

**Request for expressions of interest in delivering a highly specialised service for Hand and upper limb reconstruction using vascularised composite allotransplantation**

**(HAUL-VCA)**

**EOI No: xxxx**

Expressions of Interest (EOI) are invited from suitably experienced, competent and skilled specialist acute providers wishing to deliver a **highly specialised service for Hand and Upper Limb Reconstruction using Vascularised Composite Allotransplantation**

**(HAUL-VCA)**

**Outline of the Service Requirement**

Hand and upper limb reconstruction using vascularised composite allotransplantation is (HAUL-VCA) is appropriate to reconstruct a defective upper limb or hand or absent upper limb or hand, lost as result of trauma or infection. This is done via the transfer of a cadaveric donated hand to the forearm of an amputee. The transplanted arm is able to sense its surroundings, move naturally with strength and dexterity, looks, feels and heals like a natural hand.

For a small minority of suitable patients, transplant offers an alternative to a prosthesis (artificial hand). Up to 20% of the adult population with upper limb amputations choose not to use a prosthesis which has been prescribed to them. Of those that do accept a prosthesis, as many as 26% of adults and 45% of children and adolescents are dissatisfied with their device and choose not to use them, citing poorly developed fine motor control, absence of sensory function, weight and a lack of warmth and humanness (Biddiss EA. Prosthet Orthot Int 2007 31: 236).

HAUL-VCA is not currently considered suitable for congenital limb absence, for those with limb loss due to explosive devices or for those who have required amputation secondary to the presence of tumour.

Microsurgical techniques required for hand transplantation have been well-established for many years and advances in immunosuppressant therapy have meant that hand transplantation is a feasible therapeutic option, although lifelong antirejection treatment is required

Currently data quantifying the fraction of upper limb amputees in England that may be suitable for HAUL-VCA does not exist. However it is anticipated that this subgroup will be small as although there will be a significant number of upper limb amputees in the UK who may wish to explore the possibility of HAUL-VCA, many will be excluded on upon referral because of inherent characteristics (congenital, too young, previous history of malignancy, co-morbidities).

Complex assessment, performed within a specialist setting by a multidisciplinary team is required to carefully select the small proportion of amputees that may benefit from transplantation.

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Of 20 patients previously screened as part of a pilot HAUL-VCA programme in England, only two patients have been both suitable and, after discussion of the inherent risks of the procedure, willing to proceed. The number of patients that will seek the procedure and meet the stringent inclusion criteria including approval for surgery following psychological counselling is estimated to be between two and four patients per year.

Patients must be referred by secondary care clinicians such as hand, plastic and orthopaedic surgeons and from rehabilitation centres. Patients must be aged 18 or over before they can be referred to the service in order to have sufficient psychological maturity. There is no upper age limit for referral to the service.

NHS England is a seeking EoIs from specialist acute provider(s) which can deliver a HAUL-VCA service that meets the following **specific terms**:

* patients who, on the basis of their referral letter, may be suitable for hand transplantation, should be invited to a multidisciplinary outpatient appointment at which clinical and laboratory assessment is performed and verbal and written information provided to the patient. Patients will be assessed against strict physiological, immunological, psychological, medical, surgical and occupational therapy assessment criteria before an offer of being added to the waiting list for hand transplantation can be made. All core components of the team (surgeons including orthopaedic and plastic surgeons, transplant physicians, immunologists, prosthetists and psychologists) should be in attendance,
* physiotherapy and occupational therapy protocols should be in place for the early and intermediate management and for early mobilisation as an outpatient,
* during the waiting list period, patients should continue to be monitored for immunologic status and sensitisation which contributes to a virtual cross match at the time of donation. Specialist Nurses in Organ Donation (SNODs) employed by NHS Blood & Transplant (NHSBT) maintain vigilance for a suitable donor using visual and biometric data. NHS Blood and Transplant will remain responsible for all aspects of organ procurement.
* auditing and monitoring - functional and psychological outcomes should be closely monitored. Data should be submitted to NHS England Highly Specialised Services Commissioning Team which will then be reported on to the Rare Diseases Advisory Group (which advises NHS England on rare diseases). Data will also be submitted to international transplant registries. Normal arrangements will apply for reporting to NHS Blood and Transplant in line with legal and other requirements for solid organ transplantation.

The HAUL-VCA service requires the following components: outpatient review and assessment, inpatient care for transplantation, emergency admissions for revision surgery and wound care, follow up outpatient care, annual blood tests and maintenance medication. These are set out in detail below:

Diagnosis and Assessment:

* assessment for suitability and provision of prosthetic limbs,
* specialist laboratory based biochemical, immunological, haematological and virological and bacteriological assessment, including histocompatibility and immunogenetics,
* transplant physician assessment,
* surgical assessment,
* psychological assessment,
* radiological assessment (plain radiographs and occasionally MRI assessments).

Required Operative Components:

* single operating theatre and specialised microsurgical operating department staff,
* operating microscope and microsurgical instruments,
* provision for emergency readmissions for re-transplantation and wound infection management.

Post-Operative Components:

* routine postoperative care provided, initially in the high dependency unit followed, by standard ward care two to three days later,
* postoperative physiotherapy and occupational therapy provided three times per week for the first three months,
* therapeutic drug monitoring at regular intervals,
* psychological support to facilitate adjustment and acceptance of transplanted hand to ensure best patient outcomes,
* outpatient follow up - weekly for four weeks then monthly for six months in year one,
* outpatient follow up in year two, up to one appointment per month.

**Instructions in applying for this Expression of Interest:**

It is expected that only a very small number of specialist acute providers (one or two) will have the necessary expertise and co-located support services and infrastructure required to provide this service.

In making an EOI, potential providers of this service must demonstrate that they could:

* meet the contract terms set out in the NHS Standard contract:

http://www.england.nhs.uk/nhs-standard-contract/15-16/

* deliver an expert clinical service, including laboratory diagnosis, for HAUL-VCA.

This is not an exhaustive list but gives an indication of the scope of what is required and only organisations who can demonstrate that they can meet these requirements should consider applying.

If your organisation can meet these requirements then you should register your interest and complete an initial questionnaire by accessing the GEM Bravo Solutions e-procurement portal at the following address: <https://gemcsu.bravosolution.co.uk>

Please register and complete the Proforma reference ‘NHS England Hand Transplant EOI Proforma FINAL’ by the closing date stated in this document.

This notice is intended as part of an information exercise to gather details on potential providers and their capability. An expression of interest and completion of the questionnaire will not automatically entitle involvement in any future procurement exercise. Any procurement conducted as a result of this event will be advertised separately and all organisations wishing to participate will need to respond to the procurement advertisement as and when it is published.

Any question or other queries to be submitted via the GEM Bravo Solutions e-procurement portal at the following address: <https://gemcsu.bravosolution.co.uk>

**EOI Applications Close at:**

The closing time for responses to this notice is **7th August 2015 at 17:00hrs.**

**Principal Contact:**

For the purposes of this expression of interest the Principal Contact will be:

Fiona Marley, Head of Highly Specialised Commissioning

NHS England

Contact: fiona.marley@nhs.net