Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)
Welsh Health Specialised Services Committee (WHSSC)

Specialised Services Service Specification:

Lymphovenous Anastamosis (LVA) microsurgery for Primary and Secondary Lymphoedema

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Document History

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0.1	01/05/15	1.1 Introduction – classification of mild to moderate lymphoedema added. 2.1 Service Model – inclusion of access criteria including lower age limit and symptom improvements. Annex (i) – amend post surgical evaluation timetable Annex (ii) – include assessment form LVA CRF Annex (iii) – include patient information leaflet.	0.2
0.2	14/05/15	Remove Annex (ii) – include assessment form LVA CRF instead reference CP087b	0.3
0.3	17/06/15	Change to referral management and age criteria in line with feedback from formal consultation exercise	0.4
0.4	24/06/15	Consultation updated to included Management Group	0.5
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Consultation		
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Contents

1. Aim

1.1 Introduction

The document has been developed as the service specification for the provision of Lymphovenous Anastamosis (LVA) micro surgery for patients with mild to moderate primary and secondary lymphoedema who are the commissioning responsibility of NHS Wales. Mild to moderate lymphoedema can be classified by:-

- maximum of 20% excess volume difference on circumferential measurement between affected and non affected limb
- Limb shape is normal up to a maximum distortion of Distal: Proximal (DP) ratio of 0.2. (A similar amount of oedema should be present in both the proximal and distal segments of a limb).
- Tissues must be soft with no evidence of fibrosis, no skin creases or folds
- There must be no wounds, ulcers, lymphorrhoea or hyperkeratosis present

The purpose of this document is to:

- detail the specification for LVA treatment;
- identify which organizations are able to provide LVA treatment for patients.

Lymphoedema is the progressive swelling of a body part, usually an extremity, following developmental (primary lymphoedema) or acquired (secondary lymphoedema) disruption of the lymphatic system resulting in lymph (a protein-rich fluid) accumulating in the interstitial space. The extremities are most commonly involved, followed by the genitalia. This document covers people who are affected by mild to moderate primary and secondary lymphoedema.

The approach to developing this specification has been grounded in the Public Sector Equality Duty principles of transparency, engagement, evidence and leadership to ensure that it impacts in a fair and positive way. An Equality Impact Assessment (EqIA) has been undertaken, and a separate document has been produced outlining the findings of the assessment. WHSSC is committed to the planning and commissioning of services that are equitable, accessible and responsive to individual needs.

1.2 Relationship with other Policy and Service Specifications

This document should be read in conjunction with the following WHSSC documents:

- Clinical Commissioning Policy for Lymphovenous Anastamosis (CP087b);
- The All Wales Policy: Making Decisions on Individual Patient Funding Request (IPFR) Policy. The IPFR Policy is available

online via the Welsh Health Specialised Services Committee website - http://www.wales.nhs.uk/sites3/page.cfm?orgid=898&pid=59092.

2. Service Delivery

2.1 Service Model

The service outlined in this specification is for patients ordinarily resident in Wales or who are otherwise the commissioning responsibility of the NHS in Wales.

The service specified is for adults with mild to moderate primary or secondary lymphoedema who fulfill the selection criteria for Lymphatic Venous Anastamosis (LVA) as specified in the WHSSC Commissioning Policy (CP087b). All patients aged 18 or above are covered by this specification. Adult Lymphoedema patients must meet all the criteria for surgery.

The designated provider of care for Welsh patients is:

- Abertawe Bro Morgannwg University Health Board

LVA is a super micro vascular surgical technique in which a damaged lymphatic vessel is connected to a small vein permitting lymph fluid to drain directly into the blood stream and thereby reducing swelling in the tissues.

The aim of the LVA microsurgical service is to reduce the symptoms associated with mild to moderate primary or secondary lymphoedema through the implementation of a quality service as described in this service specification. Symptoms improvements include:
Reduction in cellulitis episodes (96%)

- Reduction in daily use of compression garments (70%)
- Increase in functional ability (range of movement)
- Decrease in volume of affected limb therefore reducing pain and heaviness of limb

The objectives of the service are to deliver high quality care and improve outcomes. This includes:

- Utilising evidence based patient selection criteria to identify the sub set of Lymphoedema patients most likely to benefit from treatment.
- Optimising patient outcomes by reducing the symptoms associated with mild to moderate primary or secondary lymphoedema.
- Reducing unacceptable variations in clinical practice.
- Development and production of appropriate patient and carer information.
- Evaluation of patient outcomes at specified intervals post surgery.

2.2 Care Pathway

The pathway for LVA comprises several phases:

- Specialist investigations to select patients - appointments will be delivered locally throughout Wales via the TENOVUS Mobile Unit or community lymphoedema clinics.
- LVA microsurgery
- Post surgical follow up

In addition to the post surgical follow up patients will be required to participate in a programme of ongoing evaluation, undertaken by the Lymphoedema Network for Wales, at predefined intervals to assess quantitative and qualitative changes post surgery.

WHSSC is responsible for commissioning the LVA microsurgery phase of care only. Health Boards are responsible for commissioning the pre clinical investigation necessary for patient selection, post surgical follow up and the ongoing programme of post surgical evaluation.

Referrals in accordance with the referral criteria detailed in Commissioning Policy CP087b and submitted on the LVA Screening Referral form (see Annex (ii)) will be accepted from:

- Designated clinical gatekeepers – one gatekeeper from each Health Board Lymphoedema Clinic

A referral pathway has been developed and is attached as Annex (i)

Acceptance criteria

The criteria for acceptance of referrals are specified in the WHSSC Commissioning Policy for LVA (CP087b), which is available on the WHSSC website.

The provider will provide six-monthly audit data regarding compliance with the Policy.

Patients can be entered into clinical trials by the provider where the patient's treatment will comply with the Commissioning Policy. Where the treatment falls outside the Policy, prior approval must be sought from WHSSC before entering the patient into the trial.

WHSSC will not pay for treatment for indications which are outside the Commissioning Policy and for which prior approval has not been formally given.

Post surgical evaluation will be undertaken at the following intervals: 3, 6, 9, 12, 18, 24, 30, 36, 48 and 60 months.

Exclusion Criteria
The exclusion criteria for are specified in the WHSSC Commissioning Policy for LVA (CP087b), which is available on the WHSSC website.

Interdependencies with other services
- All Wales Lymphoedema Tenovus Cancer Care Mobile Unit
- Health Board provided Lymphoedema Services

3. Quality and Patient Safety

3.1 Quality standards

The provider must work to agreed written quality standards and provide monitoring information to WHSSC. The quality and patient safety standards for the LVA service are defined in section 4 of Clinical Commissioning Policy CP087b and include:
- Expected clinical outcomes
- Complications
- Quality of life measures
- An annual clinical audit report

Providers must work to these standards and provide monitoring information to WHSSC as the lead commissioner.

Providers are also required to comply with their host provider's clinical governance arrangements. Any serious clinical incidents, serious complaints or concerns or escalating numbers of complaints or concerns must be declared immediately to WHSSC and appropriate monitoring will be put in place. Any issues that are likely to attract media or government interest must also be immediately declared to WHSSC.

The Provider must enable patient and carer or advocate (where appropriate) informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties and those who do not communicate easily in English. Welsh language provision must be made as appropriate.

Discharge paperwork shall be sent to the relevant healthcare professionals on the day of the patient's discharge. A clearly defined after care programme should be communicated to the patient and communication should be timely and continuous.

Good quality written information must be made available to patients, see Annex (ii).

WHSSC will undertake an annual quality and monitoring visit to facilities.

3.2 Patient experience

Providers are required to use a validated patient experience tool for monitoring patient experience on, as a minimum, an annual basis

3.3 Putting Things Right: Raising a Concern

Whilst every effort has been made to ensure that decisions made under this specification are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided. The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern:

- When a patient or their representative is unhappy with the decision that the patient does not meet the criteria for treatment further information can be provided demonstrating exceptionality. The request will then be considered by the All Wales IPFR Panel.
- If the patient or their representative is not happy with the decision of the All Wales IPFR Panel the patient and/or their representative has a right to ask for this decision to be reviewed. The grounds for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated. The review should be undertaken, by the patient's Local Health Board;
- When a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure with a copy of the concern being sent to WHSSC.

4. Performance Monitoring and Information Requirements

4.1 Performance Monitoring

WHSSC will be responsible for commissioning services in line with this service specification. Providers are responsible for taking reasonable action to meet the service specification and for highlighting any deficits to WHSSC. For the services defined in this policy the following approach will be adopted:

- Service providers to evidence quality and performance controls
- Service providers to evidence compliance with standards of care

WHSSC will conduct performance and quality reviews on an annual basis.

4.2 Coding and activity monitoring

The provider shall develop and approach to improving the recording and collection of routine activity and performance data.

4.3 Key Performance Indicators

Providers will be expected to monitor against agreed key performance indicators:

- 100% compliance with acceptance criteria
- Maximum 42 cases to be undertaken in year 1 (2015/16), subject to review following evaluation
- Zero patients waiting >36 weeks for LVA from referral to treatment.
- Complication rates as specified in section 4.1 of Clinical Commissioning Policy CP087b

The provider should also monitor the appropriateness of referrals into the service and provide regular feedback to referrers on inappropriate referrals, identifying any trends or potential educational needs.

The additional data required to comply with this service specification is as follows:

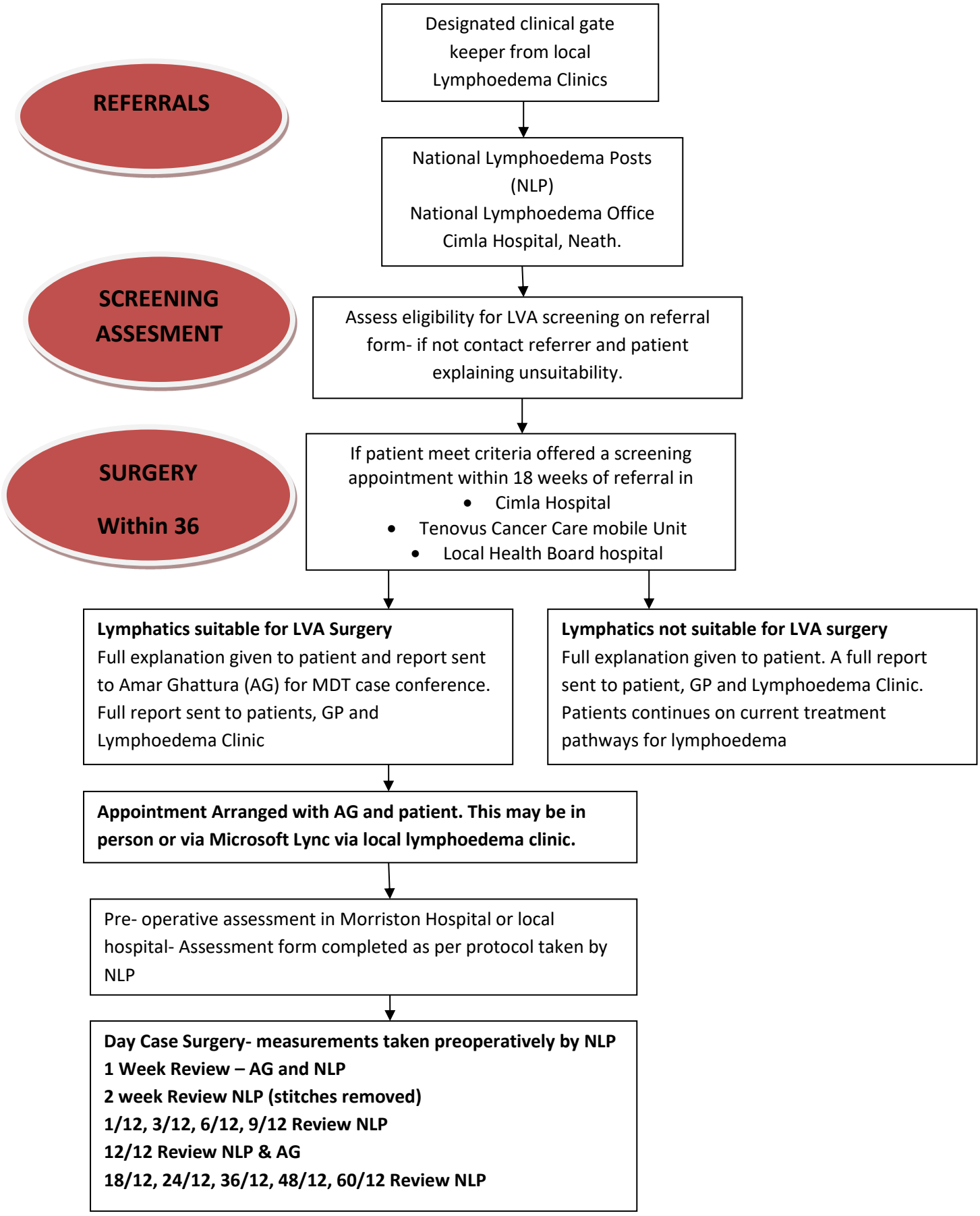
- Monthly reporting of LVA activity and waiting times.
- Immediate exception reports on adverse clinical incidents.
- Immediate exception reports if patients breach agreed RTT waiting times.
- Annual clinical audit report to be presented at WHSSC plastic Surgery Audit Day.
- Annual report on post surgical evaluation of patients
- Annual report on patient experience.

5. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment. The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

Flow diagram of LVA Referral and Assessment Process **Annex (i)**



Annex (ii)

Lymphoedema Network Wales

Curing Lymphoedema through Lymphatic Venous Anastamosis (LVA)

What is LVA?

LVA is a super-micro-surgical technique where a damaged lymphatic vessel is connected to a small vein. This allows the lymph fluid to drain directly into the blood stream reducing swelling in the tissues. The surgery has reported

- Improvement in swelling in 74%
- Symptom reduction in 96%
- 70% of patients stopped wearing their compression garments
  The surgery if you are suitable will be a day case lasting a few hours and held at a hospital in Swansea.

What are the criteria to be considered for LVA surgery?

- Diagnosis of Lymphoedema in your arms or legs
- Mild to moderate swelling
- Your skin must be normal- no creases or folds from the lymphoedema
- Tissues must be soft
- BMI equal to or lower than 30
- No active cancer disease
- You must be compliant with lymphoedema self-management treatment
- Past medical history to include cellulitis episodes
- No fungal infections

Precaution: If you have any Iodine allergies please let your therapist know as you will have to be screened at Morriston Hospital, Swansea.

You will not be eligible for LVA screening if you have the following

- Untreated fungal infections
- Body Mass Index over 31
- Kidney problems or liver disease
- Blood in your urine
- Pregnant
- Smoker
- Previous anaphylaxis shock reaction to a dye

How do I know if I am suitable for LVA assessment?

Your local lymphoedema clinician will identify if you are suitable to be screened for LVA surgery. If you meet the criteria then you will be invited to attend a local assessment with the National Lymphoedema Therapists local to your home.

What happens at the LVA assessment?

Your lymphatic system will be scanned by injecting an iodine dye into the skin between the web space of your fingers or your toes in your swollen limb. Your limb is then scanned using a hand held device which immediately shows how your lymph vessels are working. The image is shown on a computer screen as the dye moves up your limb. If we identify good lymphatic channels that are clearly defined and end abruptly in an area of swelling, then you would be a good candidate for surgery.

Do the injections hurt?

Like all injections there is some discomfort when the needle first enters the skin and the dye is inserted. The discomfort only lasts for a few minutes though and should not cause any long lasting pain. Worse case is that there may be some bruising and some temporary green staining of the skin at the injection site.

How long will I have to attend for the LVA scanning?

You will be assessed and asked some questions about your health and lymphoedema. The injection and scanning usually takes around twenty minutes. You will then be asked to go for a walk and you will be rescanned with an hour. The whole process takes around 1.5-2 hours.

What happens if I am suitable for LVA surgery?

Your scan images will be saved and sent to the Consultant Micro-Surgeon who will then review the images to confirm you are suitable for LVA surgery. If you are suitable, then the Consultant will contact you, your GP and lymphoedema specialist and then plan details of the surgery.

What happens if I am not suitable for surgery?

Your lymphoedema therapist will continue to support and help you manage your lymphoedema.

How long will I have to wait for the LVA scanning and then surgery?

There is a process that we have to follow as the funding for the machines has come from the Welsh Government Health Technology Grant. We are aiming that scanning and surgery is available in 2015. When you have been referred we are aiming that scanning and surgery will all take place within 36 weeks.

If I have the LVA surgery how soon will I see any benefit?

Most patients can expect an improvement within the first 18 months although some patients say benefits occurred up to three years after surgery.

Will my lymphoedema get worse if I have LVA surgery?

No that is very unlikely, as with all surgery and anaesthetic there are some risks which the consultant will discuss with you.

If you would like to discuss this in more detail, please contact Melanie Thomas, Karen Morgan or Cheryl Pike on 01639 862767 there is an answer phone please leave a message and we will get back to you.

Annex (iii)

Evaluation Protocol

STUDY SUMMARY/SYNOPSIS TITLE	A Qualitative and Quantitative Study exploring Secondary Lymphoedema Patients undergoing Lymphatic Venous Anastamosis in Wales.
SHORT TITLE	Study exploring Secondary Lymphoedema Patients undergoing LVA in Wales.
Protocol Version Number and Date	Version 0.1. 20/10/2014
Methodology	This research study will be mixed methods using quantitative and qualitative methods. After consent is given data will be collected on each participant prior and post surgery as well as being followed up every 3,6,9,12,18,24,30,36, 48, 60 months post intervention. On each follow up appointment participants will be asked to complete a ☐ EQ-5D questionnaire ☐ Angela Williams Lymphoedema PROM questionnaire Quantitative Data will be collected on the following at each appointment: 1. Tape measure circumference measurements every 4cm of the affected limb and unaffected limb. 2. Perometer measurements of both affected and unaffected limbs

	3. Pitting oedema test thumb held down firmly for 60 seconds+ or – result 4. Moisture meter Test on 2 set parts of the limb on the affected and unaffected. (The moisture meter is a device that gives a record of water in the tissues 0-99%, using a high frequency low power electromagnetic wave. The water content is increased in oedema patients) 5. Bodystat quad scan 4000 is a bio impedance machine which measures fluid and body composition analysis. 6. Weight and BMI 7. Number of cellulitis episodes: a. Days in hospital b. Antibiotics given and duration c. Time off work d. Effect on day to day living 8. Pain score 0-10 on distress thermometer 9. Range of Movement a. Overall movement scored by physiotherapists using visual assessment and scoring 100%, 75%, 50%, 25% and 0% 10. Heaviness in limb 0-10 on distress thermometer 11. Timed up and go- (stand from sitting walk 3 Metres turn around and sit back down) number of seconds recorded. 12. What effect does lymphoedema have on your hobbies 0-10 on distress thermometer 13. What effect does lymphoedema have on your

	work 0-10 on distress thermometer 14. How anxious does your lymphoedema make you feel 0-10 on distress thermometer 15. How long do you wear your compression garments daily? a. nil b. 1-5 hours c. 6-12 hours d. 13 plus hours 16. What treatment have you received for your lymphoedema since last saw a. nil b. MLD c. Bandages d. SLD e. Compression garments f. other 17. Is the skin soft? Yes / No 18. Are any of the tissues fibrosed? Yes / No 19. Stemmers sign positive/ negative 20. Staging of lymphoedema recorded ISL: a. Stage 0 b. Stage I c. Stage II d. Stage III 21. Staging of Lymphoedema recorded British Lymphology Society a. Stage 0 b. Stage 1 c. Stage 2 d. Stage 3a e. Stage 3b f. Stage 4 Palliative

	An in depth interview will also occur at month 6 with each of the patients giving consent to aid qualitative experience of the effect of the LVA.
Study Duration	April 2015- April 2019
Study Centre	ABM UHB, Tenovus Lymphoedema Mobile Unit, Bridgend.
Objectives	1. Qualitatively explore the effect LVA surgery has on people diagnosed with secondary lymphoedema. 2. Quantitatively identify the impact LVA surgery has on the size of the affected limb, cellulitis episodes 3. Identifying how undergoing the LVA surgery has impacted on their relationships, employment and on activities of daily living for people diagnosed with lymphoedema.
Number of Subjects/Patients	42 patients having LVA per annum for April 2015 thus 2 years of patients =84 potential for follow up for 3 years. Minimum 50 patients would be acceptable. 50/84= 60% take up.
Main Inclusion Criteria	• Diagnosed with secondary lymphoedema and undergone the LVA super micro surgery; • Aged over 18; • Previous history of cellulitis; • Ability to communicate in English; • Ability to give written informed consent to participate in study; • Willing to attend for follow ups at hospital as per schedule;

	• Willing to consent to the research
Statistical Methodology and Analysis	All data will be recorded on a CRF for each patients enrolled onto the study. All data will be recorded directly on to the CRF. All entries will be initialed and signed by the project manager. This information will be analyzed using SPSS. A statistician from Swansea University has agreed to support. The in depth interviews will be digitally recorded and all transcripts transcribed and a thematic approach used. Transcribing and reading the transcripts will be achieved as quickly as possible and will assist in identifying key themes and categories intrinsic within the data. All transcripts will be entered onto NVivo 8 Software programme to enable management of the large amount of data derived from the interviews as well as any field notes. On establishing main themes, further analysis and rereading transcripts whilst listening to the participants can allow confirmation and assessment of the interpretation of data into code indexing. Constant comparative analysis will be used using Braun and Clark's (2006) approach.