How to measure success in treating chronic leg ulcers

Healing is not the only desirable outcome measure

LOUISE MURRAY / ALAMY

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Optimising the care of patients with leg ulcers is problematic not least because of the lack of universally accepted evidence based guidelines.[1] Several systematic reviews into the effects of, for example, debridement, compression, topical treatments (including dressings), antimicrobial agents, and newer treatments (such as topical negative pressure devices) have predictably led to the conclusion that more research is needed.[2-7] In the United Kingdom, clinical guidelines from bodies such as the National Institute for Health and Clinical Excellence (NICE) or the Scottish Intercollegiate Guidelines Network (SIGN) are either not available or have limited value. Three linked studies concern the efficacy and costs of treatments for leg ulcers.[8-10]

The management of chronic wounds, healing by secondary intention, is challenging—a multidisciplinary approach is generally thought to be the best option.[11 12] The importance of developing systems, structures, and appropriate remuneration for caring for patients with such wounds has only recently been recognised.[13] The obvious measure of success in evaluating interventions in wound healing is complete healing. As yet, however, no single intervention has produced both clinically and statistically significant results, which has resulted in the limited adoption of new technologies.

The evidence needed to evaluate treatment interventions for leg ulcers has three components—efficacy, which could include debridement or healing; efficiency, which may include frequency of dressing change or admission to hospital; and effectiveness, which could assess patients' quality of life or cost effectiveness.[14] The three linked studies illustrate some of these factors.[8-10]

Dumville and colleagues report a three-armed, randomised, controlled trial that compared the effects of hydrogel, loose larvae, and bagged larvae on debridement and healing of leg ulcers.[8] Larval therapy did not increase the rate of healing or reduce bacterial load compared with hydrogel. On a positive and clinically relevant note, however, the study found a highly significant effect of bagged or free maggots on the removal of slough and necrotic tissue (debridement) compared with hydrogel. The authors do not speculate why healing was not enhanced after effective debridement. The study's primary end point was healing, but this may be inappropriate, especially as venous and mixed arterial and venous ulcers were included. Effective debridement may have been a more useful measure of success and more valuable to clinicians in certain circumstances.

A cost effectiveness analysis of the trial found that debridement of sloughy venous leg ulcers with larvae probably costs about the same as using hydrogel.[9] However, cost effectiveness is difficult to measure accurately using these data sets because the randomised controlled trial design will exclude many patients with this condition and it is therefore difficult to demonstrate cost effectiveness with confidence; comprehensive evaluation should include studies specifically designed to study this measure.

Debridement is central to the effective management of all chronic wounds. In venous ulcers, which are relatively superficial, this can be simply, quickly, and completely achieved by sharp debridement; a relatively low-tech intervention that is easily learnt. This said, clinicians who manage chronic wounds and do not have the necessary skills or access to equipment may be attracted to alternative, relatively untested, methods of debridement such as larval therapy.

The third linked study is a systematic review and meta-analysis of two forms of compression bandages (four layer bandage and short stretch bandage) in the treatment of venous leg ulcers. It concludes that the four layer bandage significantly reduced the time to healing (hazard ratio 1.31, 95% confidence interval 1.09 to 1.58). Short stretch bandages are useful in patients who are mobile and should be replaced daily. Although the four layer bandage system is effective, its bulkiness may lead to non-adherence in some patients. It is designed to be left in place for several days, so its use is limited in highly exuding ulcers because dressings may need to be changed more often. Therefore, although four layer bandages may improve healing overall, the choice of compression bandage should reflect the patient's specific needs and circumstances.

It may be unrealistic to use complete healing as the primary outcome measure in wound healing studies, and time to healing may be an equally valid outcome measure. Effective debridement may help patients, clinicians, and the health service by improving healing and avoiding ineffective treatment. Although further research is needed, to show the efficacy of debridement by any method, the immediate priority should be to educate health professionals how to manage leg ulceration.

Rather than using healing as the only measure of success, a common error that has been made in recent years, it would be more appropriate to adopt a broader based approach to the management of the challenging and complex problems inherent in the treatment of chronic wounds.

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At what age should cervical screening stop?

Negative tests are no reason to stop screening earlier

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Ever since the first organised cervical screening programmes started in Europe more than 40 years ago discussion about the upper age limit for effective screening has been ongoing. The debate is still relevant because mass vaccination of pre-adolescent girls against two or more types of human papillomavirus (HPV) will not affect the incidence of cancer in girls born around the turn of the millennium until 2050-60. In the linked study, Rebolj and colleagues report that the incidence of cervical cancer is similar in 218 847 women aged 45-54 years and 445 382 women aged 30-44 after their third negative smear.[1]

Evidence suggests that repeating smear tests in women aged 60-65 whose previous tests have been normal has little, if any, benefit,[2] and some researchers have proposed that the age limit should be lowered to 50.[3 4] In all European programmes, cervical cancer screening stops at a lower age than breast cancer screening, and in some programmes screening intervals between age 50 and 60 are prolonged.[5]

With reservations for biological variations, this strategy is based on the following reasoning. Women acquire oncogenic HPV infections in their 20s. Some women whose infections are not cleared develop high grade cervical lesions in their 30s, which can progress to cancer in their late 40s or 50s. But women who have had several normal smears at that age have good protection for the rest of their life. This biological model is largely consistent with epidemiological data.

The paper by Rebolj and colleagues does not refute the old concepts completely, but it does pose some questions.[1] The researchers confirm that women with three normal smears have a low absolute risk of developing cancer; however, they also show that this is independent of whether the woman is above or below 45. Moreover, they find an equally accelerated increase in incidence more than 10 years after the last normal smear—the protective effect of a history of repeated negative smears has a "best before date," even at 50 years of age.

Curves that show age specific incidences for cervical cancer in areas with established cervical screening programmes typically have two peaks. One is at around 40 years of age, and the other at around 75.[6] In Sweden, this second peak has decreased only modestly with time, although today all older women have received screening invitations during their earlier life. The incidence of cervical cancer in Sweden has fallen by 65-70% in the 45-60 age groups, when the period 1970-5 is compared with the most recent period (2003-7), but the decrease has been only 22-30% in women over 75.[7] Furthermore, most advanced cancers occur in women over 70, whereas invasive cancer in younger women is more often subclinical.[8]

Should screening programmes be extended beyond 60-65 years of age? As yet, we have insufficient evidence to support this idea. We still do not know what protection is offered to older women by screening with cytology. The finding by Rebolj and colleagues of fewer precursor lesions in the older age group, although screening intensity and cancer rates were similar, agrees with other studies. However, some studies show a good protective effect from normal smears in older age groups.[8]

It has been suggested that as women leave the screening programme they should be tested for HPV ("exit test"),[9] and that surveillance should be continued in women who are HPV positive only, but evidence to support such a strategy is scarce. We know little, not only about the efficacy of testing, but also about basic HPV biology in this age group. We must also remember that studies on screening effects in different age groups are retrospective and reflect sexual behaviour and HPV transmission many years ago. In 1995 the median accumulated number of sexual partners for a woman was three times as high as in 1967.[10] We have to pay close attention to developments in invasive cancer in age groups above the cut-off point for screening and be prepared to adjust the screening ages as we learn more.

With modern computer technology we could tailor screening invitations to the individual. Rebolj and colleagues and others have found that women with several normal smears are protected against cervical cancer. This finding, and the knowledge that women with previous precursor lesions are at high risk up to old age,[11 12] could

be used to individualise call-recall systems by extending or shortening intervals and setting the upper age limit. Such information could be incorporated into future algorithms that include results on HPV tests and documentation of HPV vaccination. Resources could then be allocated away from women who would not benefit from additional smears within a certain number of years to those who would and the question of whether to screen above the age of 60 could be answered—yes, for those who benefit the most from it.

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Improving relatives' consent to organ donation

Most factors involved in the process can be modified to increase success

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RESEARCH, p 1061

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Obtaining consent from families for organ donation is the most important element of a successful transplant programme. In a recent large study of donor and non-donor families, 57% of families were predisposed to donate, 17% were unsure, and 25% were not in favour.[1] The challenge is to secure consent from those people who are predisposed to donate, convert a substantial proportion of those who are unsure, and convert a smaller proportion of those who are initially not in favour. In the right circumstances this approach can achieve an 80% consent rate.

In the linked systematic review, Simpkin and colleagues identify modifiable factors that influence relatives' decisions to allow organ donation. They conclude that modifying the process of requesting consent may be the best way to increase organ donation rates in the United Kingdom.[2] In a review published in the *BMJ* earlier this year, Rithalia and colleagues assess the effect of presumed consent legislation on organ donation rates and review data on attitudes towards presumed consent. Although many European countries have opted for presumed consent legislation in an effort to increase organ donation, the review shows that this legislation alone is unlikely to explain the variation in organ donation rates between countries, and multiple factors are probably at play because countries do not always follow their legislation strictly.[3]

Most factors involved in the consent process and outcome are modifiable. We now know much more about why families donate and factors that can increase consent rates.[1 4] Best practices to increase organ donation have been accomplished through the recent US Department of Health Human Services Organ Donation Breakthrough Collaborative—organ donation increased by a cumulative 22.5% from October 2003 to October 2006.[5-7]

In the United States the organ procurement organisation (OPO) is responsible for obtaining consent. Research has unequivocally shown that OPO staff are the best people to discuss organ donation with families.[1 4] In a large multivariate study of donor and non-donor families, one of the covariates most strongly associated with consent for donation was the time the family spent with OPO staff.[1 4] OPO staff can spend the time needed with the family and proceed at the family's pace.[8 9]

Requesting consent for donation is not simply "popping the question." It is a dynamic process consisting of observation, collaboration, planning, and action that is based on family and hospital dynamics. OPO requesters should approach the family a second time if they are initially disinterested or decide not to donate, particularly if the first request was made by healthcare providers. Reapproach should also be considered when the initial approach was made by the OPO because families often alter their original position and consent to donate.[1 4]

Data that are shared routinely and openly between the OPO and the hospital leadership should be driven by the end result—how many families in a position to donate organs actually do so?

OPO staff are more knowledgeable about donation than hospital staff; this is important because families who are given more information about the donation process are more likely to donate.[1 4] One approach is for healthcare professionals to limit their role to ensuring that OPO staff are called early in the process and to working under the direction of OPO staff to optimise the request for donation.[1]

Early and timely referral of potential donors to the OPO is essential—this allows the OPO to assess the donation request and prevents a rushed request for consent from families.[10] Notifying the OPO shortly before or at the time the patient is being considered for brain death testing is too late.[1 4 10] In the US, OPOs are usually notified within 30 minutes to one hour of a patient reaching a "clinical trigger" for referral, such as a score on the Glasgow coma scale of 4 or 5 or a plan to withdraw ventilator support. "Rapid early referral and linkage" of

the family to the OPO was a key strategy for success in the Organ Donation Breakthrough Collaborative. The subsequent team "huddle" allows OPO staff and healthcare providers to discuss the situation and the role each team member will play in the consent approach (see box bmj.com).

Having an OPO employee acting as an in-house coordinator in a single hospital makes it easier to integrate many of the modifiable factors listed in the box.[11] The main finding of a large study of nine level 1 trauma centres was that having such a coordinator increased the conversion of potential organ donors to actual organ donors.[9]

Successful requesters act as advocates for people on the organ transplant waiting list, and they clearly convey the benefits of donation for those on the list to potential donor families. They are presumptive, not neutral. A presumptive approach is one in which the requester approaches the family with the assumption—the presumption—that they are going to donate and that the requester is there only to help them with the process of donation. Instead of giving the family an option to donate, the requester gives them the opportunity to donate, with the presumption that donation is a good thing, and that if given the chance to save a life most people will do so. Presumptivity, also known as dual advocacy, represents a subtle shift in the thought process—it puts the opportunity to donate in a positive light rather than being something the family is being forced to consider.[12] Presumptive consent is perhaps the embodiment of the nuanced and varied presumed consent "practices" in Europe that Rithalia et al discuss in their review.[3]

Finally, nothing takes place in a vacuum. OPOs and hospitals should be jointly accountable and equally committed to obtaining high rates of consent to donation. The donation request is too important to delegate to those who are not expert, prepared, and focused on a successful outcome. A commitment to setting goals and measuring outcomes as well as the establishment of processes based on known best practices will produce results.

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The 2009 budget and the NHS

Doctors need to be fully engaged in saving money and improving outcomes

NEWS, p 1032

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Reassurances by ministers about the implications of the 2009 budget for NHS spending should not mask the reality that funding will become much tighter. The first effects will be felt in 2010-1, when the NHS will need to contribute £2.3bn (€2.6bn; $3.4bn) of the £5bn of public sector efficiency savings being sought that year. Thereafter, the likelihood is of real and substantial cuts as the government takes steps to deal with the effects of the recession and the banking crisis, a prospect that is much worse than seemed likely even in the autumn.[1]

An analysis by the Institute for Fiscal Studies indicates that a plausible scenario is real reductions in spending in all government departments except for international development, perhaps of about 2%.[2] These cuts will last at least until 2014, and they could extend over a longer period, depending on the accuracy of the chancellor's assumptions on economic growth. The 2009 budget therefore signals the beginning of a sustained period of disinvestment in the NHS, a mirror image of Tony Blair's commitment in 2000 to increase healthcare spending to bring it in line with the European Union average.

In anticipation of tough times ahead, the Treasury has undertaken reviews of operational efficiency in the public sector and the scope for increasing value for money. The results of the work on operational efficiency were published the day before the budget and identified potential savings of £9bn a year by 2014.[3] These savings relate to a range of measures, including better procurement of goods and services, the sharing of back office functions, improved use of information technology, and more effective use of property.

Even more important are the opportunities identified in the value for money programme. These opportunities include controls over the prices paid to hospitals under the payment by results tariff, and the scope for primary care trusts to improve performance. An example would be reducing demand for expensive hospital services by offering alternatives in the community.

In view of the high proportion of the NHS budget spent on staff, spending constraints will lead to tighter

workforce controls. This will affect the number of people employed and pay. It will also make it harder for newly qualified staff to find jobs. Workforce controls could bring the government into conflict with the trades unions, although the problems in the wider economy may serve to moderate the willingness of the unions to take radical action in support of their demands.

Two considerations should be paramount as NHS organisations decide how to cope with the more challenging financial prospects. The first is the need to focus on variations in medical practice as the most promising source of efficiency improvements. As many studies have shown, hospitals and primary care practices vary greatly in all aspects of performance. A renewed focus of attention should be on reducing these differences by cutting average lengths of stay, increasing generic prescribing, and developing alternatives to hospital treatment. Analysis by the NHS Institute for Innovation and Improvement has identified opportunities to release more than £3bn in this way (personal communication, M Jennings, 2009).

Service line reporting in NHS foundation trusts, under which doctors and managers run specialties as if they were business units, seems to be a promising way of reducing variations and eliminating waste in hospitals.[4] Service line reporting depends crucially on developing accurate and timely information about the performance of services and strengthening medical leadership.

Primary care presents a greater challenge because practice based commissioning has not achieved the level of genuine engagement among general practitioners and others that is needed.[5] Primary care trusts also have a long way to go before they can commission health care to world class standards, as the government's assessment shows. Weaknesses in commissioning are the biggest threat to efforts to improve NHS performance. Time is running short for these problems to be dealt with.

The second consideration is that efficiency should not be pursued at the expense of quality. Too often in the past the NHS has responded to straitened financial circumstances by acting quickly and often crudely to rein back expenditure without weighing the effect on patients' experiences and clinical outcomes. All the more reason therefore to ensure that clinicians play a leading part in the urgent work that now needs to be done to improve performance, and that the quality agenda set out in Lord Darzi's review is accelerated.[6]

It is worth remembering that good quality care need not cost more. Research from the United States shows that at a population level high spending states have outcomes that are no better and sometimes worse than those of low spending states.[7] And in the case of clinical care, doing things right the first time is both less costly and better for patients than care that results in readmissions and complications. Policy makers have made a modest start in linking the payment of hospitals to their results, not just the activity they undertake, but this work needs to be scaled up rapidly.

The bottom line is that far from being reassured by the budget, NHS organisations should be scared by the prospect of an era of austerity unlike anything experienced in recent history. Having overcome their fright, they should act decisively to engage doctors in the quest for changes that both save money and improve outcomes. The NHS organisations that inherit the future will be those that focus their attention on the people who are responsible for spending most of the resources provided for health care and that support them to make the necessary changes at the front line of care.

For their part, politicians should avoid the temptation to exploit the current crisis to argue that publicly funded systems like the NHS need to be reformed through a bigger role for private funding and provision. The private sector does have an important part to play alongside the NHS, but it would be folly to believe that in this direction salvation lies. The risks of magical thinking are especially acute during times of bereavement,[8] and the strengths of the current model need to be preserved while the NHS comes to terms with the loss of resources that will surely flow from the 2009 budget.

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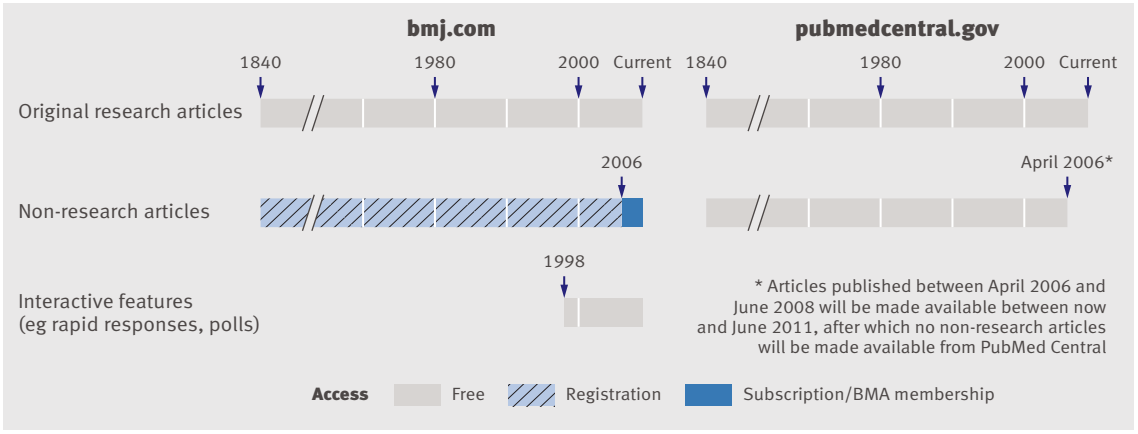
The journey began in 2000, when the *BMJ* announced it would be the first general medical journal to sign up with PubMed Central.[1] This project, to create a free digital archive of biomedical and life sciences journal literature, was masterminded by the US National Center for Biotechnology Information under the aegis of the NLM.[2] Three years later, the NLM offered to digitise the archival content of publishers participating in PubMed Central to create complete digital archives of their journals. In return for permanent rights to archive and distribute the material freely through PubMed Central, the library offered to fund the cost of cover to cover scanning back



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to a journal's first issue.[3] The *BMJ* leapt at the prospect—which included the back issue digitisation of 18 of the BMJ Group's specialist journals (among them *Heart*, *Gut*, and *Thorax*).

The next phase of the project was to round up complete runs of the group's journals. This was by far the most difficult for the *BMJ*, which started life as the *Provincial Medical and Surgical Journal* and didn't settle on its current title until 1857.[4] Much of the archive came to the NLM from the Medical Center Library in New York, which closed in 2003. We are particularly indebted to the Health Sciences Libraries of the University of Michigan, which gave up their rare early copies for digitisation.

The problems of sourcing early journals paled into insignificance when compared with the problems of scanning the articles from thin friable paper. Such paper allowed substantial "bleed through" during scanning, if it hadn't already bunched up or torn. As a result, many pages had to be scanned manually rather than by a high speed scanner. Another headache was the hyperactive renaming and reordering of journal sections—a constant feature of the journal's 169 years of innovation.

Each issue was scanned cover to cover, and PDF files of the original pages were created for every article. In addition, separate high resolution images were prepared for all illustrations.

Optical character recognition was used to create XML files for each article, which allows full text searching. Early into the project, progress was slower and costs were higher than had been envisaged. At this point, the Wellcome Trust and the Joint Information Systems Committee—both fervent supporters of freeing up access to the results of scientific research—split the bill with the US taxpayer, who had until then been picking up the tab.

In November 2008, the last *BMJ* was loaded on to PubMed Central, which means that the archive is available from there too. Last month the archive was loaded on to bmj.com; the archival material is integrated fully within bmj.com and shares the same functionality as more recently added content. Articles from the archive can be searched for, just like any other article, and old issues of the journal can be browsed from the journal's print issue archive. The BMJ Group and our online host, HighWire Press, shared the costs of this phase of the operation.

When we began our association with PubMed Central, all *BMJ* content was accessible from PubMed Central's website on the day of publication, without charge (matching the access conditions on bmj.com). From January 2006, the *BMJ* stopped providing free online access to its non-research articles (editorials, news, features, letters, analysis, education, shortcuts, reviews, obituaries, Minerva). However, research articles remain free to access from the day of publication at bmj.com and PubMed Central. This means that the *BMJ* meets the requirements of the growing number of funding agencies that mandate free access to reports of the research they fund. On PubMed Central, all non-research articles from 1840 until April 2006 are available free, without registration. On bmj.com, all non-research articles published during this time period are available free but require registration (see figure).

However it is accessed, the entire *BMJ* archive opens up a wealth of possibilities. On the basis of a single search, researchers will now be able to locate any article ever published in the *BMJ*. Although this will solve a frequently expressed frustration with bmj.com, we believe that the availability of the entire archive offers something qualitatively different to just a full set of articles. In fact, we are so convinced of this that we are offering a prize of £1000 for the most interesting use of the archive (see the journal for further details of this competition).

For an introduction to the archive, watch a series of specially commissioned videos, featuring the former head of Britain's Medical Research Council, Colin Blakemore, that focus on some of the important subjects and people that have appeared in the journal's pages.[5] And over the next year, keep an eye out for extracts from some of our key articles, which will be headlined, "From our archive." Meet John Snow, David Livingstone, Joseph Lister, Arthur Conan Doyle, Florence Nightingale, William Osler, Richard Doll, Alice Stewart, Amartya Sen, and Joseph Stiglitz—if you missed them the first time around.

Watch the video bmj.com/video

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4 Bartrip PWJ. *Mirror of medicine: a history of the BMJ.* Oxford: Oxford University Press, 1990.
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