

**Community Based Treatment for Chronic Oedema –  
An Effective Service Model**

**Running title: Community based treatment for chronic oedema**

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## **Abstract**

**BACKGROUND:** Chronic oedema care is patchy and of variable quality internationally.

This study was undertaken to develop and evaluate a system of care that would provide for patients within a geographical area of London (Wandsworth), UK.

**METHODS AND RESULTS:** A prospective cohort design with intervention of a new service design following a six month baseline period. Patients were identified through health professionals. A stratified random sample was drawn from all patients and an implementation strategy developed. Clinical assessment combined with questionnaires evaluated clinical, patient and health service outcomes at six monthly periods.

In all, 312 patients were identified in community and acute services giving a crude ascertainment rate of 1.16 per 1,000 population. The random sample of 107 was mostly female (82%) with mean (SD) age of 72.9 (12.4) in men and 68.6 (15.0) years in women. Mean reductions in limb volume achieved statistical differences at 6-12 months after implementation (difference [d] =115 ml, p=0.0001). Incidence of cellulitis dropped from 41.5/ 100 patient years at baseline to zero at 6-12 months. Quality of life showed greatest improvements between baseline and 6 months post implementation, the largest differences being in role physical (d=32.7, p=0.0001) and role emotion (d=24.0, p<0.0001). Euroqol increased following implementation by a mean score of 0.05 (p=0.007). There was a in six monthly health care costs from £50171 per100 patients at baseline to £17618 between 6 and 12 months.

**CONCLUSIONS:** This process of implementation improves health outcomes whilst reducing healthcare costs in patients with lymphoedema.

## Introduction

Chronic oedema is considered common in the community but lymphoedema is considered rare yet both scientifically and clinically they should be considered one of the same. Traditional teaching stated that 90% of interstitial fluid was reabsorbed by the venous capillaries but this is now disproved. The recent revision of the Starling principle indicates that, in the steady state, there is a net but dwindling fluid filtration along the entire length of the blood capillary with all tissue fluid drained by the lymphatic [1, 2]. This places the lymphatic centre stage in tissue fluid homeostasis. All chronic oedema represents lymphatic failure either because the lymphatic is primarily at fault or because the lymphatic is overwhelmed by an excessive lymph load (high microvascular fluid filtration).

There is a tendency in clinical practice to pigeon-hole chronic oedema according to diagnosis eg heart failure, hypoproteinaemia, lymphoedema etc, rather than consider the underlying pathophysiology. Most cases of chronic oedema seen in the community are compound. For example poor lymph drainage in the lower limbs often arises from immobility and lymphatic damage from cellulitis or chronic fluid overload. High microvascular fluid filtration (lymph load) results from chronic dependency (gravitational effects on venous pressure), heart failure, obesity (causing venous obstruction when sitting) or chronic venous disease with eventual permanent failure of lymph drainage in circumstances akin to chronic heart failure. Therefore chronic oedema and lymphoedema should be considered equivalent and will subsequently be referred to as chronic oedema (CO) in this article. Management should focus on improving lymph

drainage and normalising microvascular fluid filtration (lymph load).

When severe, CO can be painful and disabling. Because lymph drainage is important for trafficking of immune effector cells, CO predisposes to infection particularly cellulitis. [3, 4] Cellulitis may be recurrent and difficult to control unless swelling is reduced. [3] Indeed many cases of recurrent cellulitis (erysipelas) may well result from a covert, pre-existing lymphatic insufficiency [5]. A recent study of penicillin prophylaxis to prevent cellulitis demonstrated that CO was a major reason for treatment failure [6].

Major advances in lymphatic biology have revolutionised our understanding of the pathogenesis of lymphoedema. The recent discovery of several causal genes indicates molecular mechanisms are likely to underlie many forms of primary CO [4]. Cancer treatment is perceived to be the dominant cause of CO but an epidemiological study revealed only a quarter of cases, at most, were cancer related [3]. Chronic oedema frequently occurs in patients with other chronic diseases such as obesity, heart failure, venous disease, arthritis and neurodisability eg spina bifida and stroke, where immobility and a lack of stimulus to lymph flow are major contributing factors.

As yet there are no drug treatments to enhance lymph flow. This may change as more molecular mechanisms controlling lymphatic function are discovered. The first drug to be used for the treatment of breast cancer-related lymphedema is now in Phase 1 trials [4]. Diuretics are frequently prescribed but this class of drug does nothing to improve lymph flow and works by excreting salt and water so reducing microvascular fluid filtration. Management of CO is directed at increasing lymph flow by Decongestive Lymphatic Therapy [Complex Decongestive Therapy (CDT) Comprehensive

Decongestive Physiotherapy (CDP)] [7, 8, 9]. Decongestive Lymphatic Therapy utilises basic physiological principles of massage, movement and compression to enhance lymph flow.

There is growing evidence on the epidemiology and provision of care for patients suffering from chronic oedema within the population. Most epidemiological studies in western countries have however focused on specific patient populations. As an example, more than one in five of women who undergo breast cancer treatment develop CO despite improvements in surgical technique[10]. There is little published information on the prevalence of non-cancer related CO in populations. A UK study identified patients suffering from lymphoedema in a geographical population of 600,000 in South West London [3]. In total, 823 patients suffering from lymphoedema were identified through the health services, giving a crude rate of 1.33/1,000 population. This is an underestimate as it does not take account of patients who are not accessing treatment. Even in those identified, one third had not been told they suffered from lymphoedema and 36% had received no treatment for this condition. This methodology has been repeated more recently in an urban population of the East Midlands in the UK [11]. This cross sectional study was carried out in Derby City (UK) which has a population of approximately 247,100. Data were obtained from ten sources, namely: the in-patients of one acute and one community hospital, one specialist and three non-specialist out-patient clinics (dermatology, plastic surgery and diabetic foot clinic), all community nursing services, general practices (n=41) and nursing/residential homes (n=26) in the catchment area. Within the study population of Derby City residents, 971 patients were identified with chronic oedema (estimated crude prevalence 3.93 per 1,000, 95% CI

3.69-4.19). The prevalence was highest amongst those aged 85 or above (28.75 per 1,000) and was higher amongst women (5.37 per 1,000) than men (2.48 per 1,000). The prevalence amongst hospital in-patients was 28.5%. Only 5 (3%) patients in the community population had oedema related to cancer or cancer treatment. Of the 304 patients identified with oedema from the Derby hospitals or community health services 121 (40%) had a concurrent leg ulcer. There is a paucity of professional knowledge and information about CO with general agreement that the provision of care is inadequate [12].

The Lymphoedema Support Network (LSN) the UK national patient support group has identified large deficits in service provision, with many parts of the country failing to offer services [13]. This has led to poor access with patients forced to travel long distances to specialist centres rather than receiving care locally. Where care is provided, it is often delivered through acute specialist or palliative care centres. Major problems of access and discontinuity of care arise across the country.

The evidence base supporting treatment of CO is poor and has been confirmed in a number of systematic reviews [14, 15]. This may in part reflect the low profile of CO as a health care problem with little investment in research other than in the breast cancer field. This creates a challenge for any project that aims to provide patients with the best standard of care.

In 2002 the King's Fund awarded a grant to develop and evaluate a model of care for patients with all forms of chronic oedema [16]. The aim of this project was to develop, implement and evaluate health service and patient outcomes using an appropriate model of care within a London-based PCT and to use these results to develop recommendations for national care provision. The results of this community service implementation are now reported.

Primary outcome measures were:-

- 1) Quality of Life (QOL)
- 2) Incidence of cellulitis
- 3) Limb volumes

## **Methods**

### Service development

#### *Development of a Primary Care Trust Model within Wandsworth PCT*

The model of care developed reflected the shift from acute outpatient to community services where the emphasis was on healthy living, disease prevention and rehabilitation. The project involved a partnership with the Lymphoedema Support Network (LSN) who participated in all aspects of the work including leading on the assessment of patient experience.



### Community Hospital

The hub of the service was located in the community hospital in order to provide access to a multi-disciplinary team, including physiotherapy and rehabilitation. The service was led by a clinical nurse specialist in CO management. The service was supported by two trained community nurses. The nurses participated in the hospital clinic that ran for one day a week, ensuring continuity of care between the hospital and community. These nurses were able to undertake more specialised treatment in patients' homes and were able to arrange for patients to be seen by the specialist service if required. Patients were able to access the service by a number of routes and extensive advertising of the service was undertaken as part of the implementation strategy.

### *Shared care model*

A model of shared care was used for the many immobile, housebound patients. The specialist nurse visited at home with the community nurses to advise on treatment and, where necessary, refer patients to the hospital-based service for further investigation and treatment. Intensive treatment could be provided by the specialist nurse to housebound patients if required. This included a period of daily bandaging with exercise and skin care. Community nurses were supported during the transition of patients to long-term management in order to ensure that the progress that had been made during the intensive treatment episode was maintained. Increasing numbers of community nurses were able to take on more specialist aspects as their own knowledge and skills

developed. The community link nurses were also used to monitor treatment initiated in the clinic and support local staff in long-term management. The specialist nurse was also able to use key practice nurses to continue to prescribe garments and assist in long-term management with stable patients.

#### *Inclusion of Chronic Oedema within the Drug Tariff*

A major challenge for the project was the provision of appropriate compression and other materials for treatment. At the outset of the project specialist garments and materials were only available through hospital based services where they existed. Many patients had no access to these. The work of the Lymphoedema Framework, of which this project was integral, led to a change in the UK drug tariff in March 2006. At this time the recommendations from the project led to the availability of products through GP and nurse prescribing. In order to facilitate this change, links with a number of key pharmacists across the Trust were made.

#### *Development of the Best Practice for the Management of Lymphoedema*

A key objective of the project was to determine the best practice for the diagnosis and treatment of patients with chronic oedema and lymphoedema. A best practice document was developed following the systematic reviews and adopted the HTA consensus methodology [7]. This involved an international panel of expert reviewers. This document has now been adopted internationally.

## Study Design

The project was undertaken within Wandsworth Primary Care Trust (population 268,000).

The overall design used a number of implementation methods to support a three-stage study comprising pre-implementation, service development and post-implementation evaluation. Patients were followed up throughout these stages.

Patients were evaluated using the outcome measures at entry into the study (study entry – visit 1) and after a period of 6 months (baseline – visit 2) before implementation of treatment and at 6 (visit 3) and 12 (visit 4) months after implementation of treatment.

## Evaluation methods

These were established by the outcomes working group. This was a multi-disciplinary team, including patients, health care professionals and researchers. Their remit was to design a data collection tool that would allow for the evaluation of health service and patients outcomes. The design of the study involved two methods. Firstly patients were identified through health care professionals within the trust. Secondly, patients were evaluated in a pre versus post implementation model. Initially an RCT was considered for this project. However, concerns were raised about restrictions that such designs would be placed on attempting to treat all patients and the possible contamination that would be experienced by randomising patients within a single service, either individually, or as clusters. The pre implementation period allowed for patients to be followed up during their normal treatment regimen, and using this design each patient acted as their own control.

## Patient Assessment

The identification of patients followed the methods used in a previous study in south west London [3]. Briefly, this involved contacting all relevant health care professionals within the catchment area, to identify all patients they were aware of currently suffering from chronic oedema. This was defined as chronic swelling present for more than 3 months, not responding to diuretic therapy or elevation, irrespective of the underlying aetiology [2]. The aim of this was to identify all patients who would require treatment irrespective of their current level of care.

Following identification, a random sample was drawn from this patient population to allow for a more detailed examination and interview.

Patients were contacted through a letter from their GP, and followed up by a research nurse. Interviews took place according to the patient's wishes, either in a clinical area or within the patient's own home. The interviews took place at six monthly intervals, two being undertaken prior to patients starting treatment within the new service ie visit 1 and 2. This allowed for an examination of the baseline (current) treatment and outcomes prior to entering the new service.

### **Outcome measures**

At each six monthly visit patients completed a questionnaire. This consisted of a number of sections specific to the condition, and generic tools used to evaluate quality of life (SF-36) [17, 18], pain (SF-MPQ)[19] and health status (Euroqol EQ-5D) [20].

Generic tools were used to determine health related quality of life. More recent studies have since developed and validated disease specific tools. The McGill pain questionnaire (SF-MPQ) was included because a previous study had indicated that pain

was a greater problem than had previously been reported [3]. Euroqol was chosen to provide evidence of health status at different time points in order that an evaluation of changes in health status could be made.

Training was given to the four research nurses who undertook the evaluation of patients, to ensure consistency and repeatability. Limb volume measurements were made using a standard procedure as recommended by the Best Practice document [7]. Complications such as the development of infection (cellulitis) were recorded at each six monthly visit. Costs were assessed by interviewing patients about their use of health services over the previous six months. These data were combined with estimated unit costs of care derived from the British National Formulary [21], Drug Tariff [22], Unit costs [23] and NHS reference costs [24].

## **Statistical methods**

*Sample size.* The number of patients recruited into this study was not undertaken according to a pre-defined effect size, due to the uncertainties surrounding the potential changes in key parameters. The random sample was however, a reflection of the total patient group identified in this study.

Analysis was undertaken using quantitative methods. For continuous data this was undertaken using matched t-test analysis. This was chosen in order to determine whether and when a step change in outcomes occurred.

The study was supported by a steering group of relevant experts including patients and carers. The data collection tools were piloted and amended with 5 patients prior to

adaption and use. Ethical approval was obtained from the local Independent Ethics Committee. The study was performed in accordance with the guidelines of the Declaration of Helsinki <sup>(47)</sup>, and the principles of Good Clinical Practice (GCP) ICH E6 and EN540 standards <sup>(48)</sup>.

## **Results**

### *Case Identification and Prevalence Estimates*

In all, 327 patients were identified in community and acute services and were resident within Wandsworth PCT (population 267,943). Of these, 15 had swelling that resolved overnight and were excluded as they did not meet the criteria for chronic oedema set by this study. Of the total, 257 (82.4%) were women. This gave a crude ascertainment rate of 1.16 per 1,000 population. As expected, the ascertainment was highly age dependent with patients over the age of 85 years having the highest risk of chronic swelling. Women suffered to a greater extent than men, with crude ascertainment rates of 1.87 and 0.42 respectively per 1,000 population.

The site of swelling was also highly related to the patients' gender. While less than 10% of men suffered from arm swelling (4/55), this accounted for 40% of all women (99/257). Leg swelling was age dependent for both men and women, being more prevalent in the older groups. Women still experienced greater problems with leg swelling, with crude prevalence of 0.92/1,000 versus 0.39/1,000 in men. Of the total, only 112 (35.9%) had swelling related to a cancer diagnosis.

From this ascertainment study 204/256 (79.7%) were receiving some form of care for their CO. Most patients had received skin care advice from their health professional, together with exercise advice and elastic hosiery. Relatively few (10.8%) had received bandaging for their CO, but 13.8% had received bandaging for concurrent leg ulceration. Chronic oedema bandaging involves adaption of the technique to include the toes and thighs [7] whereas community leg ulcer bandaging protocols are below knee with no toe bandaging. Both manual lymph drainage (4.4%) and self massage (6.4%) were rarely used. Diuretics had been used in 16.3% despite these being generally contra-indicated in lymphoedema management, except in patients with oedema where salt and water overload occurs.

### **Cross Sectional Analysis of Patient Sample**

107 patients were randomly selected from the original 312 for further evaluation [Table I]. Swelling had been present for over 10 years in 50(47.2%), 1-9 years in 54(50.9%) and in less than one year in only 2 patients.

Over the duration of the swelling 52/103 (50%) had experienced at least one acute episode of cellulitis. Of these, 17 (32.6%) had required hospitalisation at least once for this infection. In all, 21/106 (19.8%) had experienced an acute infection within the past year, with five (23.8%) of these requiring admission to hospital [Table II].

## **Clinical results of treatment**

### **1. Health Related Quality of Life**

#### **a. SF-36**

Major improvements in the SF-36 scores occurred during treatment within the new service [Table III].

Significant improvements were identified in most HRQOL domains post-implementation (between visits 2 and 3), but particularly role physical (difference [d] =32.7) and role emotional (d=24.0) both of which achieved a level of significance of  $p < 0.0001$ .

Analysis between six months and one year (between visits 3 and 4) indicated further improvements in bodily pain, vitality, social functioning and mental health although the magnitude of change was smaller than that experienced within the first 6 months ( $d < 10.0$ ).

No significant changes were seen during the run-in pre-implementation period except in role physical where it was considered contact with and encouragement from the health care professionals may have been responsible ( $d = 15.5$ ,  $p < 0.001$ ). None of the differences above appeared to be influenced by the presence (or healing of) the concurrent leg ulceration (results not shown)

#### **b. SF-MPQ**

Pain scores improved significantly post-implementation and continued to improve from 6 months to 1 year as given by negative differences of -2.1 and -0.5 respectively (table III). There was little change in pain scores between study entry and baseline ie before



treatment was implemented.

### **c.EuroQol**

EuroQol measures physical, psychological and social dimensions of health that are influenced by the patient's experiences, beliefs, expectations and perceptions. There was noticeable consistency between scores pre-implementation and then significant improvements both during the first 6 months post-implementation ( $d= 0.05$ ) with further improvements from 6-12 months (mean difference 0.03) [Table III]. In the sub-group who had concurrent ulceration, the results were not confounded by the ulcer healing during follow-up.

### **2. Incidence of cellulitis**

There was a significant reduction in both the rate of cellulitis (-34.7 infections per 100 patient years) and the rate of admission for cellulitis (-5.6/100 patient years) between the 6 months pre-implementation and the 6 months post-implementation [Table IV]. From 6 months to one year post-implementation there were no reported cases of cellulitis, despite continuous patient follow up.

### **Reduction in swelling**

Patients with arm or leg CO experienced small but significant reductions in limb volume 6-12 months post-implementation [Table V]. Mean volume reductions were 59 ml in patients with arm disease and 155 ml in patients with leg disease (both  $p<0.001$ ). What was surprising was that no substantial reductions in limb volumes occurred during the first 6 months post-implementation. Improvements in limb volume prior to

implementation may reflect improvements in mobility generated by encouragement from health care professionals.

### **3. Cost and effectiveness of treatment**

The costs of care are presented in table VI. The costs are presented as a cost over a six month period for 100 patients, using the data collected during the study. Overall costs reduced from £50171 prior to implementation to £27352 within the first 6 months and subsequently £17618 between 6 months and one year. The results show that resources moved from the acute care setting to lower cost interventions in the community. Costs of bandaging for swelling increased with a reduction in costs for ulcer bandaging. This is not too surprising as ulcer bandaging may be reduced due to healing of the ulcer. However, the reduction in cost cannot be attributed merely to the reduction in numbers treated for ulceration. Excluding the costs of ulcer bandaging reduces the costs of care to £25303, £23622 and £15710 respectively. These changes are largely due to the shift from acute services and reduced frequency of bandaging for swelling following an initial rise. As expected hosiery costs increased as more patients were prescribed and fitted hosiery. The cost of care reduced substantially 6 months to one year after implementation.

The overall effectiveness of the new service model is given by the change in utility scores as determined by EuroQol. While there was no evidence of a change in utility during the baseline period (visits 1 and 2) there was evidence that following

implementation utility improved. [Table III]. Reduced cost with improved health outcomes demonstrate the cost-effectiveness of the service.

## **Discussion**

Chronic oedema and cellulitis, in particular, present an enormous challenge to health and social services in terms of both management and cost. A scenario frequently arises where the development of lower limb oedema further compromises mobility. Patients who are already infirm and overweight deteriorate further.

One of the difficulties in the community is implementing whole limb compression. Community staff are trained for below knee compression therapy eg venous leg ulcers but not for toe, forefoot, thigh high or upper limb bandaging. Such treatment is necessary in chronic oedema where standard below knee compression bandaging can make toe or thigh swelling worse.

The results of this study have highlighted the potential benefits of developing a service model for chronic oedema that combines a specialist and generalist approach to care. It has shown clinical improvements in terms of reduction in limb volume and reduced complications particularly cellulitis. While the clinical benefits are key to determining the potential for any service development it is important to evaluate the benefits to patients in terms of their improved quality of life. A recent case control study using the same cohort of patients has demonstrated that CO impacts on various aspects of quality of life but also on the ability of patients to cope with their condition and on their social support

[25]. Subgroups of the patient population may be impacted differently according to their clinical situation. As an example, non-cancer patients are more susceptible to developing cellulitis [26]. This analysis has not chosen to undertake subgroup analysis of the quality of life results due to the relatively small numbers and the potential for confounding factors to influence these outcomes. There is evidence that other interventions such as liposuction may offer patients benefits to their quality of life [27].

The results of this study also show that the model of care leads to reduced cost of care. This was achieved by using largely existing resources through the development of staff expertise and appropriate referral and intervention when necessary. Whilst much of the care remained in the community, support from specialist staff was essential when dealing with complex patients. The model of shared care between specialist and community staff could have been a factor that resulted in the reduction in admissions and improved outcomes, together with a standard cellulitis policy in place.

Cellulitis is the sixth most expensive emergency in the UK and is frequently recurrent as results here demonstrate [28]. Chronic oedema is one of the main risk factors for cellulitis [29]. Recent work has revealed that covert underlying lymph drainage abnormalities frequently initiate cellulitis [5]. Recurrent cellulitis can be prevented by prophylactic penicillin in the majority of cases but relapses once prophylaxis stops with compromised local immune competency related to chronic oedema a likely explanation [6].

The work has shown that admissions to acute care following the development of cellulitis occur frequently. The potential for reducing admissions is observed in this

study, and will have economic and patient benefits. Reducing needless hospital admissions is a key priority for health services. Clearly an effective prevention strategy and rapid intervention could prevent many hospitalisations. Cellulitis may also contribute to the worsening of the CO, leading to a cycle of more severe swelling, and an increase in the incidence of cellulitis and more health service resource.

A key aim of care is to identify patients at an early stage to prevent the development of complex disease due to neglect and prevent complications such as infection and immobility. This study was based on patients already identified by healthcare professionals. As the service develops it would be expected that early intervention and prevention would feature more prominently in the aims of the service. Moreover, raising awareness and clear referral pathways would encourage these to occur.

This study has a number of limitations. The sample size, although reflective of the larger population, is relatively small. Despite this fact there is evidence that they are typical of the types seen in current CO services in the UK [3, 11]. Many have had their condition for a long duration and have not had an appropriate diagnosis or treatment leading to deterioration and morbidity. As there are no agreed coding systems or requirements to screen for CO in primary care it is likely that many with mild CO will not be identified and only become apparent when complications occur. The study used well validated generic HRQoL tools, however more recently disease specific tools have been developed that may be more sensitive to change and should be incorporated into future research

[30,31]. Despite this the tools adopted for the study have been able to identify significant changes with appropriate interventions.

While it is acknowledged that a number of patients did not complete all follow up visits, this reflects the complexity of the patient population. Of the 107 patients recruited to the study 21 did not complete the final assessment due to death (7), patients being unable or unwilling to continue (13) and one lost to follow up due to moving from the area.

In summary, chronic oedema and cellulitis can be satisfactorily treated in the community providing the correct management strategy is implemented. With the appropriate investment in community staff training and resources Decongestive Lymphatic Therapy can be cost effective with healthcare costs subsequently substantially reduced.

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<b>Table I. Demographics and Details of Lymphoedema n=107</b>	
<b>Age</b>	
	<b>mean (sd)</b>
Female	68.6 (15.0)
Male	72.9 (12.4)
<b>Gender</b>	
	<b>N (%)</b>
Female	88 (82.2)
Male	19 (17.8)
<b>Family Unit</b>	
Alone	42 (39.2)
Partner	45 (42.0)
Other relative	15 (14.0)
Friend	1 (1.0)
Other	4 (3.7)
<b>Housing Type</b>	
Owner	58 (55.2)
Council rented	21 (20.0)
Private rented	13 (12.4)
Sheltered housing	10 (9.5)
Residential home	3 (2.9)
<b>Employment Status</b>	
Retired	79 (73.8)
Employed full time	12 (11.2)
Not working, illness	5 (4.7)
Employed part time	7 (6.5)
Look after home	2 (1.9)
Unemployed	0 -
Other	2 (1.9)

<b>Table II. Details of Swelling</b>	
<b>Causes of Lymphoedema</b>	
Primary	10 (9.6%)
Secondary	94 (90.4%)
Infection	10 (10.6%)
Trauma & tissue damage: cancer	45 (47.8%)
Trauma & tissue damage: non cancer	8 (8.5%)
Malignancy	3 (3.2%)
Inflammation	3 (3.2%)
Phlebo-lymphoedema	17 (18.1%)
Immobility/dependency	7 (7.4%)
<b>Infections since start of swelling</b>	
Never	51 (49.5%)
Once	27 (26.2%)
Twice	9 (8.7%)
3-5 times	8 (7.8%)
6-10 times	3 (2.9%)
>11 times	5 (4.8%)
<b>Admissions for Infection since start of swelling</b>	
Never	90 (84.1%)
Once	10 (9.3%)
Twice	5 (4.7%)
3-5 times	2 (1.9%)
<b>Concurrent leg ulceration</b>	
Yes	13 (12.1%)
No	94 (87.9%)

**Table III. Health Related Quality of Life (SF-36 & Euroqol) at different visits.**  
**PF=physical functioning, RP=role physical, BP=bodily pain GH=general health**  
**Vi=vitality SF=social functioning RE= role emotional MH= mental health**

	Pre-implementation				Post-Implementation				
	Visit 1		Visit 2		Visit 3		Visit 4		
	N	Mean (sd)	N	Mean (sd)	N	Mean (sd)	N	Mean (sd)	
<b>PF</b>	107	45.9 (33.3)	96	45.9 (32.2)	86	48.8 (32.0)	83	49.9 (31.1)	
<b>RP</b>	107	50.6 (46.4)	95	67.4 (43.2)	86	98.5 (8.0)	83	98.5 (11.3)	
<b>BP</b>	107	64.0 (30.9)	97	67.3(28.8)	86	78.2 (21.4)	83	82.0 (17.8)	
<b>GH</b>	107	59.4 (26.1)	97	60.7 (24.6)	86	64.4 (24.6)	83	63.6 (25.4)	
<b>Vi</b>	107	51.5 (24.2)	97	52.7 (23.4)	86	64.4 (16.6)	83	68.6 (13.4)	
<b>SF</b>	107	66.7 (32.5)	97	71.4 (31.0)	86	82.7 (18.8)	83	89.4 (13.8)	
<b>RE</b>	107	66.4 (44.7)	97	77.3 (40.4)	86	99.6 (3.6)	83	98.8 (11.0)	
<b>MH</b>	107	73.2 (19.2)	97	75.4 (18.0)	86	81.1 (13.6)	83	85.0 (9.9)	
<b>SF-MPQ</b>	107	3.5 (6.3)	87	3.3 (5.9)	86	0.8 (2.1)	85	0.3 (1.1)	
<b>Euroqol (EQ-5D)</b>	103	0.66 (0.33)	93	0.66 (0.31)	86	0.71 (0.25)	82	0.73 (0.20)	
<b>Changes in HRQoL between Visits (paired analysis)</b>									
	Visit 1 & Visit 2			Visit 2 & Visit 3			Visit 3 & Visit 4		
	N	Mean (95%CI)	p-value	N	Mean (95%CI)	p-value	N	Mean (95%CI)	p-value
<b>PF</b>	96	-0.6 (-4.1, 2.8)	0.71	86	2.9 (-0.3, 6.1)	0.073	83	0.8 (-0.2, 1.8)	0.10
<b>RP</b>	95	15.5 (7.7, 23.4)	0.0002	86	32.7 (23.3,42.2)	0.0001	83	0 (-2.8, 2.8)	0.99
<b>BP</b>	97	2.7 (-1.7, 7.1)	0.23	86	11.5 (7.1,15.8)	0.0001	83	4.4 (1.9,6.9)	0.0007
<b>GH</b>	97	-0.6 (-2.9, 1.8)	0.64	86	3.0 (0.3,5.8)	0.030	83	-0.7 (-2.2,0.8)	0.35
<b>Vi</b>	97	-0.5 (-3.7, 2.6)	0.73	86	11.5 (8.1,14.8)	0.0001	83	4.8 (3.2,6.4)	0.0001
<b>SF</b>	97	3.4 (-1.2, 8.0)	0.15	86	11.6 (6.6,16.5)	0.0001	83	7.0 (4.6,9.5)	0.0001
<b>RE</b>	97	8.6 (-0.2,17.4)	0.056	86	24.0 (15.3,32.8)	0.0001	83	-0.8 (-3.3, 1.7)	0.53
<b>MH</b>	97	1.0 (-1.6, 3.5)	0.45	86	4.8 (2.2, 7.4)	0.0004	83	4.0 (2.7, 5.4)	0.0001
<b>SF-MPQ</b>	97	-0.4 (-1.1, 0.4)	0.34	86	-2.1 (-3.1, -1.1)	0.0001	85	-0.5 (-0.9, -0.2)	0.005
<b>Euroqol (EQ-5D)</b>	90	0.00 (-0.03,0.04)	0.93	83	0.05 (0.01,0.08)	0.007	82	0.03 (0.00,0.05)	0.031

<b>Table IV. Incidence of Cellulitis</b>				
	Pre-implementation		Post-implementation	
	Visit 1	Visit 2	Visit 3	Visit 4
Rate of cellulitis Per 100 patient years	41.5	14.9	6.8	0
Rate of hospitalisation Per 100 patient years	5.6	2.1	0	0

<b>Table V. Limb Volume Measurement of largest affected limb at different visits ( mls)</b>									
<b>Limb volume (mls)</b>									
	<b>Pre-implementation</b>				<b>Post-implementation</b>				
	<b>Visit 1</b>		<b>Visit 2</b>		<b>Visit 3</b>		<b>Visit 4</b>		
	<b>N</b>	<b>Mean (sd)</b>	<b>N</b>	<b>Mean (sd)</b>	<b>N</b>	<b>Mean (sd)</b>	<b>N</b>	<b>Mean (sd)</b>	
<b>Arm</b>	42	2278 (1048)	37	2192 (868)	35	2214 (904)	35	2155 (869)	
<b>Leg</b>	64	4911 (3386)	51	4457 (2946)	51	4526 (3258)	49	4372 (3198)	
<b>Total</b>	106	3868 (2997)	88	3505 (2562)	86	3585 (2806)	84	3448 (2726)	
<b>Changes in Limb volume (mls)</b>									
	<b>Visit 1 &amp; Visit 2</b>			<b>Visit 2 &amp; Visit 3</b>			<b>Visit 3 &amp; Visit 4</b>		
	<b>N</b>	<b>Mean (95%CI)</b>	<b>p-value</b>	<b>N</b>	<b>Mean (95%CI)</b>	<b>p-value</b>	<b>N</b>	<b>Mean (95%CI)</b>	<b>p-value</b>
<b>Change in arm volume</b>	37	122 (-28,273)	0.11	33	27 (-41,95)	0.43	35	59 (31,86)	0.0001
<b>Change in leg volume</b>	51	160 (-159,478)	0.32	45	49 (-321,418)	0.79	49	155 (67,243)	0.0009
<b>Change in volume (total)</b>	88	144 (-48,336)	0.14	78	39 (-172,254)	0.71	84	115 (62,168)	<0.0001