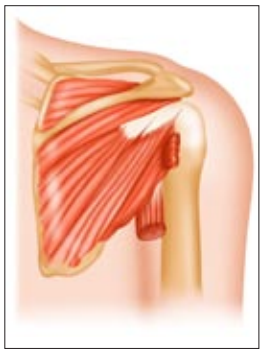
Corticosteroid injection for rotator cuff disease

Systemic injection of corticosteroid is as effective as local injection



WELLCOME IMAGES

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In the linked randomised controlled trial, Ekeberg and colleagues compare the effectiveness of ultrasound guided corticosteroid injection in the subacromial bursa with systemic corticosteroid injection in people with rotator cuff disease.[1] They found no significant difference in pain and disability between the two groups after six weeks. This suggests that the exact location of corticosteroid injections is not important.

The diagnosis of patients with shoulder pain can be difficult.[2] This is illustrated by Ekeberg and colleagues' study, in which general practitioners referred patients with suspected rotator cuff disease to an outpatient clinic, and those with confirmed disease were entered into the study. They referred 312 patients, but 140 were subsequently excluded because they had other diagnoses.[1] Rotator cuff disease is diagnosed in up to 70% of people with shoulder pain.[3]

The optimal management of shoulder pain is still debated. One of the available treatments is injection with a corticosteroid. The evidence for the efficacy of steroid injections for shoulder pain is inconclusive. A systematic review found little evidence to guide treatment because of the small sample sizes, variable methodological quality, and heterogeneity.[4] Subsequent systematic reviews have been similarly inconclusive.[5,6] Overall, the evidence indicates that subacromial corticosteroid injections are more effective than placebo injections for the short term relief of rotator cuff disease, but are no better than non-steroidal anti-inflammatory drugs.[4,7] The long term efficacy of steroid injections is not well investigated, but the evidence indicates that they have no clear benefits in the long term. The efficacy of steroid injection compared with active physiotherapy (which is often used) is also not yet established. Direct comparisons of both strategies have produced conflicting results and further high quality studies are needed.[7]

Guidelines on managing shoulder pain in primary care recommend a wait and see approach in the first instance that consists of educating patients, awaiting the natural course of the disease, and prescribing analgesics if needed. Steroid injections are reserved for patients with shoulder pain that does not respond to this approach.[8]

The next question is whether the location of the corticosteroid injection influences the outcome. People who believe in the importance of local infiltration have developed methods (fluoroscopy, ultrasound) to ensure correct placement of the needle and delivery of the drug. Others rely more on the systemic effect of corticosteroids and are less focused on the exact location of the injection.

The study by Ekeberg and colleagues randomised 106 patients with rotator cuff disease lasting for at least three months to receive a local or systemic injection of corticosteroids. People in the local injection group had an ultrasound guided corticosteroid and lidocaine injection in the subacromial bursa plus a lidocaine injection in the gluteal region. Those in the systemic injection group had a corticosteroid and lidocaine injection in the gluteal region and an ultrasound guided lidocaine injection in the subacromial bursa. The primary outcome of score on the shoulder pain and disability index after six weeks did not differ significantly between the two groups. The results of two secondary outcomes (score on the western Ontario rotator cuff index and change in main complaint) significantly favoured the local injection, but the size of these differences was relatively small and the statistical difference may have been the result of multiple testing.

Ekeberg and colleagues' study was not designed to answer the question of whether corticosteroid injections should be used in rotator cuff disease.[1] The improvement in both study groups, though modest, could be explained by the natural course of the disease, placebo effects associated with the injection procedure, or the effect of the lidocaine injected in the subacromial bursa.

Future studies need to compare the effectiveness of different types of corticosteroid injection with other common interventions. Studies should look at the effects of the localisation of the needle, frequency of injections, drug dosages, and timing of the injections together with the influence of comedication. For the time being, however, the evidence indicates that local (even sonographically guided) and systemic corticosteroid injections have similar outcomes in patients with rotator cuff disease.

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Preventing and treating postnatal depression

Comprehensive screening programmes and better organisation of care are key

A/ PHOTO/SPL

RESEARCH, p 276, p 280

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Jane Morrell, lead author of the linked research paper, talks about its findings in a *BMJ* podcast at http://podcasts.bmj.com/bmj/

Two linked studies assess different approaches for preventing and treating postnatal depression.[1 2] This condition is a common form of maternal morbidity that affects about one in eight women from diverse cultures.[3] It is also a leading cause of maternal mortality. The UK Confidential Enquiry into maternal deaths found that psychiatric disorders contributed to 12% of all maternal deaths, with suicide being identified as the leading cause of maternal mortality in the United Kingdom.[4] Postnatal depression can also have serious consequences for the health and wellbeing of the family. Infants and children are particularly vulnerable—impaired maternal-infant interactions can affect their cognitive, emotional, social, and behavioural development. Clearly, postnatal depression is a substantial public health problem that requires attention.

Given the diversity in causes and severity of symptoms, researchers have evaluated various treatments. Although antidepressants are effective many women are reluctant to take medication, especially when breast feeding. A recent systematic review indicates that psychosocial and psychological interventions may provide an alternative to pharmacological treatment.[5] In the linked randomised controlled trial, Morrell and colleagues assessed the importance of these non-pharmacological interventions. They found that cognitive behavioural therapy and non-directive counselling provided in the home by health visitors were effective in treating depressive symptoms at six and 12 months postpartum. This methodologically robust trial provides good evidence that health visitors can be trained to identify women with depression and offer effective treatment.

The evaluation of preventive interventions has been another high priority. The second linked study is our multisite randomised controlled trial that evaluated the effectiveness of telephone based peer (mother to mother) support to prevent postnatal depression in high risk women. After web based screening of more than 21 000 women by public health nurses in the first two weeks after birth, 701 eligible mothers participated in the trial. Women who received the peer support intervention had half the risk of developing postnatal depression at 12 weeks post partum than those in the control group (13.5% *v* 24.8%; relative risk reduction 0.46, 95% confidence interval 0.24 to 0.62; number needed to treat 8.8, 5.9 to 19.6). The results are consistent with a large systematic review, which found that interventions to prevent postnatal depression are more likely to succeed if they are individually based, initiated postnatally, and targeted at high risk women.[6]

These trials add to the growing evidence that postnatal depression can be effectively treated and possibly prevented. Despite this research, postnatal depression is still undetected or untreated in many women. Why is this?

Firstly, there are substantial barriers to identifying and treating postnatal depression.[7] Women often lack knowledge about postnatal depression, with many denying or minimising their symptoms. Some women assume that the struggles they are experiencing are common in new mothers and are a reasonable response to adversity. Conversely, some women do recognise their depressive symptoms but are unaware of treatment options. Other women are unwilling to disclose emotional difficulties, especially depression, because of fear about being labelled mentally ill, having their children taken away, or being perceived as not fulfilling their maternal role. A systematic review found that health professionals can be barriers to care if they minimise symptoms or offer treatment that is not convenient, accessible, or timely.[7] The results suggest that women and family members should be educated about postnatal depression, not only to destigmatise the condition, but also to help them identify it in themselves and seek assistance. Treatment also needs to be provided in a way that fits in with a new mother's lifestyle. Home based and proactive telephone based programmes are convenient and accessible for new mothers. To improve adherence to treatment, it is important to ask women why they feel depressed and to match treatment with perceived cause.

Secondly, although new mothers typically encounter a variety of health professionals—midwives, doctors, nurses, and health visitors—all of whom are capable of screening for postnatal depression, coordinated multidisciplinary efforts rarely occur. Screening programmes for postnatal depression have not been widely implemented, even though they meet many of the necessary criteria for implementation, such as there being a good understanding of the condition, a validated screening test with appropriate cut-off values, and the availability of effective treatment for those who screen positive.[8] All health professionals who interact with new mothers should proactively screen for postnatal depression. To enhance the accuracy of identification, health professionals need to understand the traditional postpartum rituals and practices seen in diverse cultures[9] and the different cultural perceptions of depression.

Finally, the effective delivery of high quality clinical care requires a specialist multidisciplinary perinatal service provided by primary, secondary, and tertiary care.[10] This perinatal service can be established in each locality to provide direct services, consultation, and advice to maternity, mental health, and community services. Clear referral and management protocols for services across all levels of a stepped care framework for depression[11] are needed

to ensure effective transfer of information and continuity of care.[10] Care pathways with defined roles and competencies for all professional groups are also required. A systematic review found that care pathways can improve the effectiveness of treatment for depression compared with usual care for people with mild to moderate depression for up to 12 months.[12] These care pathways included interdisciplinary collaboration, intensive patient education, case management, and telephone support. Only by overcoming the barriers to treatment, providing comprehensive screening programmes, and ensuring the delivery of appropriate and timely care will we effectively prevent and treat postnatal depression.

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Rationing new medicines in the UK

A fair and consistent process is needed for dealing with absence of evidence

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In England and Wales the National Institute for Health and Clinical Excellence (NICE) issues guidance on the appropriate use of medicines that is based on an assessment of evidence submitted by the manufacturer. The scope of the assessment depends on whether the appraisal concerned is a single technology appraisal or a multiple technology appraisal (box). NICE recently terminated four single technology appraisals of cancer drugs because it did not receive submissions from drug companies that met the institute's specification of evidence.[1] As a result, NICE was unable to recommend the use of the products for the clinical indications for which they were licensed, but it stated that, after considering the reasons for the lack of guidance, NHS organisations could still use the drugs. In contrast, the Scottish Medicines Consortium approves medicines only if drug companies submit evidence, so non-submission results in a recommendation not to use the drugs concerned in the Scottish NHS.[2]

This situation is one consequence of NICE's switch to undertaking more single technology appraisals, the main advantage of which is a shorter time between the drug's marketing approval and a preliminary decision. However, in shortening the time allowed for the appraisal, NICE is largely reliant on information provided by the manufacturer, whereas under the original (multiple) technology appraisal process, the independent review group contracted by NICE also undertook an analysis.

One concern is that, in the future, companies could terminate an appraisal by failing to submit data if they thought the chance of a positive NICE recommendation was small. Clinicians or patient organisations could then bring pressure to bear on local decision makers, whereas this would not be possible after a negative NICE appraisal. In most jurisdictions that use an evidence based approach to drug use, this situation cannot arise because a formal application must be made by the manufacturer for inclusion on the national formulary or "positive list."[3] In the United Kingdom, however, most licensed drugs are automatically available for prescribing on the NHS, unless guidance from NICE, the Scottish Medicines Consortium, or the All Wales Medicines Strategy Group limits their use. If terminated appraisals effectively delegate decisions to the local level, this could exacerbate the "postcode lottery" that NICE was created to tackle.[4]

So what could be done? Moving towards a comprehensive approach for evaluating the clinical effectiveness and cost effectiveness of all new drugs, linked to listing for reimbursement, raises a wide range of questions, not least that of whether NICE could cope with the workload. Certainly, without substantial extra resources it would have to simplify its procedures greatly. In particular, it would need to limit stakeholder involvement and perhaps be less rigorous with its reviews, thereby increasing its reliance on manufacturers' submissions.

Single technology appraisal
One drug or technology for a single indication where assessment is based on submission of data from the manufacturer alone.

Multiple technology appraisal
More than one drug or technology where data submitted from the manufacturer are supplemented by independent analysis by NICE

Alternatively, NICE could follow the approach used by the Scottish Medicines Consortium and, in the absence of a submission, rule that the drug is not recommended for use. This approach would remove the incentive not to submit. However, this equates absence of evidence with evidence of absence (of clinical effectiveness and cost effectiveness), and it may deny patients access to drugs that might be cost effective. A third option would be for NICE to negotiate a "coverage with evidence" agreement with the manufacturer. Under this scenario, the drug would be available for use in NHS patients, but access would be conditional on a commitment by the manufacturer to provide evidence on outcomes and costs at a set date in the future when the NICE decision would be reviewed. This approach may be useful if non-submission reflects an absence of evidence for the relevant patient group (for example, the terminated appraisals on carmustine implants for recurrent glioma (TA149) and cetuximab for colorectal cancer (TA150)). However, it would be of little use if the drug company chose not to submit because the limited available evidence indicates that the drug is unlikely to be cost effective when assessed against NICE's cost per quality adjusted life year threshold (for example, bevacizumab for breast cancer (TA147)). In such situations a coverage with evidence approach could provide a perverse incentive for companies to claim that no data exist, to increase the chances of market access for their product.

A fourth possibility, arguably more in keeping with NICE's ethos, would be to commit to convert a single technology appraisal to a multiple technology appraisal if and when it becomes clear that the manufacturer is not intending to make a submission in accordance with the institute's specification. This might lengthen the appraisal process and may be unsatisfactory if the manufacturer fails to give access to unpublished data. However, it is more likely to encourage submissions from manufacturers wherever possible, because the incentive to the manufacturer would be to ensure that its point of view was adequately reflected in the appraisal.

None of these strategies is without its drawbacks. Nevertheless, simply terminating appraisals runs the risk that the NHS in England and Wales will have to make difficult decisions in the context of an absence of evidence. The fourth option, of converting single technology appraisals to multiple technology appraisals when the manufacturer fails to make a submission, would be the best way forward.

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The NHS carbon reduction strategy

The battle plan is written, but will the NHS go to war with its emissions?

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Climate change kills at least 150 000 people each year, and the suffering it causes will increase as we continue to pollute the atmosphere.[1] The effects of climate change on health will continue to be concentrated in the poorest parts of the world and will mainly affect children.[2] The NHS is responsible for 25% of England's public sector emissions—more than 18 million tonnes of carbon dioxide a year. The NHS carbon reduction strategy for England, "Saving Carbon, Improving Health," was published this week; it sets out how the NHS aims to lead the way to a low carbon world.[3]

The strategy builds on a strong evidence base—the groundbreaking NHS carbon footprinting exercise published in 2008.[4] However, the strategy quickly runs into its first obstacle. The largest part (60%) of the NHS carbon footprint is from procurement—the manufacture and transport of goods and services purchased by the NHS from other organisations. Pharmaceuticals contribute most to procurement emissions, being responsible for four million tonnes of carbon dioxide a year. The strategy is weak in this area, saying that "research will be undertaken into the carbon footprint of pharmaceuticals within the NHS to better understand this and to inform actions to produce significant reductions." This sounds like a dodge.

The NHS could reduce drug related carbon emissions either by reducing the carbon intensity of drug production or by reducing drug use. The NHS already pays a high price for drugs—much of the basic research that underpins drug development is funded by the public, which enables the drug industry to cream off the profitable part.[5 6] Because the global atmosphere also bears some of the costs, the real cost of drugs is even higher than the monetary cost. The NHS can and should use its purchasing power to press the drug industry to decarbonise.

The Department of Health should also give the prevention of disease the priority that it deserves but currently lacks. For example, the United Kingdom is predicted to be a predominantly obese society by 2050.[7] If we want to avoid a situation where more than half of the population is taking carbon intensive drugs to suppress their appetite or to prevent their bodies from absorbing fat, then we will need to do much better than Change4Life, the new "lifestyle revolution" recently launched by the Department of Health to stem rising obesity.[8]

The government would have us believe that obesity is a personal failing by weak willed people who make the wrong selections from a wealth of lifestyle and diet choices. However, a decade of research into obesity shows that fatness is an environmental problem not a personal foible.[9] People in the UK are getting fatter firstly because they are surrounded by low priced, heavily marketed, energy dense food, and secondly because fossil fuel powered transport means they move their bodies less than ever before. Serious government action to stem the oversupply of food and encourage sustainable transport (walking and cycling) would reduce the carbon footprint of the NHS and the whole of British society as well.

The strategy points out that the NHS is one of the largest purchasers of food in the UK, and that in future patients, visitors, and staff can look forward to healthy low carbon menus with much less meat, dairy produce, and eggs. Evidence shows that as far as the climate it concerned, meat is heat.[10] Providing land for cattle grazing results in deforestation, and the methane released from animal manure and enteric fermentation is a powerful greenhouse gas. Eating less meat would also have health benefits, such as reducing the risk of colon cancer.[10]

The strategy says that all trusts should have approved plans for tackling NHS related travel. The strategy recommends a flat reimbursement rate for NHS business mileage, regardless of the mode of transport (car, cycle, or foot), and it urges that travel related NHS emissions are monitored. The strategy also asserts that greater efforts should be made to reduce NHS related travel, and that the delivery of health care will move closer to home. There are also important key actions on reducing water consumption and avoiding waste.

The enthusiasm of everyone in the NHS workforce will be enlisted to deliver the strategy through an ambitious low carbon workforce development programme. All NHS organisations "should" sign up to the NHS good corporate citizen assessment model, should produce a sustainable development management plan, and should embed carbon reduction in their financial mechanisms. The lack of any "musts" is concerning. The strategy is garnished with a rousing quotation from Prime Minister Gordon Brown about our "historic and world changing" mission to build a low carbon economy, a quotation worthy of any wartime Churchill. As a battle plan, the NHS carbon reduction strategy is an excellent start, and the NHS Sustainable Development Unit must be congratulated for its leadership. But only time will tell whether the NHS will actually go to war with its emissions and win.

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The manufacture and transport of pharmaceuticals to the NHS produces four million tonnes of carbon dioxide a year

MARIJAN MURAT/EPA/CORBIS

A constitution for the NHS

A helpful summary, but what next?

NEWS, p 255

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Today's NHS is shaped by a mass of laws and regulations that are old, new, and often obscure. Until now, no one has clarified in one document what the NHS is now, what it offers, and the level of service it aspires to.

The NHS constitution, published on 21 January, does just that. It is a "declaratory document" that sets out the rights and responsibilities of patients, staff, and groups providing NHS funded services in a 12 page constitution and accompanying 140 page handbook.[1] The constitution was developed as part of the NHS next stage review led by Lord Darzi,[2] and it has been drawn up after extensive consultation. It applies to people entitled to receive NHS care in England and to staff providing NHS funded services in England.

For patients it sets out 25 rights, which are legally binding, plus pledges and responsibilities, which are not. For example, patients have the right to receive NHS services free of charge (apart from limited exceptions sanctioned by parliament); to access their personal health records; and in certain circumstances, to go to other European Economic Area countries or Switzerland for treatment that would be funded in full or in part by the local primary care trust commissioner. The pledges, which the NHS "is committed to achieve," include providing easily accessible treatment; sharing with patients any letters sent between clinicians about their care; and involving patients in decisions about their own care. Patients' responsibilities include keeping appointments if they want to "receive treatment within the maximum waiting time"; following the course of treatment agreed with clinicians; and participating in important public health programmes such as vaccination.

Staff and groups providing NHS funded care also have legal duties and expectations. The rights are distilled from employment law, which constantly changes. The pledges may be familiar from job plans—to provide all staff with clear roles and responsibilities, personal development and training; and to engage staff in decisions that affect them. There is a list of legal duties, many of which are the regulations of professional regulatory bodies, such as not to discriminate against patients or staff, to adhere to legislation on equal opportunities and human rights, and to be honest and truthful in applying for a job and in carrying out that job. Expectations include maintaining the highest standards of care; sustainably improving services by working in partnership with patients, the public, and communities; and trying to view the services provided from the standpoint of the patient.

If the constitution is a summary of existing laws, regulations, and aspirations, is it helpful? For the first time, this constitution provides a clear explanation of patients' rights and the basis for any redress. Some people fear it might become a lawyers' charter. Time will tell, but the constitution is equally clear on what is not a legal right.

For staff it may be useful on at least two counts. Firstly, the clarity about pledges and expectations on staff providing services could be a good basis to set consistent objectives for local services, teams, and individuals in job plans. Secondly, the overarching vision that the rights, duties, expectations, and pledges paint may help bind managers and clinicians in a more explicit and joint picture of what is expected at work. The expectations in particular could mean quite radical changes in how some clinicians go about their work.

But perhaps the most interesting question about the NHS constitution is why, and why now? The initial rationale for developing it according to the NHS next stage review was "to secure the NHS for the future," "empower patients and the public," and "empower and value staff" (in that order).[2] Given the emphasis on reorientating the NHS towards considering users first, and the increase in the use of non-NHS providers of care and autonomous foundation trusts (more than half of all trusts at present), it makes sense to clarify the rights, pledges, and expectations of NHS funded services.

Some wryly suggest that the constitution is an attempt to "Tory proof" the NHS—meaning that by making the level and type of service offered by the NHS more explicit, any future attempt to reduce that offer by a Conservative government (or an NHS board if that element of Conservative policy is implemented) will be made more difficult. But arguably the biggest threat to the NHS offer in the immediate future will come from the likely financial squeeze as a result of the current economic problems. The constitution by itself does not offer much protection from rationing or cuts.

Where next? The new legal duties expected to come into force this autumn require organisations providing NHS funded care to "take account of" the NHS constitution in "performing their NHS functions." What that means is opaque. Whether this will have any effect on the ground depends on how seriously the non-legally binding parts of the constitution are taken by these organisations, or indeed by external institutional regulators (such as the Care Quality Commission and Monitor) or professional regulatory bodies. Or perhaps, as Albert Einstein noted about the US constitution, "The strength of the constitution lies entirely in the determination of each citizen to defend it."

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