1. Population Needs

1.1 National/local context and evidence base

There have been no randomised controlled trials of autologous intestinal reconstruction in adults (AuGIR) but there have been more than 400 AuGIR procedures and several reviews reported in more than 40 publications in the peer-reviewed literature to date.

Most reports are of relatively small series (less than 50 patients) with approximately 50% of patients either weaning from home parenteral nutrition (HPN) completely or experiencing a substantial reduction in their requirement for HPN. The experience of the 62 procedures undertaken at Royal Manchester Children’s Hospital is that AUGIR allowed more than 90% of patients to become independent of HPN³.

2. Scope

2.1 Aims and objectives of service

Adult patients in the UK with chronic intestinal failure usually receive home parenteral nutrition (HPN). The aim of the specified service is to employ surgical techniques for autologous intestinal reconstruction and lengthening (AuGIR). If successful, this treatment would allow the patient to gain nutritional autonomy and thus cease to require, or have a reduced requirement for, HPN.

The acute service in Salford is associated with the provision of HPN for approximately 180 patients and there are approximately 475 similar patients managed at other centres in England. This is equivalent to a UK prevalence of 14.6
patients per million population and an incidence of 2 new patients per million population / year. (Home Intestinal Failure Network (HIFNET) 2008, British Association of Parenteral and Enteral Nutrition (BAPEN) 2009).

While some patients with a short small intestine may regain enteral autonomy as a result of a spontaneous, adaptive increase in intestinal surface area, 94% of patients who remain dependent on HPN for more than 2 years (usually patients with < 100 cm of small intestine in continuity with their colon or < 200 cm of small intestine without colon) usually remain dependent on HPN for the rest of their lives (Messing 1999). Studies in Europe have suggested that 30% of patients on HPN fall into this category, but the proportion of patients with short bowel syndrome requiring long term HPN is probably higher in the UK, as HPN is used far less frequently than in Europe for home palliation of patients with advanced malignancy (van Gossum 1999).

There is an unmet need to develop treatments for chronic intestinal failure which are safer, better tolerated and less expensive than HPN (which costs a minimum of £50,000 per annum). The ideal treatment would restore enteral autonomy, obviating the need for patients to be fed intravenously, and return patients to a normal lifestyle.

The surgical approaches in this service will involve restoration of continuity of excluded or previously bypassed segments of intestine, serial transverse enteroplasty and longitudinal lengthening and tapering (LILT), either alone or in combination, as well as reversed intestinal loops.

Patients suitable for AuGIR will be adults and will have required HPN for a continuous period of at least two years, despite maximal medical treatment (i.e. they have been proven to be unable to wean completely from HPN). Suitable patients will have 50-100 cm of small intestine and colon (which may or may not be in continuity) or 100-200 cm of small intestine alone.

Surgery will be (at least initially) limited to patients with short bowel syndrome due to volvulus, mesenteric vascular thrombosis and non-inflammatory gastrointestinal disease. Patients with Crohn’s disease will not presently be considered for AuGIR because it is currently unclear whether the required techniques would be feasible in such patients.

Successful AuGIR will allow patients to wean from HPN and restore nutritional autonomy. Patients who have weaned from HPN should, in effect, be able to regain a virtually normal lifestyle, thus avoiding the numerous complications and lifestyle constraints described above.

Some patients may not wean fully from HPN but at least achieve a significant reduction in the frequency with which they require HPN. Since quality of life in HPN patients relates inversely to the frequency with which HPN is required, we also anticipate that these patients will also consider their treatment to have been of benefit.
Objectives

The evaluation criteria for the clinical outcomes of the service will be:

- morbidity and Mortality associated with treatment (notably hospital and 30 day mortality, surgical site infection, intensive care unit (ICU) and high dependency unit (HDU) stay, hospital length of stay)
- Nutritional adaptation at 6, 12, 18 and 24 months following AuGIR, as indicated by:
  - Reduction in parental nutrition use (nights/week)
  - Nutritional status (weight, mid arm muscle circumference and triceps skin fold thickness)
  - Fasting plasma citrulline concentration (a marker of functional gut mass)
- Quality of Life (measured by questionnaire at 6, 12, 18 and 24 months)

2.2 Service description/care pathway

Description of the disease condition

Patients with chronic intestinal failure (also referred to as “short bowel syndrome”) are unable to survive without regular intravenous infusions of nutrients, fluid and electrolytes. Prior to the mid 1970’s, it was impossible to deliver this treatment effectively and patients with chronic intestinal failure inevitably died within a few months of diagnosis. The advent of parenteral nutrition has made it possible to treat many patients with chronic intestinal failure and there has been a steady, annual expansion in the numbers of patients receiving this treatment in the UK. There are currently more than 650 adult patients in England receiving home parenteral nutrition (HPN) according to the results of the British Artificial Nutrition Survey (BAPEN 2009). The lives and wellbeing of these patients depend on regular intravenous feeding and fluid therapy, usually delivered through dedicated, implanted intravenous access devices.

While HPN may prevent early death from inanition, life expectancy is reduced by 10-30% even at 1 year, not only as result of the diseases which led to intestinal failure in the first place, but also because of complications associated with HPN (Howard 2006, DiBaise 2008). 20% of deaths are attributable to the complications associated with long term delivery of HPN (DiBaise 2008, Messing et al 1999). These include catheter related blood stream infection, catheter and central vein thrombosis, and progressive liver dysfunction and metabolic bone disease (Howard 2006, DiBaise 2008). Repeated removal of catheters because of infection or thrombosis may lead to loss of intravenous access, which is one of the most common indications for small intestinal transplantation (Sudan et al 2005).

Even in the absence of these complications, patients on HPN suffer from significant limitations to their lifestyle and quality of life. Patients on HPN report frequent complaints of interference with sleep, mobility, fatigue, social isolation and psychological problems related to the difficulties associated with adaptation to a demanding and highly regimented lifestyle (Staun et al 2009). Very few patients on HPN return to full (or even significant) employment. (Carlson et al 1995, Richards &
Irving 1997, Howard 2006, DiBaise 2008). Data from the UK BANS database suggested that only 45% of patients described their quality of life on HPN as satisfactory (Elia et al 1999), while in other reported series, over 60% of patients on HPN were found to have depressive disorders, of which 17% were severe (Staun et al. 2009).

The service will be based at Salford Royal NHS Foundation Trust (SRFT) and will run in concert with the existing nationally commissioned Severe Intestinal Failure Service.

Patients suitable for AuGIR will be adults who have:

- required HPN for a continuous period of at least two years, despite maximal medical treatment (i.e. they have been proven to be unable to wean completely from HPN)
- 50 -100 cm of small intestine and colon (which may or may not be in continuity) or 100-200 cm of small intestine alone.

Suitability for AuGIR will initially be assessed according to the criteria outlined above. Surgery will be limited to patients with short bowel syndrome due to:

- volvulus
- mesenteric vascular thrombosis
- non-inflammatory gastrointestinal disease

Patients with Crohn’s disease will not be considered for AuGIR because it is currently unclear whether the required techniques would be feasible in such patients.

Once suitable patients have been identified, they will be counselled regarding the risks and potential benefits of AuGIR. Provided they express an interest, provide informed written consent, and the decision to offer AuGIR is ratified by the National Small Intestinal Transplant Group (see below), patients will be offered AuGIR.

Surgery will involve longitudinal lengthening and tapering (LILT) and serial transverse enteroplasty, either alone or in combination, reversed intestinal loops, as well as restoration of continuity of excluded or previously bypassed segments of intestine.

After discharge from hospital, patients will be followed up in clinic where nutritional requirements and the process of weaning from HPN will be carefully monitored. Patients will be seen initially at monthly intervals and body composition, nutritional status and parenteral fluid and electrolyte and nutrient requirements will be assessed. Patients who successfully wean from HPN will continue to be followed up in clinic to assess long-term outcome.

The programme has been developed after consultation with the patient group PINNT (Patients on Intravenous and Nasogastric Nutrition Therapy). The national intestinal failure centre in Salford has close links with members of PINNT who act as patient advocates and speakers on educational programmes to raise awareness of intestinal failure. PINNT members have agreed to join a programme management group which will be established in Salford to oversee the development of the AuGIR programme.
Risk management

Care delivered by the AuGIR service providers must be of a nature and quality to meet the care standards, specification and Agreement for the service. It is the Trust’s responsibility to notify the commissioner on an exceptional basis should there be any breaches of the care standards. Where there are breaches any consequences will be deemed as being the Trust’s responsibility.

Patients must be managed in line with the specification and care standards. Any deviation from these which has not been approved by NHS England is at the Trust’s risk both clinically and financially. It is the Trust’s responsibility to inform the commissioners of any such non-approved deviations on an exceptional basis.

Where a patient’s presentation challenges the assumptions that underpin the specification, service standards and contractual arrangements it is the Trust’s responsibility to inform the commissioners on an exceptional basis, prior to any treatment (except for emergency treatment) so that the implications of the patient’s requirements can be considered. This does not affect situations where the Individual Funding Application process applies.

Service model and care pathways

Patients suitable for AuGIR will be adults and have required HPN for a continuous period of at least two years, despite maximal medical treatment (i.e. they have been proven to be unable to wean completely from HPN). Suitable patients will have 50 - 100 cm of small intestine and colon (which may or may not be in continuity) or 100 - 200 cm of small intestine alone. Surgery will be (at least initially) limited to patients with short bowel syndrome due to volvulus, mesenteric vascular thrombosis and non-inflammatory gastrointestinal disease. Patients with Crohn’s disease will not presently be considered for AuGIR because it is currently unclear whether the required techniques would be feasible in such patients.

The programme will be run in concert with the existing nationally commissioned acute severe intestinal failure programme, thus benefiting immediately from the availability of specialist medical, nursing, dietetic, pharmacy and surgical expertise, a considerable proportion of which is common to both AuGIR and conventional reconstructive surgery for acute intestinal failure (currently delivered as part of the existing nationally commissioned programme).

Patients receiving HPN and being managed in Salford will be identified from our existing patient database, and then the search for eligible patients (using the same criteria (see above) extended to all centres who have registered adult patients on the British Artificial Nutritional Survey (BAPEN) database, via the lead clinicians in their respective centres, following direct approach by the applicants.

We propose initially to undertake AuGIR procedures and provide regular postoperative follow up in 30 patients currently receiving HPN over a five year period. Subject to demonstration of acceptable short term (morbidity and mortality) and long term (weaning from or reduction in requirement for HPN) outcomes during
The programme will be led by Professor Carlson (lead consultant surgeon) and Dr Lal (lead consultant gastroenterologist), who will initially assess suitability for AuGIR in Salford, according to the criteria outlined above, following an outpatient visit. Once patients who might potentially benefit from AuGIR have been identified, they will be counselled regarding the risks and potential benefits of AuGIR and provided with a detailed information sheet regarding the procedure, its aims, and potential risks and benefits. Provided they express an interest they will be admitted to Salford Royal NHS Foundation Trust for an inpatient assessment of suitability and fitness for surgery. This will include detailed psychological evaluation. If appropriate, the decision to offer these patients an AuGIR procedure will be presented for ratification at one of the regular meetings of NASIT, the National Small Intestinal Transplant Group. Once NASIT have ratified the decision, patients will be seen again in the outpatient clinic to address any outstanding questions or concerns and informed consent obtained prior to admission for surgery.

All surgery will be undertaken jointly by Professor Carlson and Mr A Morabito (consultant surgeon and clinical lead for intestinal rehabilitation, Royal Manchester Children’s Hospital) until sufficient expertise in the surgery has been gained to allow expertise to be shared with the 3 other consultant surgeons routinely involved in the management of intestinal failure in Salford.

After discharge from hospital, patients will be followed up in clinic where nutritional requirements and the process of weaning from HPN will be carefully monitored. Patients will be seen initially at monthly intervals and body composition, nutritional status and parenteral fluid and electrolyte and nutrient requirements will be assessed by the multidisciplinary medical and dietetic team. Patients who successfully wean from HPN will continue to be followed up in clinic to assess long-term outcome until they are deemed sufficiently stable to be discharged from follow up. The pathway is summarised below:

- patient suitable for AuGIR is identified / referred
- patient has 2 outpatient appointments to assess suitability and options. Patients will be seen by the Multi-disciplinary team (MDT) including psychology and referred for further psychology if necessary
- AuGIR MDT meeting to discuss patient
- meeting with National Small Intestine Transplant (NASIT) group for ratification of MDT decision
- outpatient appointment with the patient to discuss going forward with the procedure
- five-day pre-operative inpatient assessment – to include review of all imaging and histology, detailed gastroenterological, (including liver,) nutritional, psychological and anaesthetic assessment (including cardio-pulmonary exercise testing (CPEX) and ICU assessment). Additional medical input may be required (e.g. cardiac, respiratory). Assessment of current venous access arrangements.
- if patient is suitable, arrangements made for surgery
- two-day pre-operative stay to ensure HPN is stabilised etc, and patient is

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The NHS Commissioning Board is now known as NHS England
optimised

- theatre list for AuGIR to include anaesthetist, surgeons and clinical fellow.
- 48hrs stay on ICU
- 5 days stay on HDU
- 7 days stay on ward
- Home on day 14 with HPN
- Clinical review (FU) 1 month post op
- Clinical review every 2 months for 2 years.

All treatment in Salford connected with AuGIR will be subjected to review by the Trust clinical effectiveness committee and conducted in accordance with the existing Trust arrangements for clinical governance and quality assurance.

**Days/hours of operation**

To be determined as service develop

**Discharge criteria and planning including any transition arrangements**

Discharge of patients will be guided by clinical considerations on a case-by-case basis. The patient will be included in any discussions regarding their discharge from hospital and their subsequent outpatient care.

**2.3 Population covered**

This service covers patients registered with an English General Practitioner, resident in the European Union and eligible for treatment in the NHS under reciprocal arrangements.

Patients from Scotland, Wales and Northern Ireland are not part of this commissioned service and the Trust must have separate arrangements in place.

**2.4 Any acceptance and exclusion criteria**

Any issues relating to Equality Impact Assessments are covered within the main contract between SRFT and associate commissioners.

Patients suitable for AuGIR will be adults who have:
- required HPN for a continuous period of at least two years, despite maximal medical treatment (i.e. they have been proven to be unable to wean completely from HPN) and
- 50 -100 cm of small intestine and colon (which may or may not be in continuity) or 100-200 cm of small intestine alone.

Suitability for AuGIR will initially be assessed according to the criteria outlined above.
Surgery will be limited to patients with short bowel syndrome due to:
- volvulus
- mesenteric vascular thrombosis
- non-inflammatory gastrointestinal disease.

Patients with Crohn’s disease will not presently be considered for AuGIR because it is currently unclear whether the required techniques would be feasible in such patients.

Response time, detail and prioritisation
To be determined as service develops

2.5 Interdependencies with other services
The National Small Intestinal Transplant (NASIT) group, have agreed that AuGIR and intestinal transplantation must be coordinated to provide integrated and holistic care for patients with chronic intestinal failure. NASIT supports the incorporation of AuGIR into the NASIT programme, thus widening the remit of NASIT to oversee the use of both AuGIR and transplantation in the management of intestinal failure.

Services that could impact on the delivery of AUGIR include home care HPN companies, and within SRFT the Intestinal Failure Unit, General Surgery and Gastroenterology.

The relevant groups that AuGIR will feed into are:
- The National Small Intestinal Transplant (NASIT) group. NASIT supports the incorporation of AuGIR into the NASIT programme, thus widening the remit of NASIT to oversee the use of both AuGIR and transplantation in the management of intestinal failure.
- Patients on Intravenous, and Nasogastric and Nutrition Therapy (PINNT): A representative will join the AuGIR management team in order to ensure that the development of this new service consistently meets the needs and expectations of patients.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College
The service will be fully integrated into their Trust’s corporate and clinical governance arrangements.

The commissioners and service will conduct a formal Joint Service Review at least every six months

Continual service improvement plan
The nationally designated provider of the AuGiR service is required to demonstrate continual improvement in patient care and service delivery. This process will be informed by clinical and service audit, patient and public engagement and awareness of national and international clinical and policy developments that could inform service development.

The service will agree service development improvement plans with NHS England commissioners and demonstrate progress at Joint Service Review meetings.

4. Key Service Outcomes

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<thead>
<tr>
<th>Quality Performance Indicator</th>
<th>Threshold</th>
<th>Method of measurement</th>
<th>Consequence of breach</th>
<th>Report Due</th>
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<tr>
<td>Parenteral nutrition specific quality of life (QOL) tool at clinically appropriate times</td>
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<td>Morbidity and Mortality associated with treatment (notably hospital and 30 day mortality, surgical site infection, ICU and HDU stay, hospital length of stay)</td>
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<td>Nutritional adaptation at 6, 12, 18 and 24 months following AuGiR, as indicated by: • Reduction in parental nutrition use (nights/week) • Nutritional status (Weight, mid arm muscle circumference and triceps skin fold thickness • Fasting plasma citrulline concentration (a marker of functional gut mass)</td>
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<td>Quality of Life (measured by questionnaire at 6, 12, 18 and 24 months)</td>
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Quality and performance standards

SRFT will provide agreed activity monitoring data on a monthly basis, and performance/quality information by at Joint Service Reviews every six months.

Where any elements of this deviate from the agreed plan, the service will provide a
brief explanation accompanying the submission of the report. The commissioner may wish to follow this up and request further information to inform any necessary actions that will be agreed between the service and commissioners in the context of the terms and conditions of the Agreement.

## 5. Location of Provider Premises

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<th>Subcontractors</th>
<th>Not applicable</th>
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**Location of service delivery**

Salford Royal NHS Foundation Trust
Stott Lane
Salford
M6 8HD