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EDITORIALS

Functional status and long term outcome of stroke

Despite undoubted progress, we still have much to do

DAVID M GROSSMAN PHOTOTAKE INC / ALAMY

RESEARCH, p 376

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Despite advances in prevention, acute care, and rehabilitation the prognosis after acute stroke remains poor: 20-30% of patients die within a month and 13% of survivors are discharged to institutional care.[1 2] In the accompanying prospective cohort study, Bruin Slot and colleagues report that functional status at six months after stroke is associated with long term survival.[3] The median survival of patients who were independent at this stage was 9.7 years compared with 6.0 years for those who were dependent. The effect of functional outcome at six months on mortality was independent of age and stroke subtype. The study gives no details about the causes of death or whether secondary prevention was optimised, but these survival data again emphasise the impact of stroke. They also suggest that early treatment known to reduce dependency at six months may have a substantial longer term effect.

Stroke care and the evidence base on which services are developed have improved considerably since 1981, when one of the cohorts described in the study (the Oxfordshire community stroke project) was established.[4] In the past, people with stroke were too often discharged without consideration for their ongoing needs and carer support.

Most acute trusts in the United Kingdom now have a stroke unit and in the United States the Brain Attack Coalition recommended similar primary stroke centres in 2000; at that time only 7% of hospitals surveyed met all recommended elements, although 44% provided most services. Furthermore, many shortcomings still need to be resolved. The UK 2006 national sentinel stroke audit found that although all eligible patients with ischaemic stroke received antiplatelet drugs, only 70% received blood pressure lowering drugs, only 78% received cholesterol lowering drugs, and only 34% of patients in atrial fibrillation were anticoagulated at discharge. Thus, secondary prevention could be improved and mortality and morbidity after stroke could be reduced if these highly effective treatments were more widely implemented.[2] These problems in implementation of the evidence base are not unique to the UK.

Stroke units improve independence and survival at six months, but in 2006 only 62% of patients in the UK were admitted to a stroke unit and only 54% spent more than half of their inpatient stay on one.[2] Thrombolysis given within the first three hours of ischaemic stroke reduces death and disability at three to six months,[5] yet only 30 trusts in the UK provide this service, and even fewer provide it at all hours of the day.[2] Up to 20% of stroke patients may be eligible for thrombolytic treatment, yet in 2006 only 218 patients—less than 0.5% of patients with acute ischaemic stroke in England, Wales, and Northern Ireland—received thrombolysis.[2] In a large study in the US the equivalent rate was 1.12%. Early supported discharge by a specialist stroke team can also improve outcome, yet provision of this service is limited.[6] All of this emphasises the problem of translating research into practice, which was highlighted by the recent Cooksey report.[7]

Service development and research have focused on prevention and care soon after stroke. Relatively few studies, however, have looked at interventions for improving longer term outcomes for survivors of stroke and their carers.[8] Service provision focusing on long term needs is also sparse. Patients with stroke and their carers often report feeling abandoned after discharge and that they are badly informed and supported, both practically and emotionally.[1 9]

Even less is known about how to minimise the long term effects of stroke. The 2001 national service framework for older people suggested that patients with stroke and severe disability should be reviewed at six months.[10] One of the purposes of the review would be to deal with patients' and carers' concerns. Bruin Slot and colleagues suggest that prognostic information could be given to patients and their relatives at six months.[3] Arguably, before providing more information about risks and prognosis at six months, much could be done to improve communication soon after a stroke. The information needs and priorities of patients and their carers change over time, and it is important for the right information to be provided in the right way, at the right time, and in the right format.[11 12]

It is increasingly acknowledged that patients and carers should be active participants in decisions about the care they receive. Enabling patients and carers to have meaningful input into service development and to be actively involved with clinicians about deciding treatment options will result in care that is responsive to their needs and likely to lead to better outcomes.

The national stroke strategy, published by the UK Department of Health in early December 2007, once again emphasises the importance of implementing evidence based practice as well as involving patients, carers, health professionals, social services, and charities in shaping local stroke services.[1] Let us hope that these admirable aims will become the template for both commissioners and providers of care to seize the opportunity to enhance the health and wellbeing of a substantial and, to date, underserved group of patients.

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Self management training in refractory angina

May improve health related quality of life and cut treatment costs

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Refractory angina pectoris is a major clinical problem characterised by unremitting symptoms of angina (equivalent to severity score class III-IV on the Canadian Cardiovascular Society classification), which are resistant to conventional treatments including nitrates, calcium channel and β adrenoceptor blockade, percutaneous coronary interventions, and coronary artery bypass grafting.[1] Although there are limitations in current surveillance systems worldwide, estimates from data on revascularisation and hospital admission suggest a prevalence of refractory angina somewhere between 600 000 and 1.8 million in the United States and an incidence of 30-50 000/year in continental Europe.[1 2]

Patients with refractory angina experience persistent anginal pain, poor general health status, psychological distress, restriction of activity, and inability to self manage their symptoms—all of which have a negative effect on health related quality of life.[1 2]

Self management training that includes cognitive behaviour techniques is showing promise in angina.[3 4] Indeed, it could be a welcome standard addition to the current technically based effective interventions aimed solely at reducing ischaemia.[1 2]

Among the most feasible, well established, and widely used therapeutic options at present are neuromodulation techniques such as transcutaneous electrical nerve stimulation and spinal cord stimulation.[1 2] These techniques can relieve anginal pain secondary to reducing ischaemia. Their anti-ischaemic effect is probably a product of decreased myocardial oxygen consumption,[1] although amelioration of coronary blood flow and neurohormonal mechanisms may also contribute.[5] Spinal cord stimulation can also significantly improve health related quality of life.[6] Invasive analgesic strategies, such as stellate ganglion blockade and thoracic epidural analgesia, are also an important part of the current armamentarium.[1 2 7]

These treatments are expensive, however, and they require specialist angina centres with the requisite surgical and technical expertise. For example, one technique—enhanced external counterpulsation—involves application of a series of pneumatic cuffs that sequentially compress the calves and thighs.[8] It reduces anginal symptoms and the need to use nitrates, and it improves time to exercise induced ischaemia, but a typical treatment regimen comprises more than 30 treatment sessions of one hour over the course of several weeks.[8]

Self management training is a promising adjunct to the treatment of refractory angina that needs relatively few resources, but few studies have been carried out in this patient population. Self management training interventions are multimodal treatment packages that use learning materials and cognitive behaviour strategies to promote effective self management of disease. In the past decade, a few small self management trials have shown significant reductions in the frequency of angina symptoms, use of nitrates, stress, and aspects of self reported health related quality of life.[3] While these findings are promising, they come from trials in single sites that have short term follow-up (three to six months); methodological problems such as small sample sizes, lack of standardised and replicable interventions, and heterogeneity of measures. These trials have also included patients with less severe Canadian Cardiovascular Society class I-II symptoms. All of these factors limit the interpretation and generalisability of the findings.[3]

A more recent and robust trial with 142 participants showed that a self management programme based on cognitive behaviour therapy significantly reduced anxiety, depression, frequency of symptoms, nitrate use, and physical limitations ($P<0.05$) at six months compared with usual care.[4] This model was designed and tested for patients with newly diagnosed angina, and this research should be adapted and tested for patients with refractory angina.

Investing time and money in robust trials of self management in refractory angina could be worthwhile. Rigorous trials of patients with other complex diseases have accrued overwhelming evidence for the feasibility, long term effectiveness, cost effectiveness, and widespread dissemination of self management interventions led by healthcare professionals and peers.[9-12] For example, self management training significantly improves health related quality of life in patients with complex chronic pain,[9] arthritis,[10] and other chronic illnesses.[11] Significant reductions in rates of admission to hospital, length of hospital stay, mean number of visits to doctors, and direct out of pocket costs to patients have also been consistently reported.[10 11]

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Interpreting trends in fecundity over time

Is complicated by the lack of direct markers

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Infertility is a common problem in affluent societies. It affects around 15% of couples trying to conceive, although not all seek medical help.[1] In some countries, up to 6% of children are conceived through assisted reproductive techniques.[2] Many young men have sperm counts that fall short of the limit known to be associated with reduced fecundity.[3] It is still unclear whether the past decades have seen a substantial change in the fertility of couples in general or in the fertility of men in particular.[4]

The few studies that have examined changes in fecundity over time (or menstrual cycles)—from discontinuation of contraception to pregnancy—show conflicting results.[5] Fertility in couples is determined by social, behavioural, and biological factors that cannot be reliably ascertained in studies based on retrospectively collected data. Therefore, we will never know if biological fertility has changed.[5] Findings of numerous studies of secular trends in sperm counts are far from conclusive, but a study by Jensen's group provides convincing evidence of a pronounced difference in semen quality between populations.[6] Moreover, another recent paper from the same group shows that in cohorts of Danish women born between 1960 and 1980, birth rates decline progressively after adjustment for children conceived by assisted reproduction. The results are even more pronounced when the sharply declining rate of induced abortions is accounted for.[7]

However, biological fecundity is just one of the many determinants of fertility. These include sexual behaviour, desire for a given family size, social conditions, the age at which people start to have children, use of family planning methods, and the availability of assisted reproductive techniques. These cultural and social norms may mask more subtle biological changes in the population. More direct markers of fecundity are urgently needed, and the time has probably come to include fecundity in ongoing representative health surveys. Drawing on the present understanding of the methodological pitfalls in fertility research, we may be able to collect prospective data that are sufficiently comparable over time. Such studies may detect changes in fecundity similar in size to those reported in the past.

In any case fecundity is expected to decline over time, even if no evident causative environmental exposures are present.[8] This is because fecundity probably has a strong genetic component. With the advent of assisted conception, subfertile couples may have as many children as fertile couples, so that genetic factors linked to infertility will become more prevalent in the generations to come.[9]

From a public health perspective research should focus on avoidable causes of subfecundity. Such studies should look at exposure from the time of development of the sexual organs in the fetus to the time of trying to become pregnant. The first time point may be at least as important as the second. Thus, promising new results show that intrauterine exposure deserves close attention, and that both lifestyle and environmental factors should be the focus of further studies.[10 11] One study found a threefold higher prevalence of DNA damage in infertile men with *Chlamydia trachomatis* infection of the genitourinary tract than in fertile men without infection.[12] Treatment with antibiotics reduced the signs of DNA damage, and the female partners of a small subset of patients became pregnant after the treatment ended. The cross sectional design of the study means the findings should be interpreted with caution, and further studies are needed to confirm the results.

The best way to counteract infertility and help couples to have children naturally is to deal with the avoidable causes of subfecundity. Disappointingly, a large new programme for establishing research centres in reproduction and infertility in the United States devoted little attention to the environmental causes of subfecundity. There are good grounds for promoting further research and for trying to make up for the many years during which research into infertility has been neglected. The endocrine disruption hypothesis—which states that environmental chemicals may cause adverse development of sexual organs by interference with hormonal regulation—is just one of many hypotheses that deserve attention from funding agencies.[11]

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Quality failures in the NHS

Changes in leadership and culture are needed to improve learning from mistakes

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The report of the committee of enquiry into Ely Hospital, Cardiff, in 1969, was the first major inquiry into quality failures in the National Health Service. Thirty years later the report of the expert group chaired by the chief medical officer, *An Organisation with a Memory*, emphasised the need for the NHS to learn from its mistakes, and to be more systematic in acting on inquiry reports. A new analysis by the Healthcare Commission builds on these reports by summarising lessons from 13 major investigations it has undertaken since 2004.

Readers of the commission's report can be forgiven if they experience a strong sense of déjà vu. Although the investigations it undertook covered a wide range of services in different parts of the country, the general themes that emerge are depressingly familiar. The quality failures examined resulted from the interplay of several factors, including weak leadership, conflicting targets, inadequate use of data, and lack of teamwork. One of the problems highlighted in the commission's report is the poor standard of care found on general hospital wards, including examples of patients not being helped to eat their food and not being given their drugs.

Why is it so difficult to learn from mistakes and reduce avoidable errors? Part of the answer lies in the sheer size of the NHS and the large number of interactions between patients and providers that occur each day. In the absence of well developed systems to promote consistently high standards of care, mistakes are likely to occur, sometimes with tragic consequences.

In fact, the problems investigated by the commission were less the result of individual failings than the consequence of institutional shortcomings. The story that emerges from its report is of hospitals and services lacking effective direction and tolerating ways of working in which quality failures are accepted rather than challenged. In the words of the chief medical officer's report, the institutions concerned lacked a "safety culture" and were therefore at risk of patients being abused and adverse events occurring.

What needs to be done to restore memory to NHS organisations? A major step forward would be for ministers and civil servants to heed the warnings contained in the report about the negative consequences of continuous organisational restructuring on the quality of patient care. As the report states, "if not carefully managed, the process of organisational change can divert management away from maintaining service quality."

Equally important is the need to ensure that NHS boards pay as much attention to quality and safety as financial balance and hitting government targets. In theory, the duty of clinical governance laid on the NHS in 1999 should have persuaded chief executives to take quality seriously. The evidence reported here shows that this has not happened universally, nor have board members always used and questioned the data presented to them to exercise their stewardship role effectively.

Even more challenging will be bringing about the changes in culture that will enable the NHS to achieve the same level of safety as the airline and nuclear power industries. Among other things, this entails putting in place systems designed to reduce errors, providing appropriate training and development for staff, and ensuring that mistakes are measured and monitored. Above all, NHS organisations need to encourage the open reporting of adverse events and avoid staff feeling they will be blamed when things go wrong.

Diagnosing what needs to be done is relatively easy; making it happen is much more difficult. *An Organisation with a Memory* emphasised how important it was for the NHS to learn from mistakes and to do this actively rather than passively. The analysis produced by the Healthcare Commission shows that this has yet to happen, so that inquiries and investigations in the future may find similar failings, unless leaders at all levels make a commitment to ensuring that quality and safety are taken seriously.

If this is to happen, the NHS needs to match its record of achievement as a "doing organisation" and become a "learning organisation." Governments have rightly focused on priority areas—for example, cutting waiting times and improving areas of clinical priority such as cancer and heart disease—because of the legacy of poor performance in the NHS. Success in dealing with these priorities needs to be complemented by a focus on continuous quality improvement, in which clinical teams are supported to build on what works well and to learn from things that have gone wrong.

How to make this happen can be gleaned from a new study of high performing healthcare organisations in different countries, which describes the journey taken by these organisations and the factors that have contributed to their success. As the study makes clear, achieving high levels of performance cannot be reduced to a cookbook approach in which organisations implement lessons from the study of failure and success. A more nuanced approach is needed, starting from the position that each organisation has to find its own path of improvement appropriate to the context in which it operates and based on making changes on several fronts at the same time.

An area of common ground between this study and the report of the Healthcare Commission is the emphasis placed on leadership in bringing about change. Of particular relevance for the NHS is the commission's view that continuity of leadership is important (one of the organisations it investigated had seven chief executives in 10 years). Strengthening leadership for quality improvement may be the key that will finally unlock the secret of learning from mistakes, provided that this is done in the clinical teams providing care as well as at board level.

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Stronger European medical research

Needs investment in people, not simply more money

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How can Europe produce medical research that will best increase its citizens' health and its countries' wealth? This debate will run on and on, of course, but a new white paper from the European Medical Research Councils (EMRC) provides important evidence on funding and conducting effective, relevant, and world beating research (box 1).[1] Summing up the white paper in Frankfurt last month, Professor Liselotte Højgaard, EMRC chair, quoted British physiologist Ernest Starling's advice to the British Research Council in the 1920s, "get the best of men, give them the equipment you can afford, and leave them alone."

This white paper is one of several responses to last year's green paper from the European Commission, which contained proposals on how to overcome the fragmentation of research activities, programmes, and policies across Europe.[2] The EMRC's response is a pragmatic and readable document that pulls together evidence on whether Europe is finding the best researchers and whether it is spending enough on research to give them the tools they need. It does not, however, advocate leaving these workers alone as Starling suggested. If research in basic science and clinical medicine is to be successfully translated into practice, all those responsible—peer reviewers, journal editors, authors of reviews and guidelines, policy makers, and researchers themselves—need adequate training, support, and evaluation.

Many initiatives—such as the European roadmap for innovative research—are already in place across Europe for finding and training the best researchers in universities, laboratories, industry, and healthcare settings.[3] The EMRC endorses the best of these and puts them—along with research ethics,[4] sharing of research data,[5] and effective information technology and other essentials—into its toolbox for best practice (box 2). It also warns that unequal opportunities for researchers will hold Europe back. The white paper highlights the relative paucity of women among leaders of publicly funded research and in scientific decision making, and it stresses that women are less likely than men to succeed when applying for research grants of equal quality.

Is Europe providing the tools that its medical researchers need? With extra demands on health care

Box 1 | EMRC recommendations for strengthening medical research in Europe

- Implementation of best practice for funding and performing medical research—with distribution of funding based on excellence and evaluated by peer review
- Strengthened collaboration and coordination of medical research in Europe through the EMRC and its membership organisations, via the European Commission, the European Research Council, and the learned medical societies
- Revision of European Commission directives related to medical research
- Implementation of equal opportunities for all researchers
- A doubling of public funding of medical research in Europe within the next 10 years—to a minimum of 0.25% of gross domestic product

Box 2 | EMRC tool box: "best practice" for medical research in Europe

Primary goals

All three to be facilitated by interdisciplinary research and public-private partnerships

- Strong basic research
- Strong clinical research
- Strong translational research—sharing knowledge between research and practice

Tools to reach these goals: people

- Career track schemes with attractive possibilities for researchers taking advantage of cofunding strategy
- European Medical Scientific Training Programme for physicians and scientists scaling up existing successful initiatives
- The highest level of research ethics and no scientific misconduct

Tools to reach these goals: research infrastructure

- Investment in national and European research infrastructure—covering the whole range from laboratory equipment in basic science laboratories and research facilities in hospitals, to the largest pan-European infrastructures, as outlined in the European Strategy Forum on Research Infrastructure's roadmap
- A call for proposals to directly support—on a highly competitive basis—a league of top performing biomedical research centres of excellence, integrated into regional clusters
- More support for personalised medicine based on the human genome and molecular analyses of tumour markers
- Intelligent and coordinated use of information technology
- Review of European Commission and national regulations—for example, on biobanks—to facilitate collaboration across countries

Tools to reach these goals: research funding

- Adequate research funding based on scientific excellence and high quality peer review
- Common criteria and methods for evaluating research outcomes

Tools to reach these goals: societal means

- Globalisation and collaboration—sharing of research and results
- Public engagement about medical research and its possible effects
- Preparedness for the future

that include an ageing population, emerging and rapidly spreading infectious diseases, and climate change, Europe needs to keep on its toes. But it is investing much less than the United States, which is facing the same challenges. In 2004, the US non-industrial sector spent twice as much as Europe on biomedical research (around 0.40% of gross domestic product compared with 0.17% in the EU15—the 15 countries in the European Union before the accession of 10 candidate countries on 1 May 2004—a difference that would have been greater if all EU countries were included) and almost three times as much when adjusted for the size of the two populations.[1] The EMRC is calling for a doubling of public funding for medical research in Europe within the next 10 years and, at a minimum, spending the equivalent of 0.25% of gross domestic product.

Health research also has to compete within Europe for its slice of the science funding pie. The Seventh Framework Programme for Research and Technological Development doubled overall funding for science research to more than €50bn (£37bn; $73bn) between 2007 and 2013,[6] but only €6.1bn of this will go to health research, with much more going to physics—participants at Frankfurt noted that particle accelerators are costly and physicists have a lot of influence in European policy. Competing with other scientific funding is a challenge in the US too, and Elias Zerhouni, director of the US National Institutes of Health (NIH), has said, "if we don't find ourselves at the table discussing the role of medical research, we'll find ourselves on the menu" (Stefano Bertuzzi, science policy analyst at NIH, personal communication, Frankfurt, 2007).

Underfunding for medical research disadvantages Europe's citizens, the white paper argues, because medical research funding can yield up to a sixfold return on investment as a healthier population creates more wealth. But ways to evaluate the outputs and outcomes of research funding—including bibliometric analysis, retrospective case studies, surveys, peer review, and economic analysis—are still in their infancy, and the EMRC supports calls for common criteria and methods.[7]

Peer review largely determines which research is carried out and published, but it is a far from perfect tool. For instance, peer reviewers are biased towards American research,[8] which might partly explain the 10% difference in citation rates for US and EU research. Moreover, we still know relatively little about the strengths and limitations of peer review, and the evidence base is mainly about peer review of journal submissions rather than grant proposals. Worse still, peer review is given little support. Reviewers' workload is constantly increasing, yet they receive no specific training, no protected time, and no academic recognition for this work. Indeed, the Frankfurt meeting heard that grant giving bodies are running short of good reviewers who are willing and able to appraise lengthy proposals, and it concluded that peer review of grant proposals needs better scrutiny and evaluation and much greater support.

Some good news for Europe emerged from the EMRC white paper—the research euro is getting a bigger bang than the research buck. Although the EU spends less on research than the US, it is producing only one medical research paper less than the US per 10 000 inhabitants (3.9 papers *v* 4.9 in 2005).[1] This says nothing about the quality of research, however, so the EMRC has also looked at citation rates. Between 1996 and 2003 40% of the world's citations to biomedical publications were for research done in the EU15 countries, compared with 50% for work from the US. Given the big difference in funding, this reflects well on Europe. The challenge now is to keep on catching up.

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