adequate provision of Level 2 care will improve capacity in the system at this crucial time.

1.1.2. Evidence Base

National reference documents relating to the service standards for paediatric critical care services, and referenced in this specification are:

- Department of Health (2008) Commissioning Safe and Sustainable Paediatric Services: A Framework of Critical Interdependencies
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_088068
- Department of Health (2006) Review of Commissioning Arrangements for Specialised Services (the Carter Review)
http://webarchive.nationalarchives.gov.uk/;+http://www.dh.gov.uk/en/Managingyourorganisation/Commissioning/Commissioningspecialisedservices/DH_4135174

- Department of Health (2006) The acutely or critically sick or injured child in the district general hospital
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_062668
- Department of Health (2006) Critical Care Minimum Data Set (CCMDS)
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_116368
- Department of Health (2003) Getting the Right Start: National Service Framework for Children; Standards for Hospital Services
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006182
- Department of Health (1997) A Bridge to the Future: nursing standards, education, workforce and planning in paediatric intensive care
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005506
- Department of Health/Health Services Directorate (1997) Paediatric Intensive Care: “A Framework for the Future”
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005760
- Healthcare Commission (2007) Improving Services for Children in Hospital
http://caredirectory.cqc.org.uk/db/documents/Improving_services_for_children_in_hospital.pdf
- Paediatric Intensive Care Society (2010) Standards for the Care of Critically Ill Children (v.2, 4th ed.) http://www.ukpics.org.uk/documents/PICS_standards.pdf
- Royal College of Nursing (2011) Health care service standards in caring for neonates, children and young people
http://www.rcn.org.uk/data/assets/pdf_file/0010/378091/003823.pdf
- Safeguarding children and young people-roles and competencies for health care staff. Intercollegiate document, September 2010. <http://www.rcpch.ac.uk/safeguarding>
- Protecting children and young people: responsibilities of all doctors. GMC Sept 2012.
www.gmc-uk.org/guidance_

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

Currently there are no outcome measures specifically for level 2 PCC. Key Outcomes:

3. Scope

3.1 Aims and objectives of service

This Service aims to provide high quality Paediatric Critical Care which meets the standards set out in national guidance as close to home as possible for:

- Critically ill children whose severity of illness does not require acute invasive ventilation or specialist care.
- The care of long term ventilated children, either while waiting for discharge to the community or during treatment of episodes of inter-current illness.

The **Level 2 PCC** Service will achieve these aims by:

- Admitting children for care in designated Level 2 PCC beds aligned to the Level 3 PCCU service or in designated local services outside the Level 3 PCCU / regional critical care unit. These limited Level 2 PCC facilities will operate as part of a Paediatric Critical Care Clinical Network
- Facilitating both the avoidance of admission to Level 3 PCCU and rapid repatriation to a 'network' Level 2 PCC facility where that is safe and appropriate
- Avoiding unnecessary transfer for the child to a regional centre where appropriate care

can be delivered locally

- Reducing disruption and costs to parents of travel and support
- Enabling improved capacity at regional centres , therefore improving access for other critically ill children

3.2 Service description/care pathway

Level 2 PCCUs will work as part of a Network and will be responsible for the provision of level 2 care to their agreed catchment population.

The level of complexity of patients will vary as described in the table below:

PCC level	Provided in:	Description	Nurse dependency level	Nurse: patient ratio
1	Level 1,2 & 3 PCCU	Children requiring monitoring or interventions defined by PCCMDS HRG 1	High dependency care (basic)	0.5:1 (1:1 if in a cubicle)
2	Level 2 &3 PCCU	Children requiring monitoring or interventions defined by PCCMDS HRG 2	High dependency care (advanced)	
3	Level 3 PCCU	Children requiring ventilatory support or support of two or more organs systems. Children at level 3 are usually intubated to assist breathing. HRG 3&4	Intensive care	1: 1
		Children undergoing complex monitoring and/or therapeutic procedures, including advanced respiratory support. HRG 5&6	Advanced Intensive care	1.5 : 1
	Level 3 PCCU which supports cardiac surgery	Children receiving treatment by extra-corporeal membrane oxygenation (ECMO) HRG 7	Specialised intensive care	2 : 1

There are two requirements for **Level 2 PCC capacity** – in the care of critically ill children and in the care of the long-term ventilated (LTV) child.

3.2.1 Critically Ill Children

Critically ill children present to all hospitals which admit children. At presentation they are assessed and stabilised. On-going care depends on the level of intervention required following stabilisation and on the hospital's capacity to provide it.

They may require:

- General ward care and Level 1 PCC which is provided in every DGH
- Level 2 PCC, which can be provided in tertiary paediatric centres, either within Level 3 PCCU or on Level 2 PCCs, or in larger DGHs on Level 2 PCCs.
- Advanced level critical care, which is usually provided in regional Level 3 PCCUs but can

occasionally occur in Adult Intensive Care Units.

General ward provision **and level 1 PCC** is outside the scope of this Service Specification.

3.2.2. Long Term Ventilation

The numbers of children requiring invasive Long Term Ventilation (LTV) are increasing by the year. Their care is initiated in a **Level 3 PCCU** or neonatal unit. Discharge to home is usually a protracted process, often requiring multi-agency involvement, adaptations to the home or rehousing and the recruitment and training of a care team. In many areas, care continues to be provided in the regional centre while this process is taking place. This involves persistent disruption and travel for the family, may incur substantial cost to the commissioner and may reduce critical care capacity in the central unit.

Provision of **level 2 PCC** facilities in some District General Hospitals (DGH's) will enable earlier discharge so care of these children will take place closer to home, will enhance the skills of the DGH staff and will enable staff and family to become familiar with each other. The child may then be admitted to their local hospital for the treatment of some inter-current illnesses.

A list of interventions to define Level 1 and 2 PCC were described within the Paediatric Critical Care Minimum Data Set (PCCMDS). Further work has shown these to be inadequate to describe the work and modification to PCCMDS have been requested. The definition is improved by adding four variables and combining some terms. The proposed definition is shown below:

Basic Level Paediatric Critical Care Definitions are attached in appendix 1.

3.3 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).

Specifically this service is for critically ill children whose care needs exceed the capacity of a general ward or **Level 1 PCCU** as defined by reaching PCCMDS level 2 **and** do not meet the criteria for **Level 3 PCCU** as defined in the PCCMDS level 3 and above.

In addition, there is a population of post-operative children admitted to PCCU in tertiary centres whose care needs are not included in PCCMDS, but for whom there is a local agreement that PCC care is appropriate.

Children up to the age of 16 are normally cared for in a Paediatric Critical Care environment, although the *National Service Framework for Children* (section 1.2 for link) states the age range for inclusion within paediatric care is 0-18 years (up to but not including the 19th birthday).

PCC services shall be available to all critically ill children from the point of discharge from maternity or a neonatal unit until their 16th birthday. **In addition, on rare occasions a PCC unit may be deemed to be the most clinically appropriate place to provide critical care to**

young adults between the ages of 16-24 years (up to but not including the 24th birthday) – for instance as part of a long-term pathway of care managed by a paediatric team or because of their stage of physical or emotional development. Young people who have not completed transition to adult services will usually be cared for in a PICU unless they, or their carers, express a different preference.

Some providers have policies in which patients up to the 19th birthday are classified as children / young people. In the case of these providers LEVEL 2 PCC will accept patients up to their 19th birthday.

Children are also admitted to LEVEL 2 PCC directly from a neonatal unit.

* Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

3.4 Any acceptance and exclusion criteria and thresholds

3.4.1. Acceptance Criteria

Referrals:

The service will accept referrals inward from secondary care clinicians. Children will be under the care of a consultant tertiary specialist and/or a paediatrician.

The service will accept referrals from providers within their Paediatric Critical Care Network, including general and specialist paediatric wards, emergency departments, children's assessment units, neonatal units and LEVEL 3 PCCUs.

The service will also accept referrals from other providers of Paediatric Critical Care Services, either to provide specialist care that is not available in the referring unit, or to enable care to be delivered closer to the patient's home.

3.4.2. Criteria for referral

The service will accept referrals for children who meet one of the following criteria:

- PCCMDS level 1 care that has persisted for more than 24 hours.
- PCCMDS level 2 care.
- Post-operative care of children, subject to local agreement.

Patients will be accepted subject to capacity. Where demand exceeds capacity a network-wide process of prioritisation will be required.

In addition, in order to qualify for provision of PHD service providers will:

- Meet the 'Core Standards' PICS Standards set out in Appendix 2.
- The RCPCH/PICS Level 2 PCC standards which are for publication in 2013 will be

recommended from 2014.

- Submit PCCMDS data to SUS
- Be a member in a Paediatric Critical Care Network
- Audit activity within their **LEVEL 2 PCC**

3.4.3 Exclusions

- Adults
- Infants who have not been discharged from a neonatal unit.
- Children for whom this level of care is deemed to be inappropriate as the result of an agreed end-of-life pathway or DNAR order.

3.5 Interdependencies with other services/providers

Interdependencies in **Level 2 PCC** depend on site and speciality.

For an Level 2 PCCU in a DGH General Paediatric, Anaesthetic and ENT services must be co-located i.e. available 24/7 on the same hospital site:

For Level 2 PCCU in a specialist or tertiary centre the dependencies are defined within the PICS standards document.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

Not applicable

3.1.1 Core Standards	Providers will need to meet the general obligations for the provision of paediatric services as outlined in the National Service Framework ⁵ and “Commissioning safe and sustainable specialised paediatric services: a framework of critical inter-dependencies DoH 2008 ⁶ ”). Standards for the provision of Paediatric High Dependency Care have been published by the Paediatric Intensive Care Society (Paediatric Intensive Care Society - Standards 2008 ⁷ PICS) and are being update by a group convened with the Royal College of Paediatrics.
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References:

5. http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/document_s/digitalasset/dh_4090552.pdf
6. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_088068
7. http://www.ukpics.org.uk/documents/PICS_standards.pdf

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

3.1.1 Core Standards	Providers will need to meet the general obligations for the provision of paediatric services as outlined in the National Service Framework ⁵ and “Commissioning safe and sustainable specialised paediatric services: a framework of critical inter-dependencies DoH 2008 ⁶ ”). Standards for the provision of Paediatric High Dependency Care have been published by the Paediatric Intensive Care Society (Paediatric Intensive Care Society - Standards 2008 ⁷ PICS) and are being update by a group convened with the Royal College of Paediatrics. A compendium of the current standards is attached as appendix 2
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References:

5. http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/document_s/digitalasset/dh_4090552.pdf
6. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_088068
7. http://www.ukpics.org.uk/documents/PICS_standards.pdf

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

Not applicable to Level 2 PCC at this time.

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

Not applicable to level 2 PCC at this time.

6. Location of Provider Premises

The Provider's Premises are located at:

Not applicable

7. Individual Service User Placement

Not applicable

14/15 Specification Draft - Stakeholder Testing Stage

Appendix 1:

Basic Level Paediatric Critical Care Definitions

Level 1 unit interventions (limited to those in PCCMDS and the four additional candidate items)

Oxygen therapy + pulse oximetry + ECG monitoring (NB includes high flow oxygen)

Arrhythmia requiring IV anti-arrhythmic

Diabetic Ketoacidosis requiring continuous infusion of insulin

Severe Asthma requiring IV bronchodilator therapy

Reduced conscious level (GCS 12 or below) AND hourly (or more frequent) GCS monitoring

Upper airway obstruction requiring nebulised adrenaline

Apnoea

Level 2 unit interventions

Any of the above where there is a failure to respond to treatment as expected or the requirement for intervention persists for > 24 hours

CPR in past 24 hours

Nasopharyngeal airway

Acute non-invasive ventilation, including CPAP

>80 mls/kg fluid bolus in 24 hours

*Status epilepticus requiring treatment with continuous IV infusion (eg midazolam)

*Arterial line

*Central venous pressure monitoring

*Epidural

*Care of tracheostomy (first 7 days of admission)

*Inotropic/ vasopressor treatment

*Acute cardiac pacing

*IV thrombolysis

*Acute renal replacement therapy (CVVH or HD or PD)

*ICP monitoring or EVD

*Exchange transfusion

*Plasma exchange

*MARS therapy

Invasive ventilation of the Long Term Ventilated Child (which is coded as an advanced critical care intervention)

Note: * denotes those interventions that are almost always performed in a tertiary centre.

Appendix 2:

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Standardised mortality	remain within 99.9% confidence limits	To be agreed	Non compliance with contract General Conditions 8 & 9
Domain 2: Enhancing the quality of life of people with long-term conditions			
Ensure working within a Network of Care with the Level 3 PCC and other paediatric units as required	To be agreed	To be agreed	Non compliance with contract General Conditions 8 & 9
Effective and timely communication is supplied to receiving health care professionals following transfer / discharge from level 2 PCC	To be agreed	To be agreed	Non compliance with contract General Conditions 8 & 9
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Facilitating both the avoidance of admission to Level 3 PCCU and rapid repatriation to a 'network' Level 2 PCC facility where that is safe and	To be agreed	To be agreed	Non compliance with contract General Conditions 8 & 9

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
appropriate Avoiding unnecessary transfer for the child to a regional centre where appropriate care can be delivered locally	To be agreed	To be agreed	Non compliance with contract General Conditions 8 & 9
Domain 4: Ensuring that people have a positive experience of care			
Ensure appropriate escalation to level 3 care is timely and repatriation from level 3 to level 2 is undertaken in a timely manner. Timely discharge documentation to facilitate smooth transition to home/other services.	To be agreed	To be agreed	Non compliance with contract General Conditions 8 & 9
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
Levels 2 PCC should work within a network and have agreed protocols with the Lead level 3 unit.	To be agreed	To be agreed	Non compliance with contract General Conditions 8 & 9

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Appendix 2

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	<i>E07/S/c</i>
Service	<i>Paediatric Long Term Ventilation</i>
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

National Context:

Recent clinical advances in Neonatal and Paediatric Intensive Care have increased the incidence of survival of children with life threatening or life limiting conditions. Over the same period technological advances have produced a range of portable, easy to maintain, reliable and efficient mechanical ventilators. As a result, children who have long-term breathing difficulties needing either temporary or permanent ventilatory assistance have an increased potential for survival and must be offered an integrated care pathway from hospital to home and coordination of Long Term Ventilation (LTV) specialist input across organisational boundaries.

Children on long term ventilation are a high cost group with complex and varying underlying medical conditions requiring input from multiple teams, including among others, neonatal intensive care, paediatric intensive care, paediatric respiratory medicine, cardiology, ENT, spinal injury, neuromuscular and neurodisability specialists, as well as access to palliative care.

Ventilation can be delivered via a tracheostomy (invasive ventilation) or through a mask or other device that is not directly connected to the airway (non-invasive ventilation). Most tracheostomy ventilated children start their journey in a critical care environment and have already had intensive medical input. Children on complex non-invasive ventilation often have underlying co-morbidities or associated life limiting illness, and these children require coordination of care across the relevant specialisms within paediatric medicine, as well as a clear pathway of transition to adult services.

Most children on long term ventilation progress to a point of medical stability where their clinical needs can be met outside of the hospital environment. However, children on invasive long term ventilation

(LTV) or complex non-invasive ventilation can remain in an inappropriate intensive care or hospital environment while awaiting a home care package to be established in the community. Work is taking place nationally to improve discharge processes in order to reduce inappropriate lengths of stay. The scope of this specification covers children who have long term ventilation initiated on a Paediatric or Neonatal Intensive Care Unit, regardless of whether the interface for delivery of that ventilation is mask or tracheostomy.

Evidence base

Currently, the numbers of LTV children are recorded separately by each LTV centre and collation of this data nationally is not routinely available. Recent medical literature from the UK demonstrates a significant rise in number of children on long term ventilation (Wallis et al 2010, Goodwin et al 2011). From recent review undertaken for PIC Clinical Reference Group (CRG) workshop the average length of hospital stay from identification of the need for long term ventilation to discharge home is an average of 7-9 months, which has not improved in the past 20 years, although the population remains a relatively small volume, specialised and high cost one.

As part of a PIC CRG stakeholder engagement exercise it was possible to determine that there are approximately 80-100 new onset tracheostomy ventilated children presenting in PICU per year (anticipated maximum 125 per year). No data are available on the underlying diagnostic groups but professionals report that there is a trend towards increasing medical complexity. A proportion of these children will wean off ventilation, some will succumb to their underlying life limiting condition, and others will eventually progress to adult services but there is no database available to demonstrate outcomes of institution of ventilation.

There are an increasing number of complex children managed on non-invasive ventilation, even in the newborn period and early infancy, for example current practice for Congenital Central Hypoventilation Syndrome includes the option of tracheostomy or mask ventilation depending upon local clinician preference and the needs of the child and family. Regardless of interface the needs and level of the patient remain significant and require a complex package of care to be delivered in the home.

From the review undertaken for the PIC CRG workshop the number of tracheostomy ventilated children managed out of hospital is approximately 250-275, with a further 1000-1300 children with complex needs dependent upon non-invasive ventilation under specialist respiratory follow-up.

The model of care for all long term ventilation children is for them to be cared for in a normal home environment. The Royal College of Paediatrics and Child Health's Modelling the Future paper recommends that services for children with long-term conditions could be greatly improved if they were commissioned according to individual pathways of care. The child who remains in an intensive care setting may be a long distance away from parents and carers who may have limited resources to travel and carry out other family responsibilities.

The Department of Health Continuing Care Framework for Children and Young People (2010) provides a tool for assessing whether a child has ongoing complex needs and requires a home care package and provides exemplar timeframes for some of the key tasks required to achieve timely hospital discharge and care at home.

The Children's and Young People's Health Outcomes Forum 2013 has called for better integration of services around the child and family.

Children on Long Term Ventilation who remain, inappropriately, in critical care beds may restrict the ability to provide paediatric critical care services for elective episodes of care. This may lead to cancellations of operations and outcome measures not being met in other clinical services.

For the critically ill child, limited access to the closest Paediatric Critical Care Unit may cause delayed transfer, and the need for the child to be transported further to receive critical care. Restriction in

accessing paediatric critical care services may not only have an adverse impact on meeting the needs of the local population but can also lead to capacity problems in other specialist services.

Currently the financial cost of the hospital episode for recent onset complex long term ventilation is high due to expensive resources being utilised inappropriately and for longer lengths of stay and additional costs incurred through out of area admissions.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

Key Outcomes*:

1. Providers of LTV services keep robust data for every patient with at least the following information available to commissioners and service managers:

- Number of patients entering LTV integrated discharge pathway
- Number of patients exiting LTV integrated discharge pathway
- Availability of identified Hospital Key Worker (or team of HKWs)
- Weekly report of 'Medical Stability'
- Monthly report of 'Multidisciplinary Discharge Planning Meetings'
- Identify and report episodes of medical instability during discharge of medically stable LTV patient
- Date of Fit for Discharge from ICU/HDU to ward (FFD-ICU)
- Date of Fit for Discharge from hospital to community services (FFD-HOSP)
- Identification of health, social, housing delays to hospital discharge
- Aggregated length of stay post fit for discharge (FFD-HOSP)
- Exception report for LTV children with Hospital Length of Stay > 4months from FFD-HOSP

(Domain: 2,4)

2. Appropriate training provided to parents and carers of LTV children, including at least annual updates or as required according to the needs of individual cases (Domain: 1,2,3,4,5)

3. Personal care plan available at the point of discharge, agreed by the MDT shared with community professionals and parents (Domain: 2,3,4)

4. Follow up plan for every patient, agreed at final MDT meeting/discharge, including clear plan for

shared care between LTV centre and local clinical teams (Domain: 2,3,4,5,)

*Patient outcome measures are currently being developed which will added to the specification once agreed.

3. Scope

3.1 Aims and objectives of service

3.2 Service description/care pathway

The service model provides multidisciplinary care throughout a hospital to home integrated care pathway for children on long term mechanical ventilation, regardless of ventilator interface as long as the patient journey starts in a Paediatric or Neonatal Intensive Care Unit. Transitional care or 'step down' facilities in or out of hospital, should be considered part of the hospital to home pathway and should follow the standards agreed by the local or regional clinical network and should have a process in place for facilitating timely and safe transition to home.

The scope of this specification does not include the individual home care packages, which will be commissioned by the Clinical Commissioning Groups (CCGs) or groups of CCGs in liaison with their local services, education and housing departments.

Any child in Paediatric or Neonatal Critical Care who is being considered for chronic home ventilation will be referred to the local LTV specialist before a final decision to progress down the LTV pathway.

Before elective tracheostomy for invasive mechanical ventilation there will be a process of consent for long term ventilation in the home (in addition to the standard surgical consent for tracheostomy). As part of this process the child and family will have the opportunity to discuss long term ventilation with a specialist LTV team and will have access to 'condition specific' information

A second opinion will be sought where there is concern that long term ventilation is not in the child's best interests on the grounds of futility.

As part of the consent process for long term ventilation there will be an agreement to information sharing across agencies (health, social services, education, commissioning) and parents or carers will receive specific guidance on the planned discharge pathway from hospital to home.

All children considered for tracheostomy will have a formal assessment of their potential to wean by a specialist LTV or Respiratory/PICU team. A structured approach to weaning must be in place for all children on long term ventilation, whether in hospital or the community, with the aim of delivering the least invasive and least intrusive form of respiratory support that will support the best quality of life as well as safety of the child. Specialist centres will provide advice or outreach to other providers within their region to support a structured approach to weaning.

Where invasive long term ventilation is being undertaken for a child with a life limiting condition there will be agreed written guidance around the end of life pathway and advanced care plan, including guidelines for treatment of intercurrent illness, escalation of therapy, resuscitation and emergency protocols, that is agreed between the family and professional multidisciplinary team. The agreement must will be shared with all key professionals involved with the child in hospital and community services. The guideline must be updated on a regular basis with the frequency dictated by the needs of

the child but will be reviewed at least annually in children under the long term care of community services.

Every ventilator dependent child who is an inpatient in hospital and who needs a Complex Home Care Package (CHCP) will have an identified Hospital Key Worker (HKW) or team of HKW's. The HKW should review the child and produce a weekly status report that includes (a) medical stability and (b) capture of dates when the child is medically fit for discharge from an intensive care or high dependency bed, and when they are medically fit for discharge from hospital to the community (see below). This would allow more accurate data on acute and community sector resources and enable continuous improvement of service delivery. The HKW should communicate directly with the Community Key Worker (CKW) and should enable sharing of information through Multidisciplinary Team Meetings held on a four weekly basis while the child is in hospital.

The LTV hospital to home discharge pathway will commence at the point of identification of the potential for chronic home ventilation. Children awaiting hospital discharge should be tracked along the pathway, including weekly assessment of medical stability and readiness for discharge to enable timely transition out of intensive care or high dependency to a more appropriate environment while the home care package is being established. The integrated care pathway will follow the child and family and cross organisational boundaries to ensure consistent care and communication throughout the patient journey.

Specialist follow up of the ventilator dependent child should allow for review at 3, 6, and 12 months after hospital discharge. Following this a process for team review around the child and assessment of personal care plans and parent/carer competency in basic life support should be in place on an annual basis, or more often depending upon the needs of the child and family.

LTV services will network together to support local services by, wherever possible, standardising competency frameworks and education and training materials across a local area or region.

The LTV specialist services, NHS England Commissioners and CCG commissioners of home care will work with local authorities, education and housing departments to create a joined up approach to timely hospital discharge and shared standards of care for children on chronic home ventilation. This should incorporate a structured approach to social and housing issues and exploration of standardisation and procurement of equipment by the community care provider with the support of the LTV specialist teams.

A child on the LTV integrated care pathway will have an identified lead Consultant who will provide consistent communication around the needs of the child and family and ensure that the medical aspects of the child's care are being met, and that these have been considered and communicated as part of the risk assessment for transfer of care closer to home. Communication between hospital and community providers is essential in order to maintain objectives and a structured process of sharing information in the interests of the child is essential.

Core quality standards will be developed by the local or regional LTV specialist teams and ideally be shared at a national level to ensure a consistent approach to care of the ventilator dependent child regardless of location in hospital or community.

The multidisciplinary team (MDT) must include, but is not restricted to acute and primary sector health care workers (medical, nursing and allied health including physiotherapists, speech and language therapists, occupational therapists, dieticians, psychologists), social workers, housing officers, and representatives from the education sector. All children on the LTV pathway should have access to age appropriate play therapy or education.

The MDT process will provide a central source of information for hospital and community professionals and ensure that all non-medical needs of the child and family are met.

- a 'provisional discharge date' should be agreed at the first MDT meeting.
- a 'Fit for Discharge from Hospital' date (when the child's *medical* needs can be met out of hospital) will be agreed as part of the MDT process
- the MDT process includes collation of clinical updates with a problem based approach resulting in a clear set of actions with allocated responsibility.
- in order to improve the efficiency of hospital discharge any actions agreed at an MDT meeting must be started, and whenever possible, completed *before* the next MDT meeting under the supervision of the HKW.
- a report from the MDT meeting must be shared with key professionals from hospital and community, as well as with the family and GP.

The MDT process must ensure that all children on the pathway have a Personal Care Plan (PCP) that includes, but is not restricted to, (a) escalation management in an emergency (b) list of essential equipment to take when out of the home environment (c) guidelines on communication with the ambulance service and local accident and emergency services (d) notification of utility companies (e) an equipment policy that includes service arrangements and guidance in the event of breakdown, (f) a clear plan for follow-up.

Education and training support and competency assessments will be delivered by those experienced in LTV and tracheostomy care, and be freely available to parents (or primary carers) and other members of the immediate family. For a ventilator dependent child identified in neonatal or paediatric intensive care this training is essential in order to facilitate safe transition to home, and should be commenced as soon as possible after the child has been identified.

Specific reporting of outcomes along the LTV hospital to home discharge pathway will be defined by commissioners of this pathway and a process of escalation must be in place in order to address any avoidable delays in discharge that are identified during the inpatient stay.

3.3 Population covered

The population includes all children initiated on long term mechanical ventilation, regardless of ventilator interface as long as the patient journey starts in a Paediatric or Neonatal Intensive Care Unit. Any child in Paediatric or Neonatal Intensive Care or Paediatric High Dependency who is being considered for long term ventilation and who requires a period of informed consent, or trial of weaning, is included in order to provide access to specialist LTV and respiratory teams.

Regardless of ventilator interface there must be recognition of the level of dependence on ventilation in determining clinical standards along the patient journey, whether the child is in hospital, in a transitional or step down unit, in long term residential care or respite, or at home. The LTV professional network will develop clinical standards that can be agreed at a regional or national level.

The National Framework for Children and Young People's Continuing Care (2010) has the following definition:

- High (Level 1): Is able to breathe unaided during the day but needs to go onto a ventilator for supportive ventilation. The ventilation can be discontinued for up to 24 hours without clinical harm.
- Severe (Level 2): Requires ventilation at night for very poor respiratory function; has respiratory drive and would survive accidental disconnection, but would be unwell and may require hospital support.
- Priority (Level 3): This includes those with no respiratory drive at all who are dependent on ventilation at all times, including those with no respiratory drive when asleep or unconscious who require ventilation and one-to-one support while asleep, as disconnection would be fatal.

Additional information on level of dependency should be considered to help inform the care package

and level of supervision required as per the example below.

If disconnected from the ventilator the patient:

- will be immediately compromised
- is likely to be compromised within ten minutes
- is likely to be compromised within one hour
- is likely to be compromised over several hours
- is unlikely to be compromised

A pathway of transition to adult services will be in place for those patients who remain ventilator dependent during adolescence, and long term ventilation services for adults will take over the long term and acute care for young adults who have reached the age of 19 and above.

3.4 Any acceptance and exclusion criteria and thresholds

Referral Source

- Neonatal Intensive Care Units
- Paediatric Critical Care Units
- Paediatric High Dependency Units
- Paediatric specialist consultants (e.g. respiratory, cardiology, neurology, neuromuscular)

Acceptance Criteria

- Children on paediatric or neonatal intensive care under consideration for long term ventilation
- Children on paediatric or neonatal intensive care under specialist weaning review
- Children on any form of respiratory support via tracheostomy
- Children with complex needs on non-invasive ventilation initiated in a neonatal or paediatric intensive care unit, or high dependency unit.
- Children on any level of respiratory support (including CPAP) with a critical upper airway or lower airway abnormality regardless of ventilator interface

Exclusion Criteria

- Overnight respiratory support for uncomplicated sleep disordered breathing
- Children receiving short term respiratory support during an inpatient spell on a paediatric ward, or paediatric intensive care or high dependency unit where the aim is to wean off respiratory support before hospital discharge.
- Children initiated on long term ventilation in a setting outside of intensive care or high dependency units. (these children currently sit under paediatric medicine respiratory subgroup)
- Children on invasive or non-invasive mechanical ventilation who are not medically fit for discharge from a paediatric or neonatal critical care unit.

Defining "Medical Stability" for a child on long term ventilation is challenging but is important in informing the transition from hospital to home. A clear and consistent approach to capturing this information will assist in evaluating and planning the resource required for this population, as well as providing consistent reporting of avoidable delays in hospital discharge for an individual patient. Two clear decision points should be captured which are (1) when a patient is medically fit to 'step-down' from the paediatric intensive care or high dependency unit to a paediatric ward or local centre (FFD-ICU) and (2) when a patient is medically suitable to step down from hospital to home (FFD-HOSP). There will be some discretion required on a case by case basis but applying these criteria consistently would allow more robust analysis of service integration and avoidable delays in achieving care closer to home.

(1) Fit for Discharge from Paediatric Intensive Care or High Dependency Care to Paediatric

Ward or LTV unit (FFD-ICU) based on “Medical Stability” information below:

- stable airway present
- stable oxygen requirements (if required) usually less than 40%
- arterial carbon dioxide tensions can be maintained within safe limits on ventilatory equipment that can be used on the ward (in some centres this would include children on noninvasive respiratory support using high flow or CPAP from compressed gases)
- nutritional intake is adequate to maintain expected growth and development (the child may not yet be established on full enteral feeds)
- other *acute* medical conditions are under control with no life threatening episodes of aspiration and stable acid-base and metabolic status

**An agreed medically fit for discharge (FFD-ICU) date would be captured when all of the above criteria have been satisfied for a period of two continuous weeks (or sooner at the discretion of the lead ICU and LTV consultant depending upon the ICU course and condition of the individual patient)*

(2) Fit for Discharge from Hospital to Community Based Services (FFD-HOSP) based on “Medical Stability” information below:

- stable airway present
- stable oxygen requirements (if required) usually less than 40%
- arterial carbon dioxide tensions can be maintained within safe limits on ventilatory equipment that can be operated by the family or carer(s) at home
- nutritional intake is adequate to maintain expected growth and development and is delivered by a route that can be managed by the local care provider
- all other medical conditions are well controlled, including stable doses of medication

**An agreed medically fit for discharge from hospital (FFD-HOSP) date would be captured when all of the above criteria have been satisfied for a period of two continuous weeks (or sooner at the discretion of the LTV consultant in conjunction with the local care provider)*

3.5 Interdependencies with other services/providers

Children who require **initiation** of long-term invasive mechanical ventilation are usually identified during an inpatient spell in a neonatal or paediatric intensive care unit. Neonatal or Paediatric Critical Care practitioners will therefore be necessary in the early course of the patient journey and would deliver a service consistent with those specialty standards. Access to specialist paediatric ear, nose and throat (ENT) surgeons for inpatient and follow up care is essential for children undergoing tracheostomy.

Access to specialist paediatric respiratory specialist services is necessary in order to offer specialist respiratory investigations, to assess adequacy of ventilatory support, for example through clinical assessment and sleep studies. Active evaluation of the potential to wean from ventilatory support should be undertaken on a regular basis before and after hospital discharge. Specialist respiratory support, including physiotherapy, can be delivered from a Paediatric Respiratory Specialist Service or through a Long Term Ventilation Service, or a combination of both.

Links to other specialist services will depend upon the need of the individual child and family and may include need for access to specialist support from psychology, psychiatry, neuromuscular, neurology, neurorehabilitation, spinal injuries, orthopaedics, metabolic and endocrine, cardiology and cardiac surgery, and palliative care.

A multidisciplinary team approach must include input from paediatric psychology, physiotherapy, occupational therapy, dietetics, speech and language therapy, play specialists, and social services. Access to the multidisciplinary team must not be restricted to one part of the pathway and preference should be given to a team approach that follows the child across organisational boundaries from

hospital to home.

Good communication between hospital and community professionals is essential and a working relationship between the acute sector, community providers and out of hospital transitional care centres is to be encouraged to offer the widest choice of out of hospital care for the child while the home care package is established.

For the older child (>13 yrs) links with Adult LTV services must be established and transition to adult services must be planned for.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

Not applicable.

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

- The Royal College of Paediatrics and Child Health's Modelling the Future

Report of the Children and Young People's Health Outcomes Forum.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216852/CYP-report.pdf

- Department of Health (2008) Commissioning Safe and Sustainable Paediatric Services: A Framework of Critical Interdependencies
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_088068
- Department of Health (2006) Review of Commissioning Arrangements for Specialised Services (the Carter Review)
http://webarchive.nationalarchives.gov.uk/./+http://www.dh.gov.uk/en/Managingyourorganisation/Commissioning/Commissioningspecialisedservices/DH_4135174
- Department of Health (2006) Critical Care Minimum Data Set (CCMDS)
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4116368
- Department of Health (2003) Getting the Right Start: National Service Framework for Children; Standards for Hospital Services
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006182
- Directorate (1997) Paediatric Intensive Care: "A Framework for the Future"
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005760
- Healthcare Commission (2007) Improving Services for Children in Hospital
http://caredirectory.cqc.org.uk/db/documents/Improving_services_for_children_in_hospital.pdf
- Paediatric Intensive Care Society (2010) Standards for the Care of Critically Ill Children (v.2, 4th ed.) http://www.ukpics.org.uk/documents/PICS_standards.pdf
- Royal College of Nursing (2011) Health care service standards in caring for neonates, children and young people http://www.rcn.org.uk/_data/assets/pdf_file/0010/378091/003823.pdf
- Safeguarding children and young people-roles and competencies for health care staff. Intercollegiate document, September 2010. <http://www.rcpch.ac.uk/safeguarding>
- Protecting children and young people: responsibilities of all doctors. GMC Sept 2012. www.gmc-uk.org/guidance

5. Applicable quality requirements and CQUIN goals
5.1 Applicable quality requirements (See Schedule 4 Parts A-D) Not applicable
5.2 Applicable CQUIN goals (See Schedule 4 Part E) Not applicable
6. Location of Provider Premises
The Provider's Premises are located at: To be completed by AT
7. Individual Service User Placement
Not applicable

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Appendix One

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Providing parents/primary carers and immediate family a competency booklet/training programme facilitating safe care at home	To be agreed	Audit of practice/annual report	Non compliance with contract General Conditions 8 & 9
Provision of Personal Care Plan with specific guidance on emergency management and escalation plans/community service links	To be agreed	Audit of practice/annual report	Non compliance with contract General Conditions 8 & 9
Domain 2: Enhancing the quality of life of people with long-term conditions			
Follow up plan agreed before hospital discharge with clear plan for shared care	To be agreed	Audit of practice/annual report	Non compliance with contract General Conditions 8 & 9
Annual patient clinical review, training updates for parents/carers and active assessment for ability to wean	To be agreed	Audit of practice/annual report	Non compliance with contract General Conditions 8 & 9
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Availability of a hospital key worker for liaison with child and family at least weekly	To be agreed	Audit of practice/annual report	Non compliance with contract General Conditions 8 & 9
Availability of structured form of communication between MDT with team meetings held 4 weekly during the hospital stay	To be agreed	Audit of practice/annual report	Non compliance with contract General Conditions 8 & 9

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Agreed managed hospital discharge pathway to facilitate care at home or closer to home	To be agreed	Audit of practice/annual report	Non compliance with contract General Conditions 8 & 9
Domain 4: Ensuring that people have a positive experience of care			
Local patient satisfaction survey	To be agreed	Patient satisfaction results	Non compliance with contract General Conditions 8 & 9
LTV team work in a networked way to share best practice	To be agreed	Evidence of network working	Non compliance with contract General Conditions 8 & 9
Availability of parent/carers condition specific information when LTV needs are identified	To be agreed	Audit of practice/annual report	Non compliance with contract General Conditions 8 & 9
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
Shared best practice with a networked approach - diffusing expertise throughout the patient journey from hospital to home	To be agreed	Evidence of networking	Non compliance with contract General Conditions 8 & 9
Access to LTV support/advice/information regardless of geographical location	To be agreed	To be agreed	Non compliance with contract General Conditions 8 & 9
Compliance with national paediatric standards of care/NSF	To be agreed	Audit of practice	Non compliance with contract General Conditions 8 & 9

Stage

Draft Stakeholder Test

2015 Specific

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Appendix 2

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	E07/S/d
Service	Paediatric Critical Care Transport
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Paediatric Critical Care Transport refers to the transfer of critically ill children into Paediatric Critical Care (PCC) facilities. The definitions of the full range of Paediatric critical care (PCC) is as follows:

- Level 1 Paediatric Critical Care Units (PCCUs) will be located in all hospitals providing inpatient care to children and will deliver level 1 PCC care. (provided in all district general hospitals where in-patient facilities are available and is not commissioned by NHS England)
- Level 2 PCCUs may be specialist or non-specialist and are provided in tertiary hospitals and a limited number of District General Hospitals (DGH's) and will deliver level 1 & 2 care. These were formerly classified as HDUs. (commissioned by NHS England)
- Level 3 PCCUs (PICUs) are usually located in tertiary centres or specialist hospitals and can provide all 3 levels of PCC.(commissioned by NHS England)

Paediatric Critical Care Transport Services exist to ensure that critically ill children have equitable access to timely, safe and clinically effective PCC provision wherever they present in a geographical area. Since PCC facilities are centralised in a small number of hospitals providing expert specialist care, specialist PCC Transport teams are required to deliver

expert clinical management during transfer to optimise clinical outcomes from the point of contact with the transport team. A PCC Transport Service only provides transport between hospitals and does not respond to 'primary' 999 calls.

1.2.

There are no randomised controlled trials comparing the outcomes following transfer by specialist teams with those provided by referring hospitals. However, published descriptive studies have highlighted the benefits of a dedicated transport team over non specialist teams, where inter hospital transfer of critically ill children by personnel not trained in paediatric intensive care transport has been shown to be associated with unacceptable transport related morbidity and that dedicated transport personnel may be an important determinant of morbidity and mortality.*^(1,2,3,)

*1. Ramnarayan P, Thiru K, Parslow RC, Harrison DA, Draper ES, Rowan KM. Effects of a specialist retrieval team on outcomes in children admitted to paediatric intensive care units in England and Wales: a retrospective cohort study. *Lancet* 2010;376(9742):698-704

2. Orr RA, Felmet KA, Han Y, McCloskey KA, Dargotta MA, Bills DM, et al. Paediatric specialized transport teams are associated with improved outcomes. *Paediatrics* 2009;124(1):40-8

3. Edge WE, Kanter RK, Weigle CG, Walsh RF. Reduction of morbidity in inter-hospital transport by specialized paediatric staff. *Crit care Med* 1994;22(7):1186-91

1.3

Between 2009 and 2011, 17,407 transfers into PCC level 3's in UK and Ireland were recorded (PICANET Annual Report 2012). Currently there are 4,500 transfers by specialist paediatric teams each year with an expectation that these numbers will rise as a result of any national reconfiguration of specialist children's services. Other transport services (such as ECMO or neonatal) may overlap or share responsibilities with PCC Transport Services

Publications include:

- *Paediatric Intensive Care, 'A Framework for the Future', report from the National Coordinating Group on Paediatric Intensive Care to the Chief Executive of the NHS Executive*, Department of Health (1997)
- *"Getting the right start: National Service Framework for Children 'Standard for Hospital Services'*, Department of Health (2003)
- *'The acutely or critically sick or injured child in the district general hospital – a team response'*, Department of Health (2006)
- *'Standards for the Care of Critically Ill Children'*, 4th ed. UK Paediatric Intensive Care Society (2010)
- *Joint Statement from the Society of British Neurological Surgeons (SBNS) and the Royal College of Anaesthetists (RCOA) Regarding the Provision of Emergency Paediatric Neurosurgical Services (2011)*

1.4. Current Service Models for PCC Transport and Future Modelling

Traditionally, the term 'retrieval' has been used to refer to the emergency transport of critically ill children by specialist teams into a level 3 PCCU. 'Retrieval' is commissioned throughout England. However, transport of patients requiring admission to a Level 2 PCCU, and transport back to referring units from PCC facilities ('repatriation'), has been commissioned in some areas in England but not in others.

1.5.

A PCC transfer covers the entire pathway for a critically ill or injured child in to a PCC facility. PCC repatriation refers to the transfer back to the District General Hospital (DGH) or PCC facility closest to the child's home. Referral to a PCC Transport Service may originate from a DGH in-patient service, an Emergency Department or a specialist service (including other PCC facilities).

Currently there is only a single HRG currency for PCC Transport. All PCC Transport falls under XB08Z HRG. Future work is needed to allow more sophisticated commissioning of paediatric critical care transport.

At this time, this specification covers only transports into a level 3 PCCU and does not include PCC repatriations or PCC level 2 (HDU) transports.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

Key Outcomes:

1. To submit data on percentage of retrievals undertaken within agreed scope of care undertaken by the PCC transport team (Domain: 1,3,4,5,)

2. *Transfer team departs from the transport base within 30 minutes of the clinical decision that PCC Transport is indicated. (Domain 1, 3, 4, 5,)
3. The PCC Transport Service arrives at the local referring centre within three hours of the decision to retrieve the child (decision response time) (Domain: 1, 3, 4, 5)
4. Transport services collect timely (within 3 months of patient transport) minimum dataset required by PICANet (Domain: 1,3,5)
5. Governance arrangements in place that allow cross organisational learning within network. Transport teams contribute to and are active participants in the clinical governance arrangements of the NHS pathway of care. (Domain: 1,3,4,5)
6. Governance arrangements in place that allow shared learning with other transport services (Domain 1,3,4,5)
7. Annual report published summarising activity, compliance with quality standards and clinical outcomes, progress from previous year, shared with appropriate stake-holders

*These measures are part of the quality dashboard for PCC transport services.

3. Scope

3.1 Aims and Objectives of Service

Delivery of the service will not depend on in-patient care, will recognise the importance of family circumstances and provide arrangements to undertake or facilitate transfers in all categories as part of its baseline provision.

Where capacity within network does not allow for an appropriate transfer to PCCU a child will be transferred out of network by an appropriate PCC transport team ensuring a safe and timely transfer to another appropriate critical care setting.

A PCC Transport Service must be available at all times and for all units within a designated geographical catchment area providing:

- Clinical advice to referring clinicians
- Safe and effective transfers for critically ill children
- A bed location service for PCC transfers

3.1.2

PCC transfers will be performed by a dedicated PCC transport service, with the ability to:

- Operate 24 hour per day
- Staff all transfers appropriately and in accordance with the clinical condition of the child
- Transfer at least 95% of children where transfer is required within the service specification and any exceptions documented and reviewed at a network level
- Demonstrate performance against specified response time standards
- Allocate transfers according to clinical priority
- Operate in an integrated and supportive way with regional referring units

- Operate in an integrated and supportive way with other Transport Services
- Ensure appropriate governance arrangements, including data collection and audit
- Select an appropriate mode of transport (e.g. air-medical) where this would be clinically beneficial, whilst maintaining appropriate governance and safety standards. This may involve collaboration with other providers

3.2 Service description/care pathway

A specialist PCC Transport team will transfer children requiring intensive care to the most appropriate PCC facility and this process will be quality assured.

The PCC Transport Service will:

- Be contacted in any situation where a transfer may be required
- Be responsible for the organisation of any necessary transfer
- Have clear documented referral processes for all categories of transfer
- Have clear protocols for handover from referring teams to receiving PCC units.

In some cases, due to the time critical nature of the child's clinical condition, children will need to be transferred to a PCC facility by the referring hospital team.

The planning of delivery of PCC Transport should reflect seasonal and other fluctuations in demand to ensure that the standard of care provided to children referred for intensive care is not compromised.

Where such an eventuality arises and with collaborative working across the networks an alternative service will be found to undertake the transfer.

The typical peak of PCC activity between November and January each year can result in an increase in admissions by 20-30% for those months.

3.2.1 Service model:

The PCC Transport Service must be operational 24-hours daily. The ability to respond to demands on the PCC Transport Service should be prioritised based upon clinical need.

Currently, due to historical commissioning arrangements Transport Services are designed in different ways and their scope of service will vary. This will be addressed through the Service Specification Compliance Process.

Urgency:

- Time Critical – normally performed by referring units.

Time critical transfers are required for children who have a life threatening clinical condition where early intervention will have a greater impact on the outcome for these children than transfer by a specialist team e.g. emergency neurosurgery; acute abdomen.

- Unplanned/emergency
Performed by the PCC specialist transport team

- Planned/elective

If commissioned to do so, may be performed by the PCC transfer service

Reason:

- Uplift of care (transfer for care that the referring hospital does not usually provide)
- Resources/capacity
- Repatriation from the level 3 PCC unit (if commissioned to do so)

The decision on the most appropriate team should be based on the needs of the child and the agreed network arrangements.

3.2.2. Levels of care across the patient pathway

Referral to the PCC Transport Service will be based on the child's need for admission to a designated PCC bed.

The PCC Transport Service acts as a mobile intensive care unit to provide care to critically ill children in the network.

To achieve optimum outcomes a PCC Transport Service will work in partnership with the network, PCC facilities and local referring centres to ensure that within the network the following functions are provided:

- Resuscitation and stabilisation by referring staff to agreed guidelines and protocols
- Transfer of stabilised children in an appropriately staffed and equipped mobile intensive care environment to a PCC facility.
- Support for the care of critically ill children including provision of outreach education and training.

3.2.3. Capacity of Transport Service

Commissioners and providers are responsible for transfer capacity and undertake needs assessment and gap analysis on a regular basis to ensure adequate provision to enable delivery of a service at all times.

3.2.4 Staffing

The PCC Transport Service must have adequate numbers of staff with the appropriate skills to provide a safe service for children, including:

- A lead named consultant
- A lead nurse
- 24 hour transport consultant advice and availability to join the transfer team if required
- A doctor or advanced nurse practitioner appropriately trained and experienced to carry out transfers available at all times
- A nurse or other non-medical member of staff trained and experienced to carry out transfers available at all times.
- Team composition will be based on clinical need
- Staff are trained to a required standard for all aspects of equipment use, transport safety and infection control
- Staff receive full appropriate inductions, competency updates and have access to continuing professional development (CPD) programmes.

- Where the Transport Service is co-located with a PCC level 3 the Transport Service staff should not be included in the standard unit rota, and should be supernumerary to this
- Where staff are provided from outside of the network Transport Service, any service level agreement (SLA) or contract will stipulate that staff are trained to meet these standards
- Transfer training updates will be conducted at least annually for PCC Transport Service staff

3.2.5 Referral processes and sources

There should be an agreed network pathway for children referred for PCC with a single point of contact.

For unplanned/emergency transfers the PCC Transport Service provides access to clinical advice, mobilises the transfer team and locates a PCC bed. Activation of the transfer team should not always be dependent on bed availability but on clinical condition.

For a PCC Transport service that is commissioned to undertake planned/elective transfers, decisions about the need for transfer will be agreed jointly by the referring consultant and receiving consultant. The PCC Transport Service will then liaise with the referring centre to undertake the transfer in a timely fashion.

Each service must have an agreed scope of care which would include a collaborative working relationship with the neighbouring Transport Services. Written records of interaction between services must be kept

3.2.6. Equity of access to services

The PCC Transport service must be commissioned to serve the whole geographical population and must provide services equitably across the region that they operate.

Commissioning should take into account the possibility of teams transferring patients outside of their normal remit but within their clinical scope where this is in the best interests of the patient and/or family.

3.2.7. Handover of care

The PCC Transport Service must show evidence of a protocol for concise but detailed handover. The transfer of radiological supporting documentation via PACS (e.g. radiology imaging) is the responsibility of the referring centre.

The responsibility for the care of the patient is a continuum of responsibility over the whole transport event.(from the time that care is formally handed over by the referring team to the time that formal handover is undertaken with the receiving unit).

PCC Transport teams should utilise where possible IT solutions, such as inter-hospital radiology image sharing and telemedicine links, which may improve the transfer process or limit the need for transport.

Where such IT solutions are beneficial to patient care the Transport Service should work together with the PCC network to help ensure that the technology is available in all parts of the network.

3.2.8 Service user / carer information

The PCC Transport Service must have a policy for parental travel arrangements. Where possible, at least one parent / legal carers will be allowed to accompany their child during transfer.

When it is not possible to transfer a parent / legal carer with their child the PCC transport team must ensure that alternative transport arrangements have been made by the referring hospital team.

Parents where possible should always be offered the opportunity to see their child prior to transfer.

Parents and carers will be given written information about the PCC Transport Service and receiving PCC unit, including contact information. Multi-lingual output is advised.

3.2.9 Governance

The process for transfer of critically ill children must be timely, safe and efficient, requiring a high degree of coordination between all service providers. The development of this coordinated approach must be led by the PCC Transport Service, but should be wholly supported by all hospitals in the network admitting and/or referring critically ill children.

The PCC Transport Service will have governance and operational policies (e.g. medication protocols) with clear guidelines for how incidents are reported and resolved.

Serious transport incidents can be complex with several Trusts involved. The area PCC network board/lead will oversee the review process or if in place the Operational Delivery Network, ensuring joined-up cross-boundary responses and learning.

There will be clear mechanisms for quality assurance and incident review, including submission to agreed national bodies. These reports will be available for review by the Area Team Commissioners, network or other agencies and produced on an annual or more frequent basis if required. These are to conform to any agreed local or national format.

Structures must be in place to provide on-going training for those involved with PCC Transport, and to demonstrate relevant competencies for all grades of nursing and medical staff undertaking transfers.

Mechanisms will exist to ensure that all stakeholders involved in the PCC Transport Service have an active input into the delivery of the service. PCC Transport services should establish and maintain a Stakeholder Group which will include clinical personnel from the

Network Units, parents commissioners and where necessary the regional ambulance service.

The Transport Service must work collaboratively with the Network and Level 3 providers to ensure that education and training is delivered to referring centres within the network will cover assessment, resuscitation, stabilisation and maintenance of critically ill and injured children prior to the arrival of the Transport Service.

3.2.10 Reporting requirements

The Transport Service will:

- Monitor the service against agreed standards, including for activity, delays, and exceptions to network pathways.
- Record and monitor activity according to PICANet minimum data set on all referrals and transfers, including referrals that do not result in a transfer.
- Records should include the nature of any medical or nursing advice given
- Participate in annual benchmarking of PICANet minimum transport dataset
- The PCC Transport Service must keep records of all clinical incidents, which should also be included in transfer records and audited.
- Standard NHS England procedures for reporting of incidents should be followed including sharing of incidents with statutory bodies when indicated.
- Regular activity reports and an annual report will be produced and shared with all stakeholders and service commissioners.

3.2.11 Vehicles, equipment, safety and insurance

All modes of transport must comply with Care Quality Commission (CQC) standards and the Health and safety at Work Act 1974 and Electricity at Work Regulations 1989 and European Aero/Medical Institute (EURAMI) or Commission on Accreditation of Medical Transport Systems (CAMTS) standards.

The service will have policies and systems in place covering their scope of care.

3.2.12 Ambulance providers

There will be a contract for the provision of ambulance vehicles for transport.

Vehicles used to transport patients must be constructed to manufacturers' recommendations and meet the EC and UK legislation in terms of roadworthiness and also conform to current Motor Vehicle (Construction and Use) Regulations.

The vehicle provider must operate to the standards laid down by the NHS for ambulance services. Service specification to be negotiated at the time of tender

Insurance: The PCC Transport Service must ensure that there is separate provision of insurance for service personnel against loss of life or injury. The ambulance service must have a public liability insurance policy in place.

The PCC transport am must have robust communication structures in place.

3.2.13 Private contractors

Private contractors carrying out transfers are expected to be registered with the Care Quality Commission (CQC) and be compliant with CQC standards and to perform to the same criteria outlined above for the clinical teams and ambulance providers for commissioned Transport Services. This includes equipment standards, staffing and governance arrangements.

3.2.14 Communication

There will be a single point of contact through which the PCC Transport Service can be contacted and activated at all times for clinical advice and transport planning. This will include teleconferencing, call handling and call recording functionality. Clear, accurate and retrievable records of communications must be kept, in accordance with any agreed standards.

The PCC Transport Service shall have arrangements in place to receive feedback from local referring centres.

3.2.15 Documentation

- Clinical observation and record-keeping during the transfer must be to the same standard as that provided at any other time
- Documentation will include all components of the PICANet transport dataset information

3.3 Population covered

Paediatric Critical Care Transport Services are to be used for any patient that is to be transferred to and from a PCC facility.

Critically ill children are technically defined as those from 0 up to the age of 16 years; this shall include those discharged or transferred from a maternity service or neonatal unit and depending on the patient's needs this exceptionally may extend to a wider age range. Patients for transfer between neonatal units would usually be the responsibility of the Neonatal Transport Service.

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 GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

3.4 Any acceptance and exclusion criteria and thresholds

Time critical transfers are the responsibility of the referring unit

There should be agreed network transfer protocols for specific patient groups e.g. neonatal/paediatric/ECMO

The protocols will outline specific example scenarios:

- The transfer of neonates between neonatal units will usually be undertaken by the Neonatal Transport Service. (Ref: Toolkit for High Quality Neonatal Services – Principle 4)
- In some regions, the Neonatal and Paediatric Critical Care Transport Service may run as one service.
- Where the two services are separate, when a neonate is being transferred for management at a PCC facility, then the neonate may be transferred by a Paediatric Critical Care Transport Service.
- In the event of a time critical transfer there should be local guidance for the transfer of critically ill children from a referring centre to a level 3 PCCU by a District General Hospital (DGH) team.

3.5 Interdependencies with other services/providers

Critical interdependencies

Critical Interdependencies are PCC facilities, local district general hospitals, transport vehicle providers, statutory ambulance services, other adjacent Transport Services And at times air medical transfer assets

It is acknowledged that all PCC Transport Services will from time to time face acute demands which outstrip their capacity to respond. There should be documented procedures for triage and for requesting the assistance of other teams in these situations. Transport Services should collaborate with their neighbouring PCC transport providers regarding mutual-aid. Agreed regional transfer protocols will be in place to include contingency plans to support the transfer of critically ill children when the PCC Transport Service is not available.

Where a patient is to be transferred across commissioning or network borders the responsibility for the transfer lies first of all with the team covering the region where the child

falls ill.

Transport Services should have written agreement with neighbouring PCC Transport Services about referral and allocation processes unless alternative commissioning arrangements are already in place (e.g. ECMO).

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

Core Standards	<i>'Paediatric Intensive Care, 'A Framework for the Future', report from the National Coordinating Group on Paediatric Intensive Care to the Chief Executive of the NHS Executive', DH (1997). http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005760</i>
	<i>A Bridge to the future nursing standards, education and workforce planning in Paediatric Intensive Care, report of the Chief Nursing Officer's taskforce', DH (1997). http://www.dhcarenetworks.org.uk/_library/Resources/ICN/Policy_documents/Bridge_to_the_Future.pdf</i>
	<i>'Getting the right start: NSF for Children, Standards for Hospital Services' (2003). http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Consultations/Closedconsultations/DH_4085150</i>
	<i>'Standards for the Care of Critically Ill Children' Paediatric Intensive Care Society (2010). http://www.ukpics.org.uk/documents/PICS_standards.pdf</i>
	<i>National Clinical Audit & Outcomes Programme, Paediatric Intensive Care Audit Network (PICANet) participation mandatory as included in the 'Quality Account' outlined in the NHS Operating Framework, 2012/13.</i>

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

As above.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

There is a quality dashboard in place for paediatric critical care – the following measures are directly applicable to paediatric critical care transport services:

PIC13	Domain 1	Number of requests (within agreed scope of care) for retrieval of a patient requiring PIC admission which are refused
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		by the PCC transport team
PIC14	Domain 1	Number of retrievals performed within the agreed mobilisation time

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

At the current time there are no specific CQUINS applicable directly to Paediatric Critical Care Transport.

6. Location of Provider Premises

The Provider's Premises are located at:

To be determined by the Area Team

7. Individual Service User Placement

Not Applicable

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Appendix One

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
1. 95% of retrievals undertaken within agreed scope of care undertaken by the PCC transport team	95%	Local audit data PICANet submission to validate local audit data	Non compliance with contract General Conditions 8 & 9
2. Transfer team departs from the transport base within 30 minutes of the clinical decision to accept the patient	To be agreed with service provider	Local audit data PICANet submission	Non compliance with contract General Conditions 8 & 9
3. The PCC Transport Service arrives at the local referring centre within three hours of the decision to retrieve the child (decision response time)	To be agreed with service provider	Local audit data PICANet submission	Non compliance with contract General Conditions 8 & 9
4. Transport services collect timely (within 3 months of patient transport) minimum dataset required by PICANet	To be agreed with service provider	Local audit data PICANet submission	Non compliance with contract General Conditions 8 & 9

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
5. Governance arrangements in place that allow cross organisational learning within network	To be agreed with service provider	Local data to demonstrate governance arrangements	Non compliance with contract General Conditions 8 & 9
6. Governance arrangements in place that allow shared learning with other transport services	To be agreed with service provider	Local data to demonstrate governance arrangements	Non compliance with contract General Conditions 8 & 9
Domain 2: Enhancing the quality of life of people with long-term conditions			
Domain 3: Helping people to recover from episodes of ill-health or following injury			
1. 95% of retrievals undertaken within agreed scope of care undertaken by the PCC transport team	95%	Local audit data PICANet submission to validate local audit data	Non compliance with contract General Conditions 8 & 9
2. Transfer team departs from the transport base within 30 minutes of the clinical decision to accept the patient	To be agreed with service provider	Local audit data PICANet submission	Non compliance with contract General Conditions 8 & 9
3. The PCC Transport Service arrives at the local referring centre within three hours of the decision to retrieve the child (decision response time)	To be agreed with service provider	Local audit data PICANet submission	Non compliance with contract General Conditions 8 & 9
4. Transport services collect timely (within 3 months of patient transport) minimum dataset required by PICANet	To be agreed with service provider	Local audit data PICANet submission	Non compliance with contract General Conditions 8 & 9

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 4: Ensuring that people have a positive experience of care			
1. 95% of retrievals undertaken within agreed scope of care undertaken by the PCC transport team	95%	Local audit data PICANet submission to validate local audit data	Non compliance with contract General Conditions 8 & 9
2. Transfer team departs from the transport base within 30 minutes of the clinical decision to accept the patient	To be agreed with service provider	Local audit data PICANet submission	Non compliance with contract General Conditions 8 & 9
3. The PCC Transport Service arrives at the local referring centre within three hours of the decision to retrieve the child (decision response time)	To be agreed with service provider	Local audit data PICANet submission	Non compliance with contract General Conditions 8 & 9
4. Governance arrangements in place that allow cross organisational learning within network	To be agreed with service provider	Local data to demonstrate governance arrangements	Non compliance with contract General Conditions 8 & 9
5. Governance arrangements in place that allow shared learning with other transport services	To be agreed with service provider	Local data to demonstrate governance arrangements	Non compliance with contract General Conditions 8 & 9
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
1. 95% of retrievals undertaken within agreed scope of care undertaken by the PCC transport team	95%	Local audit data PICANet submission to validate local audit data	Non compliance with contract General Conditions 8 & 9

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
2. Transfer team departs from the transport base within 30 minutes of the clinical decision to accept the patient	To be agreed with service provider	Local audit data PICANet submission	Non compliance with contract General Conditions 8 & 9
3. The PCC Transport Service arrives at the local referring centre within three hours of the decision to retrieve the child (decision response time)	To be agreed with service provider	Local audit data PICANet submission	Non compliance with contract General Conditions 8 & 9
4. Transport services collect timely (within 3 months of patient transport) minimum dataset required by PICANet	To be agreed with service provider	Local audit data PICANet submission	Non compliance with contract General Conditions 8 & 9
5. Governance arrangements in place that allow cross organisational learning within network	To be agreed with service provider	Local data to demonstrate governance arrangements	Non compliance with contract General Conditions 8 & 9
6. Governance arrangements in place that allow shared learning with other transport services	To be agreed with service provider	Local data to demonstrate governance arrangements	Non compliance with contract General Conditions 8 & 9

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Appendix 2

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	E08/S/a
Service	Neonatal Critical Care (Intensive Care, HDU and Special Care)
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Neonatal services provide care for all babies less than 44 weeks post menstrual age that require on-going medical care. Neonatal services form part of an integrated pathway for high quality maternity, paediatric and family care serving a geographically defined regional population. Neonatal care services are provided in a variety of settings dependent upon the interventions required for the baby and with dedicated transport services to support babies being transferred to and from neonatal care units. In total around 60,000 – 70,000 babies (approximately 10% of all births) per year will receive some type of neonatal care (i.e. Special Care, High Dependency Care and Intensive Care Services).

In 2003 the Department of Health recommended that neonatal services be organised into managed clinical networks. In 2007 the National Audit Office reviewed the work of the networks and concluded that the development of neonatal networks had improved measures.

Under the auspices of the NHS and the Department of Health (DH) a Taskforce was commissioned to provide a Toolkit for High-Quality Neonatal Services (Dec 2009) which:

- Outlined the quality principles required of the care services providing specialist neonatal care.
- Provided a consistent definition of three categories of neonatal care.
- Described three types of units working in a network of units.
- Described a set of quality metrics.
- Gave examples of how to address Quality, Innovation, Productivity and Prevention (QIPP)

1.2

There is a growing body of evidence both nationally and internationally that suggests that caring for babies born before 27 weeks and those in other higher risk category groups (e.g. sick, more mature babies requiring prolonged intensive care) should be concentrated in relatively few centres in order to:

- Ensure that expert and experienced staff treat sufficient numbers of cases to maintain a safe high quality service and move towards the national standards;
- Maximise the use of scarce, expensive resources (staff, facilities and equipment).
- Organise retrieval services across large enough areas to be effective and economic.
- Facilities will be available to support family centred care including access to parent accommodation, particularly for families whose babies are cared for long distances from home, e.g. private and comfortable breastfeeding/expressing facilities, private room for confidential conversations and any other relevant facilities to support family centred care.

Publications include:

1. Toolkit for High-Quality Neonatal Services. Department of Health (2009)
2. Standards for Hospitals Providing Neonatal Intensive and High Dependency Care. The British Association of Perinatal Medicine (2001). Available at www.bapm.org
3. Quality standard for specialist neonatal care. National Institute for Clinical Excellence (NICE) (2010) Available at www.nice.org.uk
4. Caring for Vulnerable Babies. The re-organisation of neonatal services in England. Committee of Public Accounts (2008) 26th Report.
5. Neonatal Critical Care Minimum Data Set. Department of Health (2009) (NCCMD).
6. The Confidential Enquiry into Maternal and Child Health (CEMACH). Lewis G (ed) (2007). CEMACH became an independent charity on 1 July 2009 with the new name "Centre for Maternal and Child Enquiries" (CMACE).
7. Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer – 2003-2005
8. Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour. RCOG (2007)
9. Report of the Neonatal Intensive Care Services Review Group.
10. National Service Framework for Children, Young People and Maternity Services, Standard 11. Department of Health/Department for Education and Skills (2004).
11. Clinical Negligence Scheme for Trusts: Maternity Clinical Risk Management Standards. NHS Litigation Authority (2009) Version 2, 2009/10.
12. The Bliss Baby Charter Standards (Bliss 2009).
13. The Bliss Baby Charter Audit Tool. Bliss (2011).
14. Parents' experiences of neonatal care: A report on the findings from a national survey. Picker Institute Europe (2011).
15. Descriptions of Services for Pregnant Women with Complex Social Factors. National Institute for Clinical Excellence (NICE) (2012). Available at www.nice.org.uk
16. Children and Young People's Health Outcomes Strategy: A report of the Children and Young People's Health Outcomes Forum (2012)
17. NICEPOD Are we there yet? A review of organisational and clinical aspect of children's surgery. A report by the National Confidential Enquiry into patient outcome and death (2011).
18. NICE clinical guideline 129: Multiple pregnancy. The management of twin and triplet pregnancies in the antenatal period. September 2011.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

Key Outcomes:

1. Each Network should have the capacity to provide all neonatal care for at least 95% of babies born to women booked for delivery in the network (i.e. no more than 5% of babies born to booked women should be transferred out of network for inappropriate reasons) (Domains: 1,3,4,5,)
2. Retinopathy Screening - Babies born at less than 32 weeks gestation and / or with a birth weight less than 1,501g who receive specialist neonatal care must undergo retinopathy screening in line with national guidelines on timing. (Domains: 3,5)
3. Blood Infections - The rate of blood stream infection per 1,000 catheter days taken after 72 hours of age must be recorded. (Domains: 1,3,5,)
4. Early Surgery - Babies with antenatal diagnosed fetal malformations requiring early surgery must be booked to be delivered at a designated network surgical centre. (Domains: 1,2,3,4,5,)
5. Temperature - Newborn babies who receive specialist neonatal care must have their temperature taken within one hour of admission and temperatures of 36C or less must be recorded for audit purposes. (Domains: 1,5,)
6. Birth Place of Extremely Premature Network Babies - The number and location of birth of babies born at less than 27 weeks gestational age. (Domains: 1,3,5,)
7. Transfer of Extremely Premature Network Babies - Babies <27+0 weeks born outside of the network NICU who are not transferred into a Network NICU within 24 hours (Domains: 1,3,5)
8. Unit Closures - The number of days the neonatal unit was closed beyond 24 hours both for booked patients and network babies and in-utero transfers. (Domain: 3,4,5,)
9. Refused Ex-Utero Transfers - The number of network ex-utero transfers refused admission to the unit due to lack of capacity/staffing/equipment. (Domain: 3,4,5,)
10. Production of an annual report to include at least: activity data, quality measures performance and evidence that parent experience has been measured and responded to (Domain: 4)

3. Scope

3.1 Aims and objectives of service

The aim of the neonatal service is to:

1. To improve babies' chances of survival and minimise the morbidity associated with being born either premature or term and sick. It is a high cost, low throughput service in which clinical expertise is a key determinant of the quality of the outcomes for the baby.
2. To provide a family-centred approach to care, defined as involving families in the care of their own children, and helping parents understand their baby's needs.
3. To improve quality of care by working in partnership with other provider units and service commissioners within Operational Delivery Networks (ODNs) as part of the broader Maternity and Children's Strategic Network. This will ensure integration across the whole maternity and children's pathway of care.

The service will deliver the aim to improve both life expectancy and quality of life for newborn babies by:

1. Ensuring neonatal outcomes are in line with the type of unit where babies are cared for.
2. Ensuring neonatal outcomes across an ODN are in line with other ODNs across England & Wales.
3. Delivering care in a family-centred way that seeks to minimise the physical and psychological impact of neonatal care on the baby and their family, for example by improving psychological outcomes and breastfeeding rates.
4. Providing an environment where parents are enabled to make informed decisions about treatment and become involved in the care of their baby / babies, thereby minimising the psychological trauma of premature or sick term babies.
5. Ensuring robust arrangements for clinical governance are in place.
6. Ensuring that robust links to clinical governance in co-located maternity units are in place.
7. Working in partnership with other network neonatal services to promote delivery of neonatal care in the most appropriate setting.
8. Ensuring robust monitoring and reporting arrangements in accordance with performance requirements and evidence of continuing improvement of quality and responsiveness, year on year is demonstrated through evaluation and audit.
9. Ensuring that parents whose babies are unlikely to survive or have life limiting conditions receive sensitive support and care which follows a recognised Palliative Care Pathway.

3.2 Service description/care pathway

The following list summarises the service description:

1. Inpatient management and pathway of care for babies within each type of neonatal unit and in each category of care.
2. Pathway of specialist services for example surgical, cardiac and specialist medical conditions which is only available in designated centres to optimise outcome and remove inequity.
3. Transport of babies within a geographical region (see neonatal transfer service specification).
4. Discharge and provision of short-term and long term follow up to 2 years in some cases.

3.2.1 Categories of Care Levels (BAPM 2011):

Services must ensure that any care provided is proportionate to the need of the baby. Cots must be used appropriately according to the level of care needed. Details of criteria are found in BAPM 2011 categories of care.

Intensive Care (Health Resource Group (HRG) XA01Z):

Intensive Care is care provided for babies who are the most unwell or unstable and have the greatest needs in relation to staff skills and staff to patient ratios. This includes any day where a baby receives any form of mechanical respiratory support via a tracheal tube, both non-invasive ventilation (e.g. nasal Continuous Positive Airway Pressure (CPAP), SIPAP, Bilevel Positive Airway Pressure (BIPAP), nasal high flow) AND Parenteral Nutrition (PN), day of surgery (including laser therapy for retinopathy of prematurity (ROP)) and on day of death or any conditions listed as per BAPM categories of care.

High Dependency Care (HRG (XA02Z):

High Dependency care is provided for babies who require skilled staff but where the ratio of nurse to patient is less than intensive care. This care takes place in a neonatal unit where a baby does not fulfil the criteria for intensive care but receives any form of non invasive respiratory support (e.g. nasal, CPAP, SIPAP (infant flow system with multiple modalities), BIPAP, nasal High Flow, parenteral nutrition) or continuous treatment of their condition as per BAPM categories of care

Special Care (HRG (XA03Z):

Special Care is provided for babies who require additional care delivered by the neonatal service but do not require either intensive or high dependency care. It includes babies receiving oxygen via low flow nasal cannula, feeding by nasogastric tube, jejunal tube, or gastrostomy, continuous physiological monitoring, care of stoma, presence of an intra-venous (IV) cannula, receiving phototherapy or special observation or physiological variables at least 4 hourly.

Special Care with Primary Carer Resident (HRG XA04Z) (often referred to as transitional care):

Transitional Care can be delivered in two service models, within a dedicated transitional care ward or on a post natal ward. In either case the primary carer must be resident with the baby and providing care. Care above that needed normally is provided by the mother with support from a midwife / healthcare professional trained in delivering elements of special care but does not require a specialist neonatal qualification. Examples include low birth weight babies, babies who are on a stable reducing programme of opiate withdrawal for Neonatal Abstinence Syndrome and babies requiring special care that can be administered outside of a neonatal unit environment, such as tube feeding, antibiotics and phototherapy

3.2.2 Categories of Neonatal Units:

These are listed below.

3.2.3 Special Care Unit (SCU):

The service will provide:

1. Neonatal services commensurate with national guidelines and professional standards where singleton births are anticipated after 31+6 weeks gestational age provided the anticipated birth weight is above 1,000g.
2. ODN care pathways will define antenatal factors or conditions present soon after birth which increase the likelihood that transfer to a Neonatal Intensive Care Unit (NICU) for complex or prolonged neonatal intensive care OR a Local Neonatal Unit for short term neonatal intensive /high dependency care will be required. ODNs and the Trusts responsible for these units should monitor adherence to the care pathways.
3. Some ODNs have approved care pathway where babies born between 30+0 and 31+6 weeks gestational age receive initial care in Special Care Unit (SCU) provided the anticipated birth weight is above 1,000g and intensive care is not required.

4. Stabilisation of babies prior to transfer to an (Local Neonatal Unit (LNU) or NICU predominantly, but not exclusively for intensive care.
5. Care for local babies with high dependency or special care needs following repatriation from LNUs or NICUs within the network or from out of area in accordance with approved ODN care pathways.
6. Referrals for ongoing special care from other network neonatal units who are unable to undertake this work due to capacity reasons.
7. Care for local babies post specialist surgery following repatriation from the network surgical unit or step down from other LNUs in accordance with approved ODN care pathways.
8. Transitional care, working in collaboration with post natal services subject to local service model.

3.2.4

A Special Care Unit will not be commissioned and therefore not be expected to provide the following except under exceptional circumstances which have been agreed and formally documented by the Network NICU on an individual case basis:

1. Care beyond initial stabilisation to babies less than 30+0 weeks of gestation.
2. Care beyond initial stabilisation to babies with a birth weight < 1,000g.
3. Intensive care for any baby apart from initial stabilisation prior to transfer
4. Babies with symptoms of hypotension, DIC, renal failure, metabolic acidosis or babies requiring the following treatment and support: Inotrope infusion, insulin infusion, presence of a chest drain, exchange transfusion, prostaglandin infusion, nitric oxide, high frequency oscillatory ventilation (HFOV) and therapeutic hypothermia.

3.2.5.

Local Neonatal Unit (LNU):

In addition to all the services provided by Special Care Baby Unit's (SCU's) local neonatal units will provide:

1. Neonatal services commensurate with national guidelines and professional standards where; singleton births are anticipated after 26+6 weeks gestational age and multiple births are anticipated after 27+6 weeks gestational age providing the anticipated birth weight is above 800g.
2. ODN care pathways will define antenatal factors or conditions present soon after birth which increase the likelihood that transfer to a NICU for complex or prolonged neonatal intensive care will be required. ODNs and the trusts responsible for these units should monitor adherence to the care pathways. (Please refer to section below which outlines complex and prolonged intensive care).
3. Some ODNs have approved care pathways where all babies born between 27+0 and 27+6 weeks gestational age receive initial care in NICUs rather than LNUs.
4. Where possible, women will be transferred in-utero to the Network NICU when gestational age, anticipated birth weight or need for complex or prolonged intensive care is anticipated in accordance with ODN care pathways.
5. Limited intensive care in accordance with approved ODN care pathways (see commissioning exclusions, below)
6. Short periods of intubated ventilator support will be provided, however the clinical condition of any baby requiring this care must be discussed with a consultant in the Network NICU by 48 hours and every 24 hours thereafter if intubated ventilatory support continues.
7. An agreed management plan including decisions regarding transfer criteria will be documented
8. The stabilisation of babies prior to transfer to the Network NICU who require complex High dependency care and special care for their local population.
9. Referrals from other network neonatal units who are unable to undertake this work, due to capacity reasons and/or network guidelines.
10. Ongoing care for babies who have undergone specialist surgery following repatriation from

the network surgical NICU.

11. Care for local babies repatriated from elsewhere in the network who no longer require positive pressure ventilation.
12. LNUs will not accept out of network referrals without prior discussion with the ODN defined Lead NICU to ensure the integrity of capacity for network babies.
13. LNUs will transfer babies requiring complex care or prolonged care to the approved ODN NICU in accordance with approved care pathways.

3.2.6.

A Local Neonatal unit will not ordinarily be commissioned to provide the following:

1. On-going intensive care beyond initial stabilisation and intensive care to babies less than 27+0 weeks of gestation
2. On-going intensive care beyond initial stabilisation to babies with a birth weight below 800g
3. Complex intensive care including babies with symptoms of additional organ failure (e.g. hypotension, disseminated intravascular coagulation (DIC), renal failure, metabolic acidosis) or babies requiring the following treatment and support:
4. Support of more than one organ, for example ventilation via a tracheal tube plus any one of the following: Inotrope infusion, insulin infusion, presence of a chest drain, exchange transfusion and prostaglandin infusion.
5. Nitric oxide
6. High frequency oscillatory ventilation (HFOV)
7. Therapeutic hypothermia beyond initial stabilisation.
8. Prolonged Intensive care (intubated ventilatory support) for greater than 48 hours

3.2.7.

Neonatal Intensive Care Unit (NICU)

The service will provide in addition to services provided by SCUs and LNUs:

1. Neonatal services commensurate with national guidelines and professional standards where births are anticipated after 22+6 weeks gestation (BAPM & Nuffield Council on Bioethics).
2. Intensive care for all the babies born within the network according to ODN approved care pathways including those less 27+6 weeks gestation, or with a birth weight < 800g and any baby requiring complex or prolonged intensive care. ODNs and the Trusts responsible for these units should monitor adherence to the care pathways
3. Neonatal intensive care service for other local neonatal networks or out of area neonatal units when they cannot access a cot in their network NICU because of lack of capacity at that unit
4. Leadership within neonatology for the neonatal ODN units and 24 hour acute clinical telephone consultations as required by the network hospitals and, if required neonatal transport services. Where more than one NICU is within a neonatal ODN, there will be a sharing of responsibility to provide 24 hour acute clinical consultations.
5. Care for local network babies repatriated from elsewhere requiring ongoing care from a NICU.

3.2.8.

A Neonatal Intensive Care Unit would not necessarily be expected to provide the following which are only available in specialist centres to optimise outcome and remove inequity:

1. Extra - Corporeal Membrane Oxygenation (ECMO), which is nationally commissioned
2. Surgical care, except as part of approved ODN protocol
3. Specialised cardiac care, except as part of approved ODN protocol.

The local ODNs will determine the care pathways for the above services in designated units delivering specialist services. These Trusts will provide, in addition to the above:

1. Specialist surgical assessment, treatment and care prior to repatriation to local neonatal unit.
2. Specialist medical treatment and care, for example renal and endocrine services.
3. Specialist cardiac treatment and care.

3.2.9.

Transfers:

- Transfer of babies will be co-ordinated by the neonatal ODN transfer service in accordance with the national service specification.
- The transport for nationally commissioned services, e.g. ECMO will be arranged by the receiving specialist centre in consultation with the local network transfer team (eg for ECMO).

3.2.10

Capacity:

1. Each unit will ensure they have sufficient capacity to deliver the appropriate service for their booked maternity population.
2. Unit capacity must be planned in co-ordination with local maternity and fetal medicine services and the neonatal ODN. This should take into account the level of care provided at the unit, and so anticipating neonatal network transfers, both in- and ex-utero.

3.2.11

Staffing:

1. Trusts will ensure that adequate numbers of medical, nursing and allied health professional staff with appropriate skills are in place to deliver the level of care required for that unit.
2. A workforce plan must be in place, designed to maintain sustainable staffing levels based on the DH Toolkit standards and in line with any predicted increases in birth rate. Each unit must work towards an agreed plan with commissioners to have nurse staffing levels based on the following nurse to baby ratios:
Intensive Care 1:1
High Dependency 1:2
Special Care 1:4

3.2.12

Medical staffing rotas must be European Working Time Directive compliant at levels required for the type of unit as outlined in BAPM 2010 guidance.

1. Units must engage with neonatal ODN workforce strategies. Ongoing development and modernisation of the workforce must be reviewed to ensure skills meet future service requirements.
2. Staffing in each unit must include provision for a designated Lead Nurse, designated Lead consultant, educator, shift co-ordinator and discharge planning / outreach co-ordinator.
3. All units must have access to Dietitians, Physiotherapists, Speech and Language Therapists and Occupational Therapists in line with Toolkit requirements. Allied health professionals must have time within their job plans to provide advice and clinical care to the neonatal unit.

3.2.13

Professional Competence, Education and Training

1. Appropriate and specific training programmes for all trained and untrained staff must be in place with regular neonatal specific update training where required.
2. A minimum of 70% (special care) and 80% (high dependency and intensive care) of the nursing and midwifery establishment must hold NMC registration; & a minimum of 70% of registered nursing and midwifery establishment must hold a post registration qualification in specialised neonatal care.
3. Funded staffing levels must recognise the need to provide specialist training and allow for this.
4. Appropriate training / supervision must be provided to all staff in order to remain competent in practice.
5. Staff must adhere to all national and local guidelines and policies.

6. Staff in each unit will adhere to local, network and national programmes to actively reduce their neonatal infections.

3.2.14

Family Experience, Communication and Facilities:

1. Each unit must deliver a family-centred care approach, with sufficient emotional and practical support for parents and families, enabling them to make informed choices and play an active part in their babies' care.
2. Staff must have the appropriate skills including communication skills to provide knowledgeable and skilled advice to parents/ carers. To deliver high quality family-centred care staff should understand what parent's needs are ('be able to stand in their shoes') and have empathy with the patient/carer needs.
3. Parent information and support should be given in written and verbal format (ideally in a range of languages) including about their babies' condition and treatment, local unit information, financial help, welfare, breastfeeding.
4. There must be regular updates and communication between all health professionals and parents/ families particularly where the babies' condition or care plan is subject to change. Parents should have access to consultants/ senior staff to help them understand their babies' condition and treatment. Parents will be supported to be actively involved in their babies' care including helping them develop the skills and confidence to provide kangaroo care, breastfeeding/expressing, resuscitation training and any other relevant activities
5. Facilities should be available to support family centred care including access to parent accommodation, private and comfortable breastfeeding/expressing facilities, private room for confidential conversations and any other relevant facilities to support family centred care

3.2.15

Feedback from Families:

1. Provider Trusts will be expected to involve families not only in the health care of their own baby but also in the evaluation of the service they are accessing. There must be a continuous process for involving parents in improving the delivery of family-centred care.
2. A range of tools must be in place to measure parent experience which balances real time and retrospective feedback
3. Providers will have a named lead who is responsible for receiving concerns from parents
4. Provider Trusts must demonstrate that procedures are in place for involving families in routine audit arrangements for the purpose of evaluating service performance from a family perspective. These procedures should include a variety of methods for obtaining parent feedback and the results used to help identify future audit topics, action plans and agreed targets.
5. ODN's and providers will ensure that parent representatives are included within governance structures and that parent representatives have support and training.

3.2.16 Surgical Services:

1. Units providing surgical care must have staff with appropriate skills and knowledge to deliver high quality surgical care.
2. Parents are sufficiently informed of the risks and potential outcomes of surgery, the need for consent is explained, and decisions are made in partnership with parents and fully documented.
3. There must be a surgically experienced nurse on every shift if surgical babies are present, able to give nursing surgical advice to other units in the Network.
4. There must be a designated Lead specialist paediatric surgeon for the surgical neonatal unit and 24 hour paediatric surgical cover.

3.2.17 Discharge Route:

1. By working closely with community services, neonatal services support babies and their

families in the transition and adjustment from an in-patient stay on a neonatal unit to restored family life in the community.

2. Discharge planning will be facilitated and coordinated from initial admission to discharge date, to ensure both the baby and their family receive the appropriate care and access to resources. This includes decisions about any continuing care needs that the woman, her baby and her family may have to make following discharge from in-patient care, and should meet the following criteria:
 - Pre-discharge planning involves parent / carer and other key family members, GP, Health Visitor and the care co-ordinator and if appropriate, social care.
 - All key professionals receive copies of the discharge plan, including details of when the patient will next be seen and by whom, and emergency contact details.
 - Before discharge, parents are advised about their babies' medication and its side effects.
 - Following discharge, the baby and family are contacted by a community professional in primary care within one week.
 - Units should have written local criteria for higher risk follow-up arrangements.
 - Care plans reflect a multi-disciplinary approach to neonatal care, both within primary care and community teams.

3.2.18 Follow Up Services:

1. Medical outpatient clinic - babies born less than 32 weeks gestation and/or < 1500g or with a high risk of problems will have their medical condition followed up post discharge. Follow-up clinics will also have intent to focus on long-term outcomes of premature babies and those in at-risk groups, which may require a further follow-up programme.
2. Neonatal follow-up programmes - Structured neuro-developmental follow-up assessments will be undertaken at 2-2.5 years (corrected gestation) on all eligible babies in line with recommendations of the British Association of Perinatal Medicine (BAPM) and National Neonatal Audit Programme (NNAP). Eligible babies include, (but is not exclusive): < (or equal to) 30 weeks, <1,000grams birth weight, moderate to severe encephalopathy.
3. Clinicians will involve partner paediatricians and health professionals to carry out the 2-year assessment. The results of the 2 year assessment must be entered into the baby's electronic records.

3.2.19 Discharge Criteria and Planning:

1. Neonatal services support babies and their families in the transition and adjustment from an in-patient stay on a neonatal unit to restored family life in the community, by working closely with the community services.
2. Babies will be discharged from neonatal care as soon as condition allows with reporting to AT commissioners and the ODN of babies likely to remain on the neonatal unit beyond 44 weeks post menstrual age (4 weeks corrected gestation), taking into consideration the ongoing support for the baby and carers.
3. Local services, including neonatal, midwifery and primary care professionals, provide follow-up support to babies and families in the community after they have been discharged, and help to ensure that there is a seamless transition from in-patient stay back into family life.
4. Ongoing admission of babies with delayed discharge for social or community resource reasons must be agreed with commissioners as soon as the delay is anticipated.

3.2.20 Neonatal Out-Reach / In-Reach or Community Services:

1. Community support is provided by an integrated hospital-community neonatal team or an identifiable team of community health professionals.
2. Each Trust will ensure that these professionals undertake adequate neonatal training and have appropriate skills and competencies for neonatal out / in- reach. These staff should feel confident and able to provide consistent and appropriate advice to parents supported by the appropriate information ahead of discharge, including details of any particular arrangements

identified in the baby's care plan, in order to best support families care for their babies at home.

3. Units will enable parents to meet with the community team supporting them at home before the baby is discharged from the hospital.

3.2.21 Data Requirements:

1. Trusts must ensure that they are able to securely maintain accurate, reliable computerised records of patient-level and unit-level data systems must be capable of capturing operational activity. The data must be suitable for retrieval, analysis and presentation stratified by month, calendar year or financial year, as required.
2. Trusts must ensure that neonatal data systems are capable of generating outputs for clinical and operational benchmarking
3. Trusts must ensure that neonatal data systems are capable of generating exportable data outputs for the following purposes:
 - BAPM neonatal dataset (2012)
 - Neonatal Critical Care Minimum Data Set
 - National Neonatal Dashboard
 - National Neonatal Database (currently hosted by Neonatal Data Analysis Unit (NDAU)).
 - National Neonatal Audit Programme.
 - Mothers and Babies Reducing Risk through Audits and Confidential Enquiries (MBBRACE) Dataset.
 - Returns to the lead commissioner / ODN manager of any additional, to national, dashboard requirements.
 - Exception reporting in accordance with ODN policy.

3.2.22 Policies:

A national (Department of Health) policy document is in place to be used by all neonatal units for the use of Palivizumab to reduce the risk of Respiratory Syncytial Virus (RSV) in high risk infants.

3.2.23 Clinical Governance:

1. The clinical governance of the neonatal unit must be to the standard specified by the host NHS Trust, and clinical governance responsibility should reside with that NHS Trust.
2. Where appropriate there must be evidence of compliance with external NHS standards (e.g. Care Quality Commission (CQC), NHS Litigation Authority (NHSLA), National Institute for Health and Care Excellence (NICE)).
3. Each Trust must have in place a range of practice guidelines, protocols and pathways to ensure consistent and evidence-based clinical management. In the main, these will reflect national professional guidance, such as that available from NICE, BAPM, Department of Health Neonatal Toolkit, the Royal College of Obstetricians and Gynaecologists or the Royal College of Paediatrics and Child Health.
4. ODN approved guidelines, protocols and care pathways will be adopted by Trusts.
5. The service must have, as a minimum, written policies covering the transfer of babies both in utero and ex utero, evidence of written clinical procedures and protocols in place.

3.2.24 Contractual Definitions:

Contractual definitions and associated Health Resource Groups (HRGs) and Treatment Function Codes (TFCs) are defined by service area. The Neonatal Critical Care Minimum Data Set (NCCMDS) has been developed by NHS stakeholders for use in neonatal services. Five HRG groups are identified within the NCCMDS dataset of which 4 groups relate to neonatal care (see table below).

Service Area	HRG / Treatment Function Code	National / Local
Neonatal Intensive Care	XA01Z	National
Neonatal High Dependency	XA02Z	National
Neonatal Special Care	XA03Z	National
Special Care with External Carer (Transitional Care)	XA04Z	National
Normal Care (post natal)	XA05Z	Local
Surgical Care	HRG depending upon the procedure	National
Neonatal Community Outreach	Not known	Local
Community support	Not known	Local
Neonatal Outpatients	Depending on the respective TFC	Local
2 year Neurodevelopmental reviews	Paediatric Outpatient first multi attendance (WF02B)	National
Neonatal Transport	XA08Z	National
Major Neonatal Diagnosis	PB01Z	
Minor Neonatal Diagnosis	PB02Z	

1.2.25 Operational Delivery Network

Operational Delivery Networks have been developed for this service area. ODNs ensure quality standards and networked patient pathways are in place. They focus on an operational role, supporting the activity of commissioned providers in service delivery, improvement and delivery of a commissioned pathway, with a key focus on the quality and equity of access to service provision. This allows for more local determination, innovation and efficiency across the pathway. ODNs support the delivery of 'Right Care' principles by incentivising a system to manage the right patient in the right place.

3.3 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).

Specifically, this service is for babies who are generally (but not exclusively) less than 44 weeks post menstrual age (less than 28 days old, corrected for gestational age assuming 40 weeks defined as term) as outlined within this specification.

3.4 Any acceptance and exclusion criteria and thresholds

3.4.1. Acceptance Criteria:

1. The service will accept inward referrals from obstetric, maternity or feto- maternal services.

Within the antenatal period, high risk mothers or mothers with high risk babies will generally be under the care of an obstetrician.

2. The service will also accept referrals from other providers of neonatal services within the operational delivery network or within a defined regional pathway, particularly when the referring service is not accredited to undertake the clinical role that the baby requires. When the baby's condition has stabilised, ongoing care will be effectively undertaken at a designated provider closer to the family's home.

The service will accept referrals for babies who meet one of the following criteria:

1. From co-located obstetric and maternity services in discussion with relevant medical staff
2. Within the network as per approved in utero transfer pathways and in discussion with parents and relevant multi-professional senior staff (to include consultant-to-consultant dialogue)
3. Within referral thresholds from within the ODN as per approved network policies and in discussion with parents and relevant multi-professional senior staff (to include consultant-to-consultant dialogue).
4. From referrals for surgery, specialist care or diagnostic procedures in discussion with parents and relevant multi-professional senior staff (to include consultant-to-consultant dialogue)
5. From outside the network when capacity allows in discussion with the ODN transfer co-ordinating service and relevant senior staff.
6. From other ODN units which are closed due to capacity, staffing or infection outbreaks in discussion parents and relevant multi-professional senior staff (to include consultant-to-consultant dialogue).

The care, prioritisation and urgency required will be based upon the individual needs of the baby, network policies / guidelines and following discussion between the relevant consultants.

Referrals will be accepted by the neonatal unit based on the local baby's need and in accordance with referral criteria and the designation of the individual unit.

With the exception of neonatal referrals for foetal medicine/surgical expertise and referrals for specialist services (Ref 2.2.2), a unit within the Network will not accept referrals from outside the Network unless there is no possibility of the baby being accommodated within or near to its Network of origin.

Transfers either within the local ODN or outside will require discussion with the ODN transfer service and should follow the criteria as set out in the transfer specification.

3.4.2 Exclusions:

1. Normal care (HRG XA05Z) – This specification excludes normal care, which is defined as care given after birth primarily by the mother, with midwifery support but without the need for special investigations. This is commissioned by Clinical Commissioning Groups (CCGs) as part of the normal maternity pathway within postnatal HRGs. This includes social care provided in the case of babies waiting for foster care or safeguarding issues.
2. Ward Attendees – babies who have care provided for less than 4 hours
3. Out Patient Clinics - which form part of the paediatric service
4. Community Support – support given by Community Midwives, Health Visitors and Community Children's Teams from primary care.
5. Specific High Cost Drugs and Treatments - (individual provider contracts)

3.5 Interdependencies with other services/providers

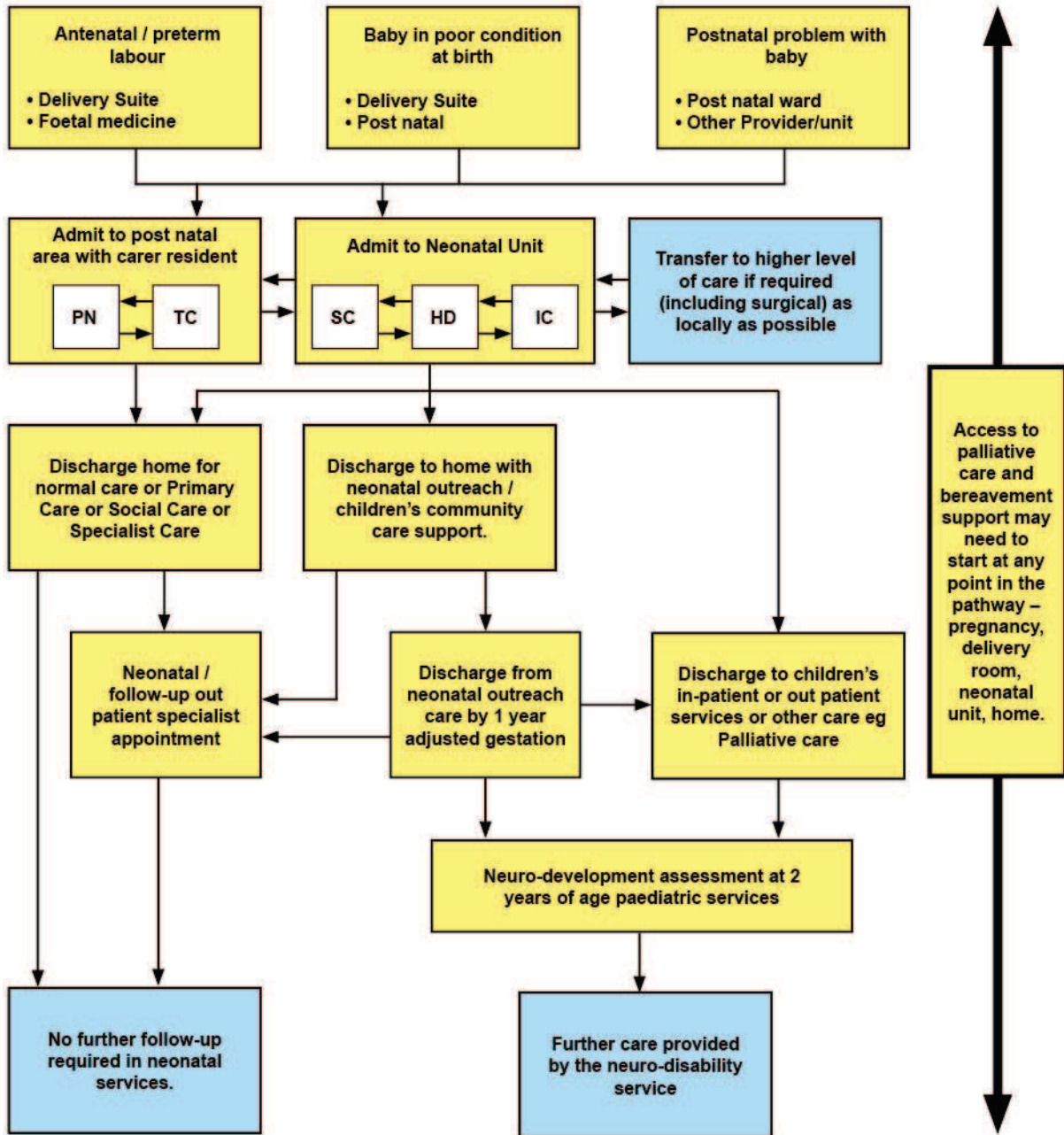
Co-located services: Neonatal units are located alongside obstetric-led services. Paediatric services for ongoing care are available either through the provider Trust or an NHS Trust in the parents' area of residence

Interdependent services: Neonatal services form part of an integrated high quality maternity and family care service serving a regional population. Neonatal services are interdependent with maternity, foetal medicine, paediatrics and specialised neonatal transport service developments.

Related services: Some babies require care which is ongoing and beyond the scope of the neonatal services. There needs to be established links with local paediatric services, community paediatric services and primary care. The following list includes, but is not limited to the following related services: community paediatric services, primary care and social care, hospice care, Children's Centres, ambulance services, psychiatric services, national screening and laboratory services, neonatal surgical services, neonatal supra specialist services. Clear care pathways must be developed to provide a seamless service for babies and their families. ODN approved care pathways should link in with pathways of care (universal and complex) if ongoing care is required.

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• Neonatal Care Pathway:



age

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

NICE Standards exist for neonatal services and can be accessed via the following link:
<http://www.nice.org.uk/media/8C6/31/SpecialistNeonatalCareQualityStandard.pdf>

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

	Standard	Measurement
1	Robust clinical governance arrangements are in place locally and across the Network to ensure safe pathways of care for the baby and family (BAPM 2011 standards)	Review at a minimum annually and endorsed corporately by providers.
2	Outcomes are benchmarked nationally and data is available and shared in accordance with Caldicott regulations.	Produced annually
3	Staffing and competency levels are achieved (BAPM 2011 Standards)	An action plan is required to be agreed as part of the contractual setting process for 13/14. The action plan is to set a baseline position and plans to ensure incremental improvements are made year on year with full achievement within a THREE year period. These plans need to be monitored on a six monthly basis through this period to demonstrate improvements.
4	Neonates are transferred for uplift in care according to the service specification criteria on gestation and complexity of care.	Exception reports made available for cases where this does not apply.
5	NICE quality standards for specialist neonatal care are measured and maintained (NICE Standards 2010)	Compliance reported six monthly, paying due regard to what has been agreed in relation to standard 3 in relation to staffing.
6	Standards are in place and parent feedback is collected and acted upon (Bliss Baby Charter 2011)	An audit of family centred care provision must be conducted and an action plan put in place to ensure progress is made year on year with full achievement within a three year period. These plans need to be monitored on a six monthly basis through this period to demonstrate improvements.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

There is a quality dashboard in place for neonates. The current list of measures is as follows:

NIC01	Domain 1	Transport Team Responsiveness
NIC02	Domain 5	Retinopathy Screening
NIC04	Domain 5	Blood Stream Infections
NIC07	Domain 5	Planned Delivery at Surgical Centre
NIC13	Domain 5	Admission Hypothermia
NIC16	Domain 5	27 week activity
NIC18	Domain 5	Unit Closures
NIC19	Domain 5	Number of refused neonatal admissions

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

There are currently 4 CQUINS on the national pick list as follows:

Improved Access to Breast Milk
Timely Admission of TPN
Timely Simple Discharge
Retinopathy Of Prematurity Screening

6. Location of Provider Premises

The Provider's Premises are located at:

Not applicable

7. Individual Service User Placement

Not Applicable

Appendix Two

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Ensuring babies are delivered in the optimum environment	To be agreed <i>Provisional level of 80% births and 90% of children admitted to NICUs</i>	Network level: all babies <27w born in Level 3 service National Neonatal Dataset	Non-compliance with contract General Conditions 8 & 9
Ensuring babies are cared for in the optimum environment		Hospital – Monthly review of inter-hospital and intra-hospital transfers and delays	Non-compliance with contract General Conditions 8 & 9
Contribution to national mortality review		Adjusted mortality for hospital and network within 95%CI for national data	Non-compliance with contract General Conditions 8 & 9
Domain 2: Enhancing the quality of life of people with long-term conditions			
Ensuring high risk babies are followed up appropriately after discharge	To be agreed <i>Provisional level set at 85% follow up to 2 years</i>	Network level: All babies under 32 weeks of gestation at birth and all children cooled following intrapartum asphyxia followed to 2 years	Non-compliance with contract General Conditions 8 & 9
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Ensuring children are cared for close to their home and family – no delay in repatriation transfer to local hospital	To be agreed	Network level: Special care provided in referral unit	Non-compliance with contract General Conditions 8 & 9
Minimising nosocomial infection		Dashboard returns for infection rates	Non-compliance with contract General Conditions 8 & 9
Domain 4: Ensuring that people have a positive experience of care			
Hospital seeks patient feedback and action upon feedback	To be agreed	Hospital level: Annual patient feedback report, including the results	Non compliance with contract General Non compliance with contract General

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Hospital has no complaints concerning care		of nationally designed questionnaire, and list of actions taken in response No. complaints and actions taken	Conditions 8 & 9
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
Monitoring of drug and other incidents	To be agreed	Hospital Level: Annual audit with learning points and actions taken	Non-compliance with contract General Conditions 8 & 9

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Appendix 2

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	<i>E08/S/b</i>
Service	<i>Neonatal Critical Care Transport</i>
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

In 2001 the Department of Health recommended that neonatal services be organised into managed clinical networks. In 2007 the National Audit Office reviewed the work of the networks and concluded that the development of neonatal networks had improved the service but that there were still issues which needed to be dealt with. In 2008 the Public Accountants Committee (PAC) also reviewed the neonatal care and made recommendations about improvements and proposed a set of performance measures.

Under the auspices of the NHS and the Department of Health (DH) a Taskforce was commissioned to provide a Toolkit for High-Quality Neonatal Services (December 2009) which:

- Outlined the quality principles required of the services providing specialist neonatal care.
- Provided a consistent definition of three categories of neonatal care.
- Described three types of units working in a network of units
- Described a set of quality metrics
- Gave examples of how to address Quality, Innovation, Productivity and Prevention (QIPP).

1.2. Publications include:

- Toolkit for High-Quality Neonatal Services. Department of Health (2009).
- Standards for Hospitals Providing Neonatal Intensive and High Dependency Care.

The British Association of Perinatal Medicine (2001). Available at www.bapm.org.
 Service Standards for Hospitals Providing Neonatal Care. The British Association of Perinatal Medicine (BAPM) (2010). (3rd Edition). Available at www.bapm.org.

- Quality standard for specialist neonatal care. National Institute for Clinical Excellence (NICE) (2010). Available at www.nice.org.uk.
- Caring for Vulnerable Babies. The re-organisation of neonatal services in England. Committee of Public Accounts (2008) 26th Report.
- Neonatal Critical Care Minimum Data Set. Department of Health (2009) (NCCMD).
- The Bliss Baby Charter Standards. Bliss (2009).
- Management of acute in-utero transfers: a framework for practice. British Association of Perinatal Medical (2008).
- Dataset for neonatal transport (2012). BAPM & UK Neonatal Transport Group.

In 2011/12 there were in the region of 12,000 to 13,000 neonatal transfers undertaken in England.

Neonates **may need** to move to a unit other than where they were born for specialist care that is not provided in their local unit. A Neonatal Transport Service is the service which moves babies between hospitals when this is required. The service is staffed by specialist clinicians and nurses to provide ongoing neonatal care before and during the journey. The service will also undertake transfers of neonates back to the local unit.

Other reasons for transfer are for tests/investigations not available at the local unit and also when the local unit has insufficient capacity to care for the infant.

Other services operate in overlapping clinical areas. The ECMO transport services transfer infants from neonatal units. Paediatric Intensive Care (PIC) transport services are often involved with transfers of infants, depending on the circumstances of the referral. These services may all at times overlap or share responsibilities with neonatal transport services.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓

Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓
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Key Outcomes:

1. Dedicated Neonatal Transport Services transfer at least 95% of patients requiring transfer for uplift within its defined catchment area on an annual basis. (Domain: 1,3,4,5,)
2. Mobilisation Time: For time critical transfers the transfer team *mobilises towards the patient within one hour from the start of the referring call (95% of retrievals annually). (Domain: 1, 3, 4, 5,)
3. Referral response time The transport team will arrive with the patient (transfers for uplift of care for intensive care patients) within 3.5 hours of the referring call on 80% of occasions.(Excludes uplifts for planned procedures e.g. PDA Ligation) (Domain: 1,3,5)
4. Timely collection of the data required by NTG/BAPM dataset.
5. Annual report published summarising activity, compliance with quality standards and clinical outcomes, progress from previous year, shared with appropriate stakeholders.

*includes time critical transfers when the team is not at base at time of referral – the clock starts when the referral is received and stops when the team is travelling toward the time critical referral. When the team is at base when the referral is taken the clock starts when the referral is received and stops when the team departs base.

3. Scope

3.1 Aims and objectives of service

Neonatal services aim to deliver a high quality, equitable, safe and effective service and to achieve the highest quality outcomes for premature and sick newborns and their families. It is a high cost, low throughput service in which clinical expertise is a key determinant of the quality of the outcomes for the baby and the family. Services are provided within geographical catchment areas in which provider units work together to provide the pathway of care mothers and babies require. Neonatal services form part of an integrated high quality maternity, paediatric and family care service serving a geographically defined regional population.

3.1.2.

A Neonatal **Transport** Service must be available at all times and for all units within a designated geographical catchment area providing:

- Safe and effective transfers for neonates.
- A cot location service for emergency neonatal transfers.
- A perinatal facility location service for in-utero transfers.

The service will be additional to the delivery of in-patient care, recognise the importance of family circumstances and provide arrangements to undertake or facilitate transfers in all categories as part of its baseline provision. Where network capacity does not allow for an appropriate transfer for an uplift of care level between the categories of neonatal service, a baby will have to be transferred out of network to ensure they receive the most appropriate care in the right care setting.

Neonatal transfers will be performed by a dedicated transport service, with the ability to:

- Operate 24 hour per day, every day
- Staff all transfers appropriately and in accordance with the clinical condition of the baby
- Transfer at least 95% of neonates where transfer is required within the service specification and any exceptions documented and reviewed at a network level
- Demonstrate performance against specified response time standards
- Order transfers according to clinical priority
- Operate in an integrated and supportive way with regional referring units
- Operate in an integrated and supportive way with other Transport Services
- Ensure appropriate governance arrangements, including data collection and audit
- Collaborate with providers of aeromedical transport where distance and logistics suggest this will be of clinical benefit

3.2 Service description/care pathway

Service Description:

The process for transfer of critically ill infants must be timely, safe and efficient, requiring a high degree of coordination between all service providers. The development of this coordinated approach must be led by the NIC Transport Service, but should be wholly supported by all hospitals in the network admitting and/or referring critically ill children.

Transfers must not compromise the standard of care provided to other babies. Where such an eventuality arises, alternative agencies will be found to undertake the transfer.

3.2.1. Service Model:

The Neonatal Transport Service must be operational 24-hours daily. The ability to respond to demands on the Transport Service should be prioritised based upon clinical need.

Categories of Transfer:

Ex Utero Transfers: Transfers will be classified at referral according to urgency and reason (NTG/BAPM Neonatal transfer dataset definitions, 2012, available at <http://www.bapm.org/publications/>)

In-utero (IUTs) are initiated and guided by the maternity teams. Neonatal Transport Services do not transfer in-utero patients, however the Transport Service will liaise with

maternity services and perinatal centres helping to locate appropriate destination facilities. The referring obstetric and midwifery teams then liaise with the receiving unit and are responsible for organising and performing the maternal transfer. **Operational Delivery Networks** should have guidelines for IUTs based on the British Association for Perinatal Medicine (BAPM) guideline for in-Utero Transfers¹. The Transport Service is responsible for the transfer back into the network of babies whose mothers were booked within the geographical catchment area. This may require liaison with the Transport Service operating for the discharging network..

Sometimes the circumstances of transfer are complex and it is not clear which is the responsible transport team. When this happens there should be clear decisions made in the best interests of the patient..

3.2.2. Capacity of Transport Service

Commissioners and providers are responsible for transfer capacity and undertake needs assessment and gap analysis on a regular basis to ensure adequate provision to enable delivery of a service at all times.

Agreed transfer protocols will be in place to include contingency plans to support the transfer of critically ill infants when the Transport Service is overwhelmed. Requests for transfer to which the NIC Transport Service is unable to respond will be monitored and audited.

Where the network Transport Service is unable to undertake a transfer, clear documented arrangements must be in place for alternative agencies to support the transfer if clinically indicated.

3.2.3 Staffing

The Transport Service must have adequate numbers of staff with the appropriate skills to provide a safe service for babies, including:

1. A nominated lead consultant
2. A lead nurse
3. 24 hour consultant advice
4. A doctor or advanced nurse practitioner appropriately trained and experienced to carry out transfers available at all times.
5. A nurse or other non-medical member of staff trained and experienced to carry out transfers should be available at all times.
6. Each service will have local operating policies outlining the type of clinical escort required for different clinical conditions.
7. Staff are trained to necessary standard for all aspects of equipment use, transport safety and infection control.
8. Staff receive full appropriate inductions, competency updates and have access to continuing professional development (CPD) programmes.

¹ Management of acute in-utero transfers: a framework for practice. British Association of Perinatal Medical (2008).

9. All clinical staff must be supervised by the designated on-call Transport Consultant
10. Where the Transport Service is co-located with a neonatal unit the Transport Service staff should not be included in the standard unit rota, and should be supernumerary to this.
11. Staff may be employed by various trusts across a defined area, but should all work towards the same skill set.
12. Where staff are provided from outside of the network Transport Service, any service level agreement (SLA) or contract will stipulate that staff are trained to meet these standards.

3.2.4. Referral processes and sources

Users of the Transport Service must ensure that all referral requests are made in a timely manner. Referrals must be made with clinical and logistical information available.

For uplift and resource transfers the Transport Service provide clinical advice, mobilise the transfer team and locate a cot. Activation of the transfer team should not be dependent on cot availability. For repatriation and out-patient transfers decisions about need for transfer will be agreed jointly by the appropriate local unit staff and receiving consultant. The Transport Service will then liaise with the referring centre to undertake the transfer in a timely fashion.

Written agreements between neighbouring Transport Services will exist to support occurrences where Transport Services carry out transfers for babies from other regions. Records must be kept and audited to monitor such incidents and shared with the network leads for these services.

3.2.5. Equity of access to services

Ensuring equity of access to any specialised service can present challenges, particularly in areas with a large geographical area and sparse population. Different regions will need to consider the specific challenges that face them due to the location of their NICU and other specialist services linked to neonatal care. Transport services should be configured, taking into account local knowledge and historical trends, to best meet these challenges as equitably as possible. Transport Services are commissioned to serve the whole population and must provide services equitably across the region that they operate.

Commissioning should take into account the possibility of teams transferring patients outside of their normal remit but within their clinical scope where this is in the best interests of the patient and/or family.

3.2.6. Handover procedure

The **Transport Service** must show evidence of protocol for concise but detailed handover with supporting documentation (e.g. radiology imaging) from the referring provider and to the receiving neonatal unit.

Responsibility for the care of the patient rests with the **Transport Service** between the time that care is formally handed over by the referring team to the time that formal handover is undertaken with the receiving neonatal unit.

Transport teams should utilise where possible IT solutions such as inter-hospital radiology image sharing and telemedicine links which may improve the transfer process or limit the need for transport. Where such IT solutions are beneficial to patient care the **Transport Service** should work together with the ODN to ensure that the technology is available in all parts of the network.

3.2.7.

Service user / carer information

The **Transport Service** must have a policy for parental travel arrangements. When appropriate and safe to do so, at least one parent / legal carer will be allowed to accompany their baby during transfer. Where it is not possible to transfer a parent / legal carer with their baby alternative transport arrangements should be made and parents should be offered the opportunity to see their baby prior to transfer.

Parents and carers will be given written information about the **Transport Service** and receiving neonatal unit, including contact information. Multi-lingual output is advised.

3.2.8.

Governance

The **Transport Service** will have a governance policy with clear guidelines for how incidents are reported and resolved. Serious transport incidents can be complex with several Trusts involved. The **Transport Service** will take a lead in ensuring joined-up cross-boundary responses and learning.

There will be clear mechanisms for quality assurance and incident review, including submission to agreed national bodies. Reports of **Transport Service** activity will be available for review by the AT commissioners and the network or other agencies and produced on an annual or more frequent basis if required. These are to conform to any agreed local or national format.

Structures must be in place to provide ongoing training for those involved with transport, and to demonstrate relevant competencies for all grades of nursing and medical staff undertaking transfers.

Mechanisms will exist to ensure that all stakeholders involved in the **Transport Service** have an active input into the delivery of the service. **Transport services** should establish and maintain a Stakeholder Group including clinical personnel from the Network Units, the ambulance service, parents and commissioners.

3.2.9.

Reporting requirements

The Transport Service will:

- Monitor the service against agreed standards, including for activity, delays, exceptions to network pathways.
- Record and monitor activity according to NTG/BAPM 2012 minimum data set on all referrals and transfers, including referrals that do not result in a transfer and records should include the nature of any medical or nursing advice given
- Participate in annual benchmarking of NTG/BAPM 2012 minimum transfer dataset

Recording the cot status of every regional neonatal unit at least once in each 12 hour period is recommended.

The Transport Service must keep records of all clinical incidents, which should also be included in transfer records and audited. Standard NHS England procedures for reporting of incidents should be followed including sharing of incidents with statutory bodies when indicated.

Regular activity reports and an annual report will be produced and shared with all users and commissioners.

3.2.10.

Communication

There will be a single point of contact through which the Transport Service can be contacted and activated at all times for clinical advice and cot / maternal bed location. This will include teleconferencing, call handling and call recording functionality. Clear, accurate and retrievable records of communications must be kept, in accordance with any agreed standards.

The Transport Service shall have arrangements in place to receive feedback from local referring centres.

3.2.11

Documentation

Clinical observation and record-keeping, including all components of the NTG/BAPM transfer dataset during the transfer must be to the same standard as that provided at any other time (reflecting the transport environment).

3.2.12

Vehicles, equipment, safety and insurance

The Neonatal Transport Service will usually operate road transport. However, on occasion, due to either clinical or logistical reasons, transfer by air may be required and the Transport Service must have policies and procedures in place to organise this. The

provision of Aeromedical Transport must be consistent with Care Quality Commission (CQC) and European Aero/Medical Institute (EURAMI) or Commission on Accreditation of Medical Transport Systems (CAMTS) standards.

The table relating ambulance cabin requirements has been removed as outside the scope of NHS England commissioning. Statement in Vehicles section below states responsibility of the ambulance provider..

Equipment and vehicle must be able to effectively support the transfer of neonates of varying maturity and dependency. It must be fit for purpose, comply with and be maintained and cleaned to agreed, published standards.

The Transport Service will have documented policies for the safety of staff, patients and attendants during transfer, including:

1. Transfer referral processes
2. Clinical management policies for all types of transfer
3. Equipment use and maintenance
4. The use of gases and power
5. The use of seatbelts
6. Speed and use of lights and sirens
7. The stowage of equipment
8. Patient restraints
9. Manual handling policies and practices
10. Infection control policies
11. Death in transfer
12. Documented arrangements for back up should any primary systems fail.

Insurance: The Transport Service needs to ensure there is adequate provision of insurance for service personnel against loss of life or injury. Arrangements need to be identified and specified within the SLA or contract with the ambulance service provider.

The insurance cover for passengers not employed by the Transport Service such as students, observers and parents/carers must be documented.

Vehicles: vehicles will comply with specified and appropriate vehicle standards that are suitable for the transfer of critically ill patients. The Transport Service will not use an unfamiliar vehicle (or equipment) unless accompanied by someone trained to operate it.

The transfer team must be able to contact the receiving neonatal unit and the Transport Service operators throughout the period of transfer, and vice versa, with appropriate telecommunications equipment.

3.2.13

Ambulance providers

There will be a contract for the provision of ambulance vehicles for transport.

As part of the contract, the provision of staff and equipment will have agreed timescales, which are aligned with national targets, against the defined categories.

These arrangements will include contact information, vehicle specification and response times.

The vehicle provider must operate to the standards laid down by the NHS for ambulance services.

3.2.14

Private contractors

Private contractors carrying out neonatal transfers are expected to be registered with the Care Quality Commission (CQC) and be compliant with CQC standards and to perform to the same criteria outlined above for the clinical teams and ambulance providers for commissioned Transport Services. This includes equipment standards, staffing and governance arrangements.

3.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England²; 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). Specifically, neonatal Transport Services are to be used for babies transferred between network intensive care units and local neonatal units. Neonates are defined as those babies who are generally (but not exclusively) less than 44 weeks post menstrual age. However for neonatal Transport Services the definition is expanded to any baby being transferred into or out of a neonatal unit of any level.

3.4 Any acceptance and exclusion criteria and thresholds

3.4.1.

Exclusions

Paediatric Critical Care Transport Services: Unless neonatal and paediatric transport services are formally commissioned to run as one service it is expected that written agreements will be in place between services covering the same geographical areas delineating clearly defined areas of primary responsibility and also areas where there is potential for overlap and collaboration. Where the resilience of services may be improved by mutual-aid agreements these should be clearly agreed between services and the limitations of each service to help the other made clear.

Clinically inappropriate transfers: There will be agreed protocols in place for situations where transfer is clinically inappropriate. This may include infants who have been discharged home or need transfer from paediatric wards. Specialist teams may be required for some transfers, such as extra corporeal membrane oxygenation (ECMO) referrals. In a situation where such patients are referred to a local network Transport Service, they will contact the specialist team to discuss transfer arrangements.

In utero-transfers are not undertaken by neonatal transport services.

3.4.2.

Acceptance criteria

2

The service will accept referrals from senior clinicians on referring neonatal units for babies requiring uplift in care, specialist care or repatriation to their local unit. Clinical indications for referral should be made in line with the categories of care levels and categories of neonatal units in the neonatal care service specification.

3.5 Interdependencies with other services/providers

Critical Interdependencies

1. Critical Interdependencies are NICUs, local neonatal centres, ambulance services, other, particularly adjacent Neonatal Transport Services and Paediatric Critical Care Transport Services.
2. Dependent on the model of service provision there will be an essential interdependency with other Ambulance Services and Aeromedical Transport services.

For NIC Transport, the integration with NIC services, NIC networks and the relevant Specialised Services and Networks for Children provide a link to parts of a wider care pathway

Neonatal Transport Services can be managed alongside or in the same service as Paediatric Critical Care Transport Services, but where this is the case it is important that neonatal-specific protocols and standards are adhered to and staff have recognised neonatal qualifications and experience. A Neonatal Transport Service may also be co-located with a neonatal unit, but neither service nor patients should be compromised by the arrangement. The Transport Service staff should not be included in the standard unit rota and should be supernumerary to this.

It is acknowledged that all Transport Services will from time to time face acute demands which outstrip their capacity to respond. There should be documented procedures for triage and for requesting the assistance of other teams in these situations. Transport Services should have written agreements with all their surrounding providers regarding mutual-aid.

Where a patient is to be transferred across commissioning or network borders the responsibility for the transfer lies first of all with the team covering the infant's booking hospital of delivery. Transport Services should have written agreement with neighbouring Transport Services about referral and allocation processes in these situations.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

Transport Services will comply with the BAPM and Neonatal Transport Group (NTG) standards for neonatal transfer dataset and classify transfers in line with this.

Including:

- For time critical transfers the transfer team departs from base within one hour from the start of the referring call³
- For all other referrals, the transfer service, including ambulance provider, provides appropriately staffed and equipped transport within locally agreed time frames.

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

As above.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

There is a quality dashboard in place for neonates – the following measures are directly applicable to neonatal transport services:

NIC01	Domain 1	Number of time critical transfers where the team departs the transport base within 1 hour from the start of the referring call during period
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5.2 Applicable CQUIN goals (See Schedule 4 Part E)

There are currently no CQUINs directly related to Neonatal Transport Services.

6. Location of Provider Premises

The Provider's Premises are located at:

ONLY LIST PROVIDERS IF THERE HAS BEEN A FORMAL DELEGATION PROCESS.

7. Individual Service User Placement

Not applicable

³ For measuring this standard time critical transfers are all the categories in the NTG/BAPM dataset definitions, and no others.

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Appendix One

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Mobilisation time for time critical transfers	95% of retrievals annually	National benchmark data return	Non compliance with contract General Conditions 8 & 9
Referral response time (transport team to arrive with the patient (transfers for uplift of care for intensive care) within 3.5 hours of the referring call	80% of occasions (excludes uplifts for planned procedures – e.g. PDA ligation)	National benchmark data return	Non compliance with contract General Conditions 8 & 9
Domain 2: Enhancing the quality of life of people with long-term conditions			
Dedicated neonatal transport services transfer at least 95% of patients for uplift within its defined catchment area	95% (for uplift)	Annual report	Non compliance with contract General Conditions 8 & 9
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Undertakes repatriation transfers to enable care to be provided as close to home as possible. Responsible for repatriation of infants to mother's booked hospital where this is within commissioned area	To be agreed	Annual report	Non compliance with contract General Conditions 8 & 9
Domain 4: Ensuring that people have a positive experience of care			
Annual report published summarising activity, compliance with quality standards/clinical outcomes	Annual Report	Annual report submitted	Non compliance with contract General Conditions 8 & 9
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
Timely collection of the data required by NTG/BAPM dataset	To be agreed	Annual report submission	Non compliance with contract General Conditions 8 & 9

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Completion of IR1's and Risk Assessments	As per national/local policies	Monthly audits and action plans	Non compliance with contract General Conditions 8 & 9

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SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	E10/S(HSS)a
Service	Gestational Trophoblastic disease (Choriocarcinoma - all ages)
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

The UK Gestational Trophoblastic Disease (GTD) Service is an internationally renowned, multi-disciplinary team which provides both clinical and psychological care, for women diagnosed with GTD and specialist advice for health care professionals involved in giving care to this patient group.

GTD is a spectrum of rare pregnancy related disorders comprising the premalignant conditions of complete (CHM) and partial hydatidiform moles (PHM) through to the malignant invasive mole, choriocarcinoma and placental site trophoblastic tumour (PSTT). Sixty years ago, most women could expect to die of GTD. Fortunately this situation has been reversed by the progressive discovery of effective therapies and appropriate management protocols together with a very sensitive biomarker of the disease activity (human chorionic gonadotrophin; hCG).

The UK national GTD service was designated in 1984 and has played a leading international role in developing these therapies, management protocols and biomarker assays and currently cures more than 98% of affected women.

Evidence Base.

- GTD is a rare disease so centralised care is necessary to ensure adequate skill levels in the teams that manage it otherwise high cure rates cannot be achieved.
- Indeed, data from a recent survey for GTD survival in countries that do not have centralised care including the USA show considerably lower survival rates (Kohorn et al 2009 International Society for the Study of Trophoblastic Disease (ISSTD) conference Cochin and J Reprod Med 2013 in press).

- Similar improved survival results have been seen with other curable malignancies. Thus, testicular cancer cure rates have been shown to be significantly higher when the disease is managed in specialised centres than in district general hospitals (Harding et al Lancet 1999, 341, 999-1002)

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

See appendix 2 but briefly:

Outcomes: Deaths as % of new cases

In addition to National Key Performance Indicators (KPI), e.g. waiting times, infection control etc; further service specific KPIs will monitor that:

- Counselling is offered to all patients during first course of chemotherapy;
- All patients have a named key worker on day of admission;
- Patient's GP is informed of admission within 24 hrs;
- All patients are issued with diary of treatment events on first discharge;
- Maximum 14 day turn around on histopathology specimens;
- Local to residence chemotherapy administration where feasible is established within three weeks of first admission

3. Scope

3.1 Aims and objectives of service

- To provide centralised comprehensive health care for women with Gestational Trophoblastic Disease (GTD)
- To provide a world-class screening, diagnostic and treatment facility across the UK for the management of GTD, identifying and treating patients with malignant forms of GTD to achieve a cure rate $\geq 98\%$ whilst minimising morbidity and psychological sequelae.

- To provide accurate (expert) diagnosis.
- To monitor GTD patients for relapse or new episodes of the disease
- To advise/teach nationally and internationally on the management of GTD
- To minimise complications (late effects) of treatment in this young fertile group of women
- To provide excellent patient experience.

3.2 Service description/care pathway

Women diagnosed with GTD, or where GTD is suspected, will be formally registered, using the official registration form, with one of the national screening centres. This will include the diagnosis of:

- Complete hydatidiform mole (classical type, androgenetic, no other foetal tissue)
- Partial hydatidiform mole (usually triploid, other foetal tissues present)
- Twin pregnancy with Complete or Partial hydatidiform mole
- Limited macroscopic or microscopic molar change judged to require follow-up
- Aypical placental site nodule.
- Referrals are also accepted in writing, or verbally in emergencies, for the diagnosis of:
 - Choriocarcinoma
 - Placental site trophoblastic tumour
 - Persistently raised HCG of unknown cause

The provider will provide:

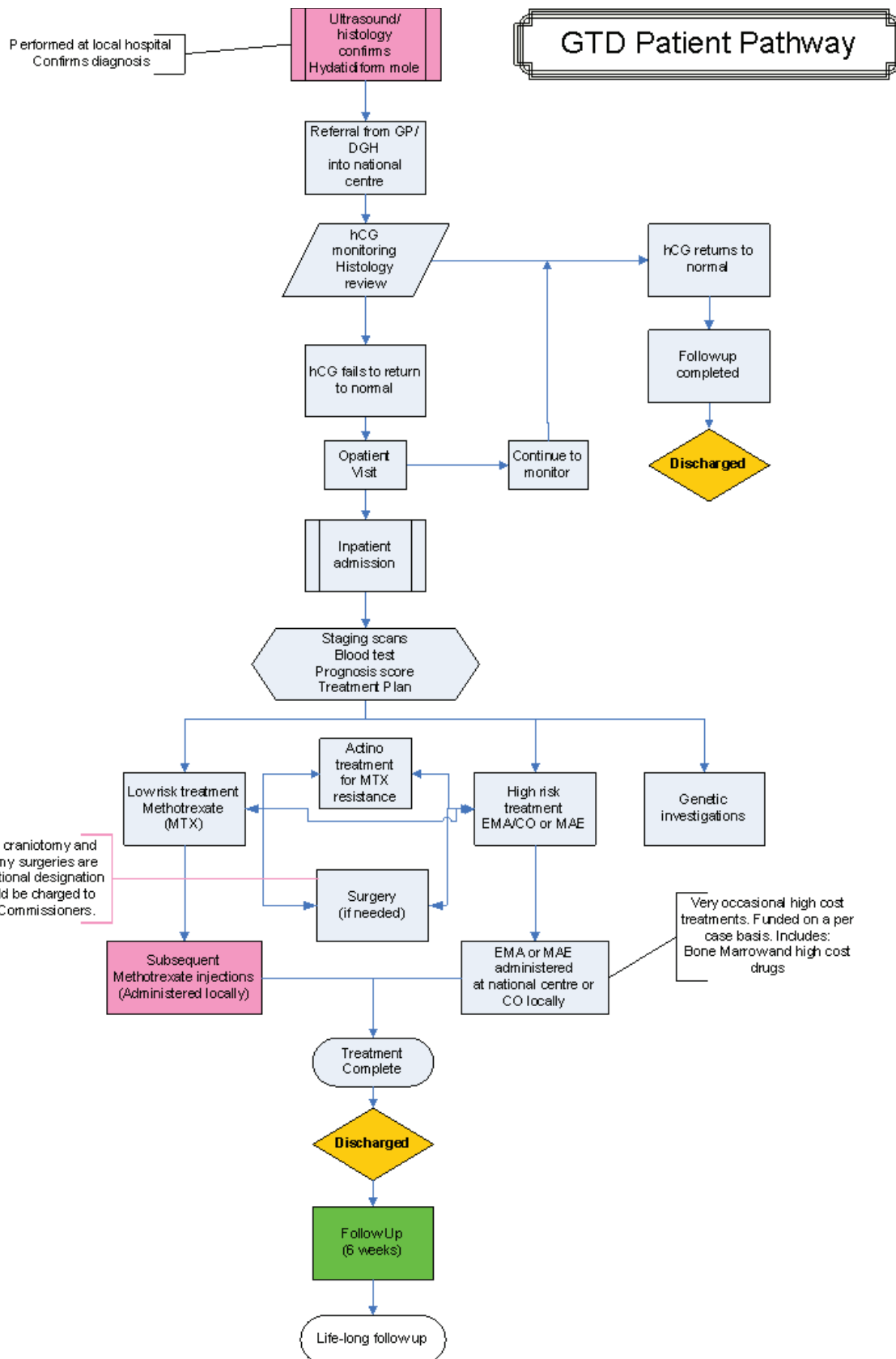
- A registration facility for molar pregnancies and other GTD events. • registration within 72 hours of referral receipt with written information sent to patient, GP and referring Gynaecologist at this point;
- Emergency telephone referral facility 24 hours a day, 7 days a week;
- A comprehensive monitoring facility including regular patient communication regarding results and progress;
- Acomprehensive treatment facility including neurosurgical, thoracic, gynaecological, urological surgery, interventional radiology, radiotherapy, intensive care and high dose chemotherapy.
- Communications at each stage of the patient journey in accordance with the service information pathway. The provider will work with NHS England to ensure sufficient considerations are given to communications;
- A comprehensive discharge process;
- A disease specific hCG assay with maximum 48 hour turnaround of commented results;
- An efficient optimal patient pathway including a robust hCG monitoring protocol identifying those women “at risk”, with timely intervention and treatment;
- 24/7 access to clinical advice;
- a telephone advisory/ results service for patients and health professionals;

- Multi-disciplinary patient support including monthly drop-in sessions and a monthly support group;
- An internationally leading service and reference centre;
- GTD related education and support to patients and carers through information booklets, websites, telephone advisory service, drop-in sessions, and counselling;
- GTD related education and support to health professionals through annual study days, information sheets, telephone advisory service and websites;
- Central pathology review with expertise available to ensure a specialist pathological opinion within 7 days of receipt of appropriate materials;
- Genetic analysis; confirmation of pathological diagnosis and discrimination between gestational & non-gestational tumours as appropriate;
- Investigation of recurrent molar pregnancies;
- Annual audit of patient experience with an action plan on patient feedback;
- Patient inclusion in service design by consultation during structured drop-in sessions and annual surveys;
- Regular audit of provider assurance and governance processes.

Risk management:

- Weekly multi-disciplinary team meetings to optimise clinical care and psychological support.
- National External Quality Assessment Scheme (NEQAS): to minimise analytical errors e.g. imprecision and bias. Monitored by daily Internal Quality Controls (IQC). All assays are registered, as required by Chemical Pathology Accreditation (CPA), with an appropriate NEQAS scheme;
- Cross-site (Charing Cross/Sheffield) meetings to harmonise service delivery;
- Datix (is a single incident reporting system for all incidents including accidents, complaints, claims and Patient Advice and Liaison Service (PALS) activities). Each incident is investigated and a report issued with remedial action if appropriate.

Figure 1. The GTD service pathway



Service model, Data Management , Audit and Governance

The patient is sent information on molar pregnancy, a sample kit with instructions and information on the advisory and support services offered. These include a telephone advisory service, manned during office hours (30,000+ calls per annum), 24 hour emergency access to an on-call clinician & rapid access to counselling. Also, an invitation to attend a monthly drop-in session where they can meet other women suffering molar pregnancy, learn more about their condition, future pregnancies and have the opportunity for face to face contact with staff to discuss any personal concerns.

Pathology is requested for review. Patients found to be non-molar on review are discontinued from follow-up once normal hCG levels are achieved. If review confirms a third molar pregnancy patients are invited to the centre for a consultation with both a service consultant and consultant geneticist. The patient is offered further genetic investigation, advice and counselling regarding future pregnancy.

The referring consultant retains responsibility for the patient's on-going clinical care, with Patient's invited to call the specialist centre directly for on-going advice and interpretation of results. The specialist centre liaises closely with the local health care providers (GP/gynaecologist) during the monitoring period, with commented results and immediate alert to any problems arising. Patients are monitored every two weeks, with serum & urine hCG measurements until levels return to normal and then by urine samples only, every four weeks until follow-up is complete. Because of possible relapse with a future pregnancy, hCG samples are requested on two occasions after each future pregnancy.

For patient's requiring admission to the specialist centre, responsibility for their clinical management passes to the specialist centre oncology team. Patients are seen in the outpatient clinic by a consultant and Clinical Nurse Specialist. They undergo blood tests, pelvic ultrasound and chest x-ray to facilitate a prognostic score, determining if low or high risk chemotherapy is indicated. Some women will require further imaging. The initial admission is dependant on the patient medical status. The specialist centre liaises closely with the local health care providers (GP/gynaecologist/oncology team) for on-going care.

Following the initial admission, the centre endeavours to arrange on-going treatment(s) local to patient residence. During chemotherapy treatment the patient is seen at the national centres regularly the frequency depending on the nature and complexity of the treatment given.

Monitoring during treatment involves at least serum hCG analysis. When the patients are at home, this is done at the local hospital phlebotomy clinics or the GP practice and forwarded by the local laboratories to the centre for analysis using the pre-paid kits provided. The national providers will liaise closely with the local health care providers (GP/gynaecologist/oncology team). A full blood count (FBC), Liver (LFTs) and kidney function (U&Es) tests are also necessary prior to each course of chemotherapy.

Data management is handled through existing electronic systems at Charing Cross and Sheffield that have been tailored for automation of tumour marker surveillance, ease of clinical audit, activity reporting and to facilitate compliance with local and national governance. These systems are already supported by dedicated IT staff.

Referral processes and sources

Referrals can be made by any doctor who has diagnosed the patient with a GTD event using a registration form for molar pregnancies (see Appendix 3) that is available:

- online at http://www.hmole-chorio.org.uk/clinicians_info_registration.html or by
- by directly contacting the Advisory services in London or Sheffield (Appendix 3) or by
- secure online registration system available at <https://nww.h-mole.nhs.uk/>.

Non molar referrals can be made by telephone, letter or email.

Discharge criteria and planning

Active discharge planning is commenced on admission or prior to elective admission as per provider discharge policy. GTT procedure Appendix 4

Tumour marker follow-up (hCG) is life-long for both low and high risk patients.

Patient-Centred Services

The patient is at the heart of the GTD service. Each patient is assigned a key worker, is offered counselling and where appropriate the necessary Teenage and Young Adult (TYA) support and paediatric support including play specialists. Clear communication with the patient and all associated teams within and external to the centre is essential and is the key to the service's successful operation.

Operational Delivery Network (ODN)

Regular satisfaction surveys of various aspects of the ODN are carried out in the GTD service including the patients, their GPs and referring gynaecologists so that improvements in the overall service are enabled. Over the years this has led to the introduction of many patient driven changes to service delivery, information enhancement and improved patient experience.

3.3 Population covered

The service is accessible to all patients with GTD.

There are approximately 120 new patients per year.

This is a UK service covering Scotland, Northern Ireland, England and Wales. Three centres have been designated for hCG monitoring and registration of new patients with GTD: Ninewells Hospital in Dundee for Scottish patients, Weston Park Hospital (Sheffield Teaching Hospitals NHS foundation Trust) in Sheffield for those women living in the north of England, central and north Wales and Charing Cross Hospital (Imperial College Healthcare NHS Trust) in London for all other regions. Treatment, if necessary, is given either in Sheffield for women in north England, central and north Wales or London for those in the rest of the UK.

3.4 Any acceptance and exclusion criteria and thresholds

The criteria for registration/referral acceptance are either pathological confirmation of GTD or clinical suspicion of GTD in the absence of pathological evidence. Referrals are accepted from consultant gynaecologists, GPs or any clinician who suspects a diagnosis of GTD following discussion with the specialist centre. Patients physically seen by the service include those identified:

- By the monitoring process as requiring further treatment
- As placental site or epithelioid trophoblastic tumours or choriocarcinomas
- With persistently raised and/or unexplained elevated hCG levels
- As having multiple molar pregnancies
- With atypical placental site nodules

Patients identified for intervention through the hCG monitoring protocol will meet one or more of the following criteria:

- Serum hCG > 20, 000 IU/L at >4 weeks post evacuation
- Rising hCG i.e. 2 consecutive rising serum samples
- HCG plateau i.e. 3 consecutive serum samples not rising or falling significantly
- Heavy haemorrhage and/or severe abdominal pain
- HCG still abnormal at 6 months post evacuation

There is no exclusion criteria providing patients reside within the areas covered by the UK scheme.

3.5 Interdependencies with other services/providers

i) Co-located Services

The effective running of the GTD service requires effective teamwork between a number of departments within the hospital including, gynaecology, histopathology, radiology, thoraco-abdominal surgery, liver surgery, neurosurgery, intensive care, psychiatry, palliative care/pain control, paediatrics and a high dose transplantation centre. Within the hospital the service is supported by a full range of ancillary services, including a comprehensive translating service, designated clinical nurse specialist, counselling specialist, paediatric play specialists, accommodation facilities for relatives, TYA services and the various other support services including a Maggie's Centre are available. The Sheffield centre is the regional TYA centre and Charing Cross is a designated TYA unit with all necessary links in place for TYA services across the country.

ii) Interdependent Services

Externally, good relationships have been built between the national centres, patient's GPs and other oncology units to deliver the centrally designated treatment close to the patient's home. There are protocols in place for chemotherapy to be administered in many local oncology units. Whilst patients are receiving treatment locally, the direction and prescription of their clinical care remains with the national centre at all times.

iii) Related Services -

The following local outside services may be engaged either before referral, during shared care treatment or after completion of therapy: Gynaecology, Oncology, Radiology, GP, Phlebotomy (tumour marker monitoring), TYA principle treatment centres (PTC), psychiatric, fertility and social workers.

iv) Data Submission: Monthly activity reports. Annual workload analysis.

Referring centres: All obstetric and gynaecology units, gynae/onc centres and any other NHS facility where the diagnosis of GTD is suspected

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

See Appendix 2

All clinical services, including treatment protocols must be in accordance with appropriate clinical guidelines and National Standards e.g. NICE/ NCAT(National Cancer Action Team), Nursing & Midwifery Council: National Standard of Conduct, Performance & Ethics for Nurses & Midwives, acute oncology, safe-guarding children and TYA(Teenage & Young Adults).

All medical laboratory services (e.g. hCG analysis) must be provided in an appropriately regulated environment, operated according to nationally accepted quality standards(UK-NEQAS-United Kingdom National External Quality Assessment Service) and have Clinical Pathology Accreditation (CPA).

The two national centres have considerable expertise in developing high standards of clinical care / maintaining databases of patients with GTD where fertility preservation is important. Moreover, Charing Cross has the world's largest experience with GTD and has an international reputation for establishing new standards of care in this area.

Potential aspirational standards for the next year will include development of:

- Shorter follow-up protocols
- An application for i-phone and android phones to provide patients and their doctors with easily accessible information about GTD and its therapy.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable CQUIN goals (See Schedule 4 Part E)

The GTD service is a highly specialised service and the quality standard goals will be determined by the two national centres in dialogue with the commissioners.

For 2013/14 the GTD service will propose to:

- Audit length of hCG surveillance required following uterine evacuation of a molar pregnancy to determine shortest, safest length thus reducing costs and enhancing the patient experience.
- Re-evaluate the impact of high dose chemotherapy to determine whether we should continue this high cost intervention in selected patients

6. Location of Provider Premises

The Provider's Premises are located at:

- Imperial College Healthcare NHS Trust (Charing Cross Hospital) London
- Sheffield Teaching Hospital NHS Foundation Trust (Weston park Hospital)

7. Individual Service User Placement
The provision of high dose chemotherapy and other services required in selected patients will be managed on a per patient basis.

Appendix One

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Deaths	< 2% overall	Deaths as a percentage of all new cases	Audit to evaluate causation and change in practice
Domain 2: Enhancing the quality of life of people with long-term conditions			
Maximising fertility rates	> 80%	Proportion of patients who are attempting pregnancy that are succeeding, assessed through questionnaires/telephone interview	Audit to evaluate causation and change in practice where feasible
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Counselling offered to all patients	>98%	Proportion of patients offered counselling	Audit to evaluate causation and remedial action
Domain 4: Ensuring that people have a positive experience of care			
All patients to have a named key worker on day of admission	> 98%	Proportion of patients who were assigned a named key worker on day of admission	Audit to evaluate causation and remedial action
Patient's GP is informed of admission within 24 h of admission	> 95%	% patient's GPs informed in this time frame	Audit to evaluate causation and remedial action
All patients to see consultant on day or within 24 h of admission	>98%	% patients who saw consultant within 24 h admission	Audit to evaluate causation and remedial action
Establishing local chemotherapy / shared care within two weeks of first admission	> 90%	% of patients achieving this where appropriate	Audit to evaluate causation and remedial action
Annual patient survey	100% offered survey	% patients achieving this	Audit to evaluate causation and remedial action
All patients on chemo offered patient diary on 1st discharge	>98%	% patients achieving this	Audit to evaluate causation and remedial action

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
Compliance with all relevant national KPIs including infection control and waiting times	As per national KPIs	As per national KPIs	As per national KPIs
Maximum 14 day turn around time on histopathological specimens	> 90%	% of total MOGCT pathology specimens not reported in this time	Audit to evaluate causation and remedial action

Appendix Two

Imperial discharge procedure for Gestational Trophoblastic Tumours

Low risk. Within 48 hours of admission:

- Organise the administration of the methotrexate (MTX) injections local to patient residence. Contact the GP to discuss, fax the referral letter, protocol and the three subsequent treatment schedules. If the GP unable to administer, contact the local oncology unit and refer to an appropriate oncologist, then fax the referral letter and treatment schedules. Provide information on methotrexate administration
- Order three courses of MTX and folinic acid tablets from pharmacy to be prepared as a To Take Away (TTA)
- Educate the patient on the safe storage and transport of drugs

Prior to discharge:

- Arrange six week out-patient appointment (OPA), give copy of letter, treatment schedules, spillage kit, purple sharps in and any other TTA's to patient
- Arrange for patient to see the clinical co-ordinator the day before discharge to collect blood test instructions for once or twice weekly hCG testing, and a letter requesting full blood count (FBC) and urea & electrolyte's (U&E's) test to be done the day before each cycle of treatment using local phlebotomy provision
- Give advice (verbal and written) on contraception, caution in the sun, alcohol consumption and exercise
- Ensure appropriate transport arrangements are in place
- Minimal/no vaginal bleeding
- Adequate storage facilities identified for methotrexate and other drugs

Upon completion of treatment:

- Arrange a six week follow-up OPA with repeat pelvic ultrasound (if required) (and chest
- X ray if lung metastases identified on pre treatment CXR)
- Give advice (verbal & written) on long term hCG monitoring, future pregnancy advice and any other issues raised
- Post six week clinical check-up
- Discharge from clinic to continue postal follow-up of hCG

High risk:

- Organise the administration of the CO infusions local to patient residence. Contact the local oncology unit to discuss and refer to an appropriate oncologist, fax the referral letter and protocol;
- Ensure all take away drugs are available;
- Educate the patient on the safe storage and use of prescribed drugs;
- Arrange a two week out-patient appointment
- Ensure appropriate transport arrangements are in place.
- Give written information, including copies of patient letters on the above including discharge after in-patient stay.

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 be fundamental to all services. The generic aspects of care:

The Care of Children in Hospital (Health Service Circular (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 minimise 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 three-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 continuous performance development (CPD)
- 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.¹ 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 acquired³ *. 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 magnetic resonance imaging (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:

1. Guidelines for Providing Anaesthetic Services (GPAS) Paediatric anaesthetic services. Royal Collage of Anaesthetists (RCoA) 2010 www.rcoa.ac.uk
2. Certificate for completion of training (CCT) in Anaesthesia 2010

3. 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 specialist 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 Care Excellence. (NICE), Royal Colleges

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 two RCNs 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 which 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:
 - Taking 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 Clinical Records Bureau 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)

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 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
- Ensures 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 Publications, 2006, London.