'Any Qualifed Provider' for venous leg ulceration: rhetoric or reality?

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here are four basic models of health service delivery: those which rely on trust, on command and control, on voice, and on choice and competition (Le Grand, 2009). There are various theoretical and empirical arguments for preferring choice and competition; such is the case for the management of venous leg ulcers (VLUs) in primary care.

It is claimed that patient choice could increase equity in the NHS setting (Barr et al, 2008). However, some years after the advent of the 'Any Qualified Provider' (AQP) scheme there is little evidence that VLU sufferers in most of England have any choice. Apart from reneging on a policy commitment, does this have any real impact on the patient?

The answer can be deduced from a review of the available evidence. Healing rates for VLUs have been derived from The Health Improvement Network (THIN) database and were found to be between 6% and 9% in 26 weeks (Guest et al, 2012). This can only

be described as a disgrace (White, 2012) and, as such, is untenable. In effect, the majority of patients with VLUs are being knowingly condemned to 'palliative care' with little or no hope of ulcer healing. The impact on patient quality of life is considerable (Green, et al 2014). The indirect costs associated with VLU management, for example, treatment of wound infection, have not been quantified but may be anticipated to be significant. The associated mortality from VLU infection and its social impact should also be considered (Kelechi and Bonham, 2008).

Evidence, albeit preliminary, suggests that this need not be the case. Where they exist, specialist community leg ulcer centres can achieve far higher healing rates (White et al, 2012). Healing rates for VLU of 73% in 12 weeks and 100% in 24 weeks were obtained. The reasons for this vast discrepancy are numerous, but include: practice nurse-led care versus tissue viability specialist-led care (O'Halloran and Winter, 2013), the better availability of resources, staff training and awareness, and a commitment to tackle the problem.

This is the exact scenario anticipated when the policy of 'patient choice and competition' was formulated and enacted in the Health and Social Care Act 2012 (The Act, 2013; Monitor, 2013). Has complacency set in with respect to the care of patients with VLU in the community? How can the poor healing rates be explained? Evidence exists for 'good' healing rates using high compression systems, but are they being delivered widely?

For a long time, the burden of chronic wounds in the UK has been accepted as approximately £2–3bn (Posnett and Franks, 2008), of which VLU constitutes £200m for the annual costs of approximately 200,000 patients — a very conservative estimate. Recent data from Wales have shown this

to be an underestimate of considerable proportions (Phillips et al, 2015). Accurate and up-to-date information for England has been gathered but not yet published: it is unlikely to be much different.

To address some of the pressing questions related to VLU care in the community, and in particular, the AQP system, a number of experts have been invited to offer their observations and perspectives. *Richard White*

Given that VLU healing rates are well below expectations, do you see the AQP system as being one solution to the problem?

SH: I strongly believe that AQP has the potential to increase healing rates — there is absolutely no doubt that is a fact.

I ran the Eastbourne Wound Healing Centre and also the AQP for Mid Sussex. Both were successful. This is not because we had a magic bullet, but because we reduced the patients' stress, gave them time, had highly trained specialists caring for the wounds, and access to the most appropriate dressings for each individual.

When AQP commenced, I understood that the idea was that the Department of Health (DH) would review the 'Tender' of each company and would hold a list of companies they signed off as fit for the AQP. This should have involved companies with a proven record of giving the service applied for, who could undertake the service within a band level (each AQP would receive the same fee). Unfortunately, this is not what happened.

AE: Chronic venous insufficiency is a progressive condition associated with deteriorating venous function (Kostas et al, 2010). The evidence suggests that the clinical picture of VLU is one of a cyclical nature, involving healing and ulcer recurrence (SIGN,

2010). VLUs become apparent at the end of a continuum of a chronic disease process involving venous disease.

Over the years, VLU management has been very conservative, involving various topical dressings and the application of compression systems, often with the use of sub-optimal compression, which is associated with delayed healing rates and high reoccurrence rates (Todd, 2014), all of which consume considerable amounts of nursing time and increase related healthcare costs (Guest et al, 2012).

First and foremost, patients with lower limb ulceration require timely, accurate diagnosis. NICE (2013) recommends referral at 2 weeks to a vascular specialist within a secondary care setting for accurate diagnosis and potential treatment of the underlying venous disease, to lower the risk of recurrence. This pathway needs to become accepted practice, embedded and reflected within local referral pathways, regardless of the lower limb ulcer care provider in the community setting. The National Early Venous Reflux Ablation study (Imperial College, London) is currently investigating the role of early venous intervention in patients with active VLUs on healing. We need to have an accurate idea of the numbers of patients with VLUs and the healing times need to be clearly audited.

Patients with VLUs need to be subsequently cared for in a community-based, specialised service that can demonstrate effective healing times and quality outcomes. AQPs could well play a role in achieving this aim, if they are able to demonstrate the necessary quality standards and criteria for service delivery.

AB: Originally, the main aim of the AQP system was to allow patients and their GPs to choose a service according to what is most important to them — geographical location, a shorter waiting list, or a service that has better outcomes. The AQP system certainly provides one solution to poor healing rates, by providing some competition for leg ulcer services, along with a system for measuring

and comparing outcomes both locally and nationally; and by setting standards expected by the NHS and rewarding providers with continued contract opportunities when performing at or above these standards.

Patients are assured of greater transparency when selecting the clinic of their choice, and care is standardised nationally ensuring they are getting optimum care wherever they live.

CA: On paper, AQPs look like a great idea, but they do not seem to be providing the answer to the wound care burden in the UK thus far.

The take up for AQP for VLU has been low, why do you think that this is the case?

SH: I was part of devising the Leg Ulcer AQP with the DH; we spent huge amounts of time designing how the service would run and set a fee. The document was uploaded to the DH's website, with the comment that this was only a guide; Clinical Commissioning Groups (CCGs) could pay whatever they wished and their service could be designed to their own requirements. However, the CCGs then tried to lower the price below the cost of a district nurse, but it was impossible to run a service with that fee.

CCGs are suspicious of private companies and find setting up an AQP in Leg Ulcers extremely difficult, reluctant to take on 'outsiders'. Tissue viability nurses (TVNs) see themselves as guardians of their patients and are reluctant to permit private providers to take up AQP in their area – there is a great deal of 'blocking', particularly as many of these TVNs, without a 'business head', believe they are capable of providing a similar service, even though they have never done it before.

AE: One of the overriding concerns with AQPs is that there is no guarantee of referrals to the service. Without these, there is little income, and providers can ill afford to lose income that may potentially impact on the quality of the service subsequently provided.

Running a VLU service requires sufficient, suitably experienced, qualified personnel. The time required for each patient and the other resources involved may deter potential AQP providers, as they are dealing with a chronic disease process in an ageing population with increasing multi-morbidities. Smaller providers, in particular, may be at a disadvantage due to the substantial time and resource costs involved. Experienced clinical practitioners would have to decide if they wanted to focus on one area of care (i.e. VLUs), which may be perceived as limiting. Providers of AQP VLU services would require an individual with sufficient legal, financial and operational experience and expertise to guide and develop the service within the community setting. There could also be concerns raised that the agreed set-up tariffs and return payments for each intervention may not cover the costs involved to provide an effective service, and regarding whether the resources committed to AQP can be recovered from the AQP cost-per-case tariff.

AB: The AQP contracts offered by CCGs have been few and far between. Those offered have requested a premium service on a budget that has restricted use of the staff and equipment required to ensure appropriate standards can be met. Therefore, providers have been reluctant to pursue those few AQPs on offer.

The application process is time-consuming and repetitive and, although AQP was originally explained as an opportunity for smaller providers (such as not-for-profit companies and social enterprises) to become involved in a service, it gives preference to larger providers who can encompass every aspect of the contract. This, at surface level, appears to be without consideration of the quality of the service or any guarantee that outcomes can be adequately demonstrated.

CA: The barriers to setting up AQPs should be analysed and removed as far as possible. Unfortunately, clinical innovators do not tend to have sharp business minds; it

is a rare beast to have a wound care expert with vision, who can navigate their way around the complicated world of business and NHS interface. We speak different languages!

What can and should be done to establish more AQPs?

SH: Fees should be fair for both sides. CCGs will have to (a) lose suspicion; (b) be prepared to permit private providers to take up the challenge for them; (c) understand that leg ulcers are extremely costly to the NHS (at present, CCGs really have no idea how many leg ulcers there are in their area or how much they are costing); and (d) reassure TVNs that they can be part of the new world, rather than being discarded.

AE: In order to establish more AQPs, there needs to be greater interest, awareness and evidence of their potential value and role in providing services for patients. Positive research findings supporting AQP development within the practice arena are required.

Many practitioners may be deterred by the processes involved in setting up AQPs and the fact that there is no guarantee that, once approved, the service will receive referrals and subsequent income to allow for continuation and development. In order to establish more AQPs, their take up would have to happen uniformly across the country. At present, it is up to individual CCGs to decide which services are offered to AQP providers; therefore, to increase the number of VLU AQPs this may have to be driven centrally.

AB: CCGs need to made aware of the importance of low healing rates for VLUs., in order that they see the importance of offering more AQP contracts This should include the impact they have on society, the cost to the NHS, including secondary care, and the affect on a person's quality of life. Much of this information has been estimated nationally, but more accurate regional data would provide the local CCG with

realistic information and lead them to see care of VLUs as a higher priority.

Realistic payments need to be offered for the contracts with the knowledge that, when standards are met and outcomes are achieved, the CCG will receive substantial cost savings and the patients will experience improved quality of life. Applications should be welcomed from a variety of different providers, with an acceptance that in some areas the contract would benefit from being shared between more than one provider.

CA: The resourcing/ allocation of funding for AQP should be handled by those expert in the field of tissue viability. In the past, the DH allowed GPs to decide end points of care and what price should be levied against these end points. Unfortunately, this led to managers and clinicians without sufficient expertise deciding on complex tissue viability matters that would tax experts in the field. The net result was an under resourced service that would never be able to meet the targets set.

In order to establish a structure in which AQP in VLU/TV may thrive, a working party of experts in the field must be utilised to inform the decisions made by the DH/NHS England.

Do you believe that GPs are aware of the incidence, costs, and current healing rates for VLU in primary care? Explain your answer.

SH: In my experience, which is quite wideranging, GPs and CCGs tend to only look at the unit cost of a product or service. This dressing costs £2, whereas another that can demonstrate faster healing rates costs £10; the second is cost-effective over time but, due to the high unit cost, is very unlikely to be taken on

The AQP service will heal a wound faster, but unit cost for each patient is higher than the cost of a district nurse. Therefore, AQP is thought to be too costly, even though it can demonstrate faster healing. Also, in my experience, GPs and CCGs have absolutely no idea how many wounds there are in their

area. It is the district nurse and practice nurse who care for the wounds and these are never audited.

At the Eastbourne Wound Healing Centre, 82% of wounds (independently verified) were healed in 6 weeks, and these were patients who had had wounds for 3.3 years before attending the clinic.

AE: To say that GPs are not aware of the incidence, costs, and current healing rates would be extremely unfair as the pressures and priorities on their time are continually growing, and the need to be well informed and up-to-date about an always increasing field of practice is as great as ever.

Traditionally, the management of patients with VLUs has been delegated and seen as a nurse-led area, probably because the expertise required relates to tissue viability and compression therapy. VLUs are perhaps not high on GPs' agendas, but the care of patients with ulceration is a relatively high cost, and takes up considerable amounts of community nursing hours at a substantial cost (Guest et al, 2012).

Chronic venous disease, including varicose veins, has for several years been seen by GPs as an area of restricted access to treatment in secondary care, and by CCGs as an area of low priority and restricted access for intervention. NICE (2013) recommends reversing this view and advocates referral to secondary care to a vascular specialist and possible intervention using the new modern methods for venous treatment, if appropriate. It would be good to see a consistency of referral pathways for patients with VLUs across the country.

AB: I believe that GPs are aware of the incidence of VLUs in primary care, but they have little knowledge of the cost and healing rates associated with them. GPs sign prescriptions for the dressings, but have minor involvement in the day-to-day care of these patients and are not aware of how much time optimum care of VLUs can involve. The practice nurses, district nurses, and in some areas, healthcare assistants, care for these patients. The training involved

can be difficult to access and outcome measurements for VLUs are not a high priority for GPs, who have a number of other medical conditions to monitor and achieve outcomes for.

CA: GPs, practice nurses and primary care managers have no idea about incidence, costs, and current healing rates for VLUs in primary care, since district nurses and TVNs tend to deal with their care. Even if the patient is lucky enough to be referred, information exchange between district nurses and GPs is poor (general practice is computerised, whereas district nurses tend to use old-style-nursing paper notes). I recently tried to complete an audit on wound care in my 10,000 patient practice: 80% of wounds (not all VLUs) were healed, but there had been no communication of this fact to the GP practice.

Tissue-viability-trained staff are rare in general practice, and GPs with tissue viability knowledge are virtually non-existent. Not only are GPs not aware of incidence rates, healing rates or costs, they are also often not very interested. It is an area that feels very foreign to them, one which is gladly handed over to the community team. In short, they are not engaged.

Is the future of community VLU care possible in the public sector, or is a private, or public-private initiative the way forwards?

SH: The future could be either private, or public-private initiative, as long as the service reduces the stress of the patient, provides knowledgeable wound care, uses the most appropriate treatment for the individual, and provides the appropriate amount of time required for high-quality care. Also, the service should have a pathway of onward referral and one that is not always policed by the *GP*, since speed of referral is often extremely important to the welfare of the patient.

AE: I personally feel that first we need to evaluate our services — pathways of care and referral processes, and the specialist

personnel involved in the current public-sector-delivered services — and decide whether they meet local needs. This process can only be achieved through ongoing audit. Examining local services currently in place will help to develop a clearer picture as to whether they are effective, efficient and provide a value-for-money, high-quality service.

In the future, the services available for VLU care could be private, public or a public-private initiative, if the needs of patients with VLUs are effectively met. If patients have the choice of specialist providers, this could mean increased competition, which could drive up the quality of services. We also have to ensure that the services provided for patients with VLUs are integrated to ensure that service provision does not become fragmented, which could have a detrimental effect on patient care.

AB: The current staffing, time allocation and financial constraints of the public sector make achieving better outcomes for VLUs difficult. Well implemented AQPs would offer the public sector allocated finances and time to manage this group of patients, with specific goals to achieve. However, without the opportunity to tender for the contract, there may be little motivation for already over-stretched senior staff working in the public sector to draw up a business plan or find the time to propose methods to enhance patient care and measure outcomes.

In my view, a public-private initiative would be the best way forward for VLU care. It would provide some healthy competition, a business model encompassing quality of life outcomes with the patient at the centre, while avoiding complete privatisation of this area of the NHS.

Public and private providers should be able to work together but also challenge one another for the patient's gain, and to make subsequent financial savings for the CCG.

CA: The future: who knows? The current NHS structure is struggling to cope, yet private profit-driven enterprise in this area fails to make patient care a priority.

Where do you expect community VLU care to be in 2020?

SH: In the future, leg ulcer care must be undertaken by those with specialist knowledge. At present, there are excellent nurses caring for the wound in the community, but they do not have and often cannot obtain access to training in treating and preventing wounds.

I would like to see centres of excellence opening that can ensure wounds are overseen by those with good knowledge in wound care, who can train community nurses to provide care that is signed-off by these centres. Each area would have AQP in process with two or three companies (private, and/or public-private) providing care. This would enable the CCG to decide which company they wish to undertake care in the future.

What I suspect will happen is that we will continue with overworked TVNs and undertrained nurses caring for wounds and little changes made in healing rates. There has been such success throughout the UK with Leg Clubs and specialist clinics, all demonstrating that we need dedicated services in each area; it is hard to understand why CCGs are so reluctant to take these excellent services on.

AE: The number of individuals with lower limb ulceration will only continue to rise with our ever increasing aging population, and these individuals will also have increasing multi-morbidity and an increasing prevalence of arterial disease.

I would like to see patients with signs of chronic venous insufficiency and subsequent ulceration being diagnosed appropriately and referred in a timely manner as per national/local referral pathways to a specialist vascular service, for timely assessment, diagnosis, management and, if appropriate, venous intervention. Timely intervention would deal with the most significant underlying components of venous disease, helping to prevent future recurrence and promoting venous ulcer healing.

These patients should receive continuing management with a community specialist service that provide treatment whilst active ulceration is present and also continue supporting with all the related and associated factors once healed, to maintain healthy, healed legs in the future.

AB: The answer to this question depends greatly on decisions made by the CCGs in the next 2 to 3 years. While I would like to see standardised, high-quality care nationally, I expect that there will be pockets across the country where leg ulcer care and contracting has been altered and improved outcomes will be evident.

This will be in the form of AQP contracts for VLU or lower limb services. I expect outcomes, including economical calculations, for these services to be published and shared. This would encourage other CCGs to offer contracts for VLU care in order to improve their own outcomes and make cost savings.

It is already 4 years since the AQP model was introduced. Change is known to take time and the hard work required to turn around care for this group of patients is appreciated. However, whether you consider the patient or NHS financial restrictions to be the driver behind implementing service improvements, there is surely no excuse for delaying the changing of current care packages and the introduction of new contracts. The Health and Social Care Act 2012 was designed to enable patient choice and effective use of the AQP system should allow this.

CA: By 2020, community VLU care will certainly not rest in General Practice, since the current GP retention crisis is predicted to continue to worsen.

I would like to see centres of excellence established whereby clinics, teaching, training, research, and voluntary organisations such as Leg Clubs work together to improve patient outcomes. One can envisage these centres being staffed by TVNs, nursing assistants, occupational therapists, and

physiotherapists, with visiting vascular, diabetes and general practice clinicians in a one-stop-shop scenario.

Various funding models could be employed: NHS, private, voluntary, and income generation via research, trials and evaluations.

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