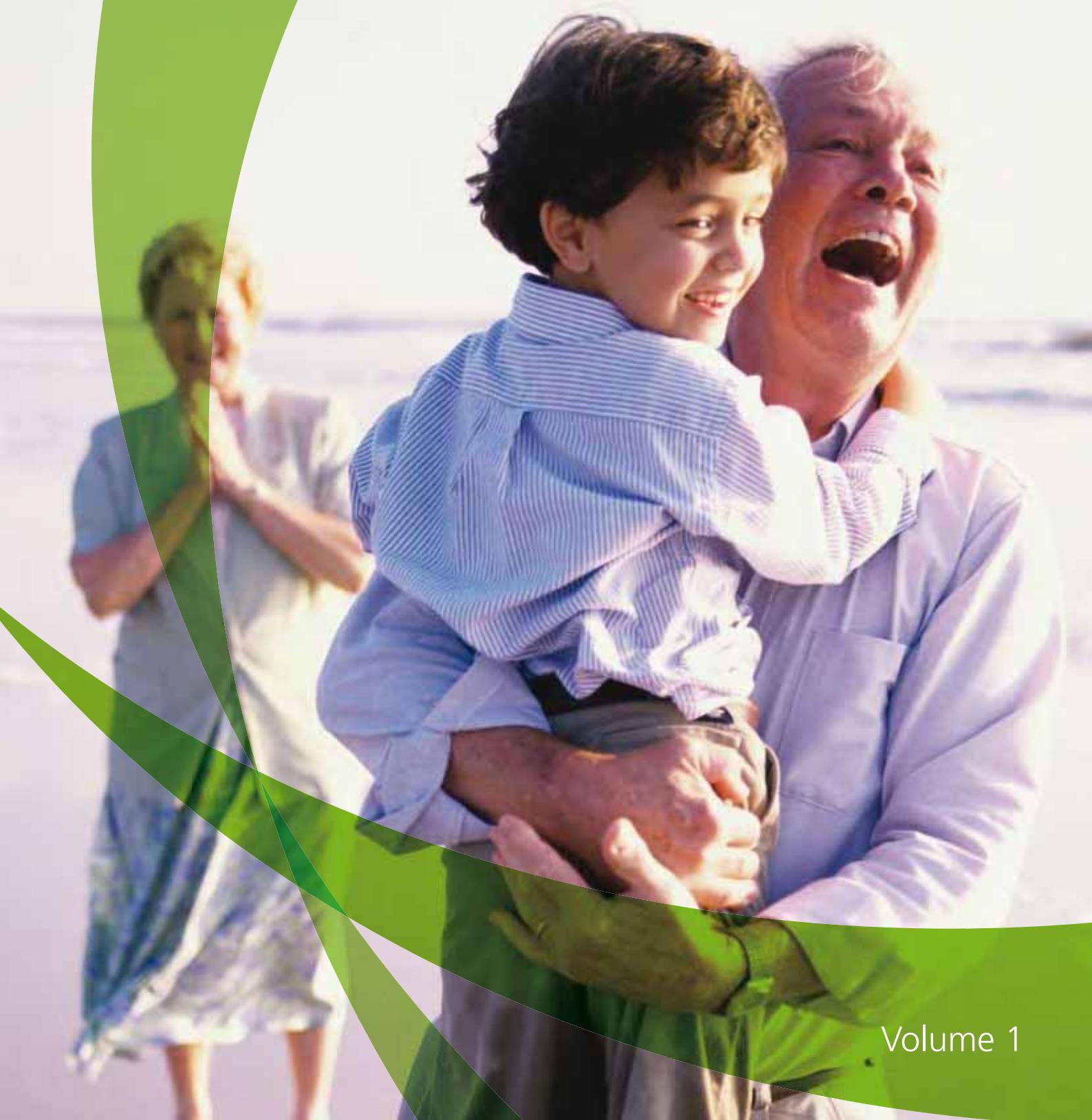


NHS

**National Institute for
Health and Clinical Excellence**

Annual Report 2006/7



Volume 1

National Institute for Health and Clinical Excellence (Special Health Authority)

Annual Report and Accounts 2006/7

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Contents

Chairman's and Chief Executive's Foreword	3
NICE overview	4
Public health	7
Technology appraisals	11
Clinical guidelines	17
Interventional procedures	23
Implementation	27
Involving patients and the public	31
Reaching out	35
About us	39
Financial overview	46

Chairman's and Chief Executive's Foreword 2006/7

The increasing expectations of those who use our guidance and those who depend on it for their care, together with sometimes intense media coverage of our recommendations, characterised a year in which we maintained a flow of diverse, high quality clinical and public health advice

Our clinical guideline on obesity encouraged the NHS and local authorities, schools and early year's providers, employers and town planners to tackle a growing threat to the health of our nation. This was the first time that evidence-base recommendations, integrating advice on prevention and treatment, had been issued at a national level. Our public health advisory bodies have continued their ground-breaking work in developing clear, concise recommendations using the best available evidence and in their use of economic analysis. We also issued guidance on preventing sexually transmitted infections and reducing under-18 conceptions, together with advice for those working with young people who are vulnerable to drug misuse.

We are constantly checking to make sure that the way we go about our work produces the best advice. In 2006, the way in which we develop clinical guidelines was the subject of an independent review by international experts from the World Health Organization (WHO). The WHO panel identified a number of strengths including the close links between our guidelines programme and the Royal Colleges, the use of a respected methodology, and our excellent work on involving patients and other stakeholders in developing guidelines. They also made recommendations about how we can improve – for example, by helping to better explain the relative importance of individual recommendations in a guideline. This was the second such review by the WHO and we intend to continue international scrutiny of our work in our other guidance programmes.

Because drugs often arrive with so much promise, it's perhaps not surprising that our advice on the use of new drugs and other treatments being made available to the NHS attracts so much attention. Patients and health professionals want our advice as quickly as possible. Last year, we introduced a new process (the single technology appraisal) to develop guidance on new drugs in half the time of our standard process. If new drugs are referred to us at the right time, we can issue draft guidance within weeks of them coming



3

onto the market. New drugs and new indications for existing drugs to treat early breast cancer were among the first to take advantage of this innovative approach.

Of course, we have a responsibility to provide guidance across the range of diseases and conditions for which we expect the NHS to offer treatment. So, last year, we produced advice on topics ranging from postnatal care through to renal cancers. In total, we produced 21 technology appraisals, 50 interventional procedure reviews, 13 clinical guidelines and 2 sets of public health advice.

None of these activities would have been possible without the dedication and hard work of the Institute's staff, and the wonderful support we receive from our growing community of external experts: the healthcare professionals, public health experts, academics and patients and carer representatives, who work with us on our independent advisory bodies and help develop guidance on our behalf. With around 230 staff and well over 2000 external advisors, we have one of the largest networks of its kind in the world. We are very grateful to them all for giving their time and expertise to improve the quality and consistency of healthcare in the United Kingdom.

Professor Sir Michael Rawlins, Chairman
Andrew Dillon CBE, Chief Executive

NICE overview

The National Institute for Health and Clinical Excellence

The National Institute for Health and Clinical Excellence (NICE) is the national organisation responsible for providing guidance on both the promotion of good health and the prevention and treatment of ill health. Professor Sir Michael Rawlins is Chairman and Andrew Dillon CBE is Chief Executive.

The roles and responsibilities of NICE

NICE produces guidance in three areas:

Public health – the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector

Health technologies – the use of new and existing medicines, treatments and procedures within the NHS

Clinical practice – the appropriate treatment and care of people with specific diseases and conditions within the NHS.

NICE has a remit to support the implementation of its guidance, which it does through the effective engagement of stakeholders, patients and the public in the selection of topics and the guidance development process. In addition, NICE has developed a programme of work with key partners to provide a supportive environment in which practitioners can implement guidance effectively with a range of implementation tools.

NICE technology appraisal guidance and clinical guidelines cover the NHS in England and Wales. The Institute's guidance on interventional procedures covers England, Scotland and Wales, while its public health guidance is for England only.

New relationship between NICE and Northern Ireland

In 2006, the Northern Ireland Health Minister Paul Goggins announced that the Northern Ireland Executive would formalise its relationship with NICE. This would allow local review of the applicability of all NICE guidance to Northern Ireland. The new arrangements became operational from 1 July 2006.

Andrew Dillon, Chief Executive of NICE, said, 'We are delighted to welcome the new relationship between NICE and Northern Ireland. This is a tremendous vote of confidence in the work of the Institute and will ensure

that patients in Northern Ireland have access to quality health services underpinned by NICE guidance.'

NICE centres of excellence

Centre for Public Health Excellence

The Centre for Public Health Excellence was established in April 2005 to develop guidance on the promotion of good health and the prevention of ill health. It produces two types of guidance – public health programme and public health intervention guidance.

Public health programme guidance deals with broad action for the promotion of good health and the prevention of ill health. It may focus on a topic, such as smoking, or on a particular population, such as young people, or on a particular setting, for example, the workplace.

Public health intervention guidance provides specific recommendations on types of activity that help to reduce people's risk of developing a disease or condition or help to promote or maintain a healthy lifestyle.

Examples of interventions are:

- **giving advice** (for example, in GP practices to encourage exercise)
- **providing services** (for example, a needle exchange scheme for injecting drug users)
- **providing support** (for example, for new mothers to enable the uptake and continuation of breastfeeding).

Centre for Health Technology Evaluation

The Centre for Health Technology Evaluation develops technology appraisal and interventional procedure guidance.

Technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS, such as medicines, medical devices (for example, hearing aids or inhalers), diagnostic techniques (tests used to identify diseases), surgical procedures (such as repairing hernias) and health promotion activities (for example, ways of helping people with diabetes manage their condition). Recommendations are based on a review of the clinical and economic evidence.

This year NICE used its single technology appraisal process for the first time. This new, rapid way of assessing drugs and other treatments has proved especially useful as a way of assessing newly licensed products.

Interventional procedure guidance evaluates the safety and efficacy of procedures where they are used for diagnosis or treatment. These procedures can involve making a cut or a hole to gain access to the inside of a patient's body, or gaining access to a body cavity without cutting into the body, or using electromagnetic radiation (including X-rays, lasers, gamma rays and ultraviolet light).

Health Minister Andy Burnham has agreed that from 1 April 2007 responsibility for running the Advisory Committee on Borderline Substances (ACBS) will transfer from NICE to the NHS Purchasing and Supply Agency (NHS PASA).

The ACBS was set up in 1971 to advise GPs on the prescription of products that are not drugs or medical devices. The committee is an advisory Non-Departmental Public Body, non-statutory and UK wide. NHS PASA has significant procurement expertise and currently facilitates contracts for ACBS-approved enteral feeds and other nutritional products.

Centre for Clinical Practice

The Centre for Clinical Practice at NICE develops clinical guidelines. These are recommendations, based on the best available evidence, on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

Good clinical guidelines aim to improve the quality of healthcare. They can:

- provide recommendations for treatment and care
- help patients make informed decisions and improve communications between patients and health professionals
- provide the basis for developing standards to assess the clinical practice of individual health professionals
- contribute to the education and training of health professionals.

In January 2007 NICE launched a consultation on a new short clinical guideline process that would allow the Institute to produce clinical guidelines covering a small number of specific clinical issues in 9–11 months, as opposed to full guidance which takes 24 months to produce and covers an entire patient pathway. Short clinical guidelines will be developed using the same rigorous methods as existing clinical guidelines. The first short guideline topic is being developed and is due to be published in July 2007.

NICE role in topic selection extended

In September 2006 the Department of Health announced a bigger role for NICE in the topic selection process. Topics are the specific treatments, drugs, or ways of caring for people with specific conditions or diseases about which NICE provides guidance for the NHS and the wider public health community, with the aim of preventing ill health or promoting good health.

Previously, healthcare and public health professionals, patients, carers and the general public could suggest topics for NICE via the NICE website. This information then went to the Department of Health, which was responsible for selecting the topics that would become part of the NICE technology appraisal and clinical guideline programmes.

Under the new arrangements, NICE is responsible for the administration of the early stages of topic selection and is the principal point of contact for individuals and organisations who want to suggest topics. It is also responsible for performing an initial 'sift' of suggestions (for example, to check that the topic isn't already part of NICE's existing work programme).

The Department of Health also asked NICE to organise seven new independent consideration panels. The panels make recommendations to the Department about the topics on which NICE should produce guidance. They are made up of individuals who:

- have expertise in one of seven subject areas: cancer; children, adolescents and maternity; vascular conditions; long-term conditions; general and acute conditions; mental health; and public health, or
- have a broad understanding of the health service and NICE's work, or
- are lay people with an understanding of wider patient, carer and community perspectives.

Ministers will continue to make the final decision on which topics are referred to NICE.

Andrea Sutcliffe, Deputy Chief Executive of NICE, said, 'We welcome these changes to the topic selection process. NICE's increased role should help the process operate more efficiently, allowing us to start working on topics suggested more quickly and so produce guidance on selected topics earlier.'



Public health

NICE set up the Centre for Public Health Excellence in April 2005 to produce guidance and supporting evidence on topics in public health for practitioners and policy makers in the NHS, local authorities and the wider public and voluntary sector. This year the Centre published two new pieces of intervention guidance and developed work on a list of topics referred by the Department of Health

New intervention guidance published

In 2006/7 NICE published two new pieces of public health intervention guidance.

Preventing sexually transmitted infections and reducing under 18 conceptions presented recommendations on one-to-one interventions to prevent the transmission of sexually transmitted infections (STIs) including HIV and to reduce the rate of under 18 conceptions, especially among vulnerable and at risk groups.

The NICE guidance on community-based interventions to reduce **substance misuse** among vulnerable and disadvantaged children and young people called for anyone working with young people to identify those who are vulnerable to drug problems and intervene at the earliest opportunity.

Programme development groups established

Work continued on public health topics that had been referred to NICE by the Secretary of State for Health in 2005/6 with the establishment of independent programme development groups for each topic.

Group members include people working directly in public health, managers in the health service and other organisations, researchers, statisticians and representatives from lay groups such as charities or patient/carer organisations.

The programme development groups look at the evidence available and consider comments made on draft versions of the guidance issued for consultation before making final recommendations.

In 2006/7 programme development groups were established for:

- behaviour change
- community engagement
- maternal and child nutrition
- physical activity and the environment
- smoking cessation.

New topics announced

In August 2006, the Secretary of State for Health referred eight further public health topics to NICE. This was in line with the Institute's remit for developing guidance on promoting good health and preventing and treating ill health. New public health topics referred to NICE were:

- strategies for reducing the harm from smoking
- information for schools on sensible drinking
- workplace health promotion
- promotion of mental health
- strategies for reducing health inequalities in the short, medium and longer terms
- promotion of physical activity in children
- health promotion in schools and colleges of further education
- management of long-term sickness and incapacity.

Case study 1

Joined-up thinking on obesity

It was 12 days before Christmas and it wasn't just the goose that was getting fat when NICE produced the first ever national clinical guideline addressing both the prevention and treatment of obesity in adults and children.

As Professor Peter Littlejohns, Clinical and Public Health Director at NICE, put it, 'Obesity is the most serious threat to the future health of our nation. Its risks are as serious as smoking and urgent action is needed to tackle this problem now.'

The guideline contained wide-ranging recommendations, not just for the NHS but also for schools and early years' providers, local authorities, employers and town planners. It was the first clinical guideline to cover a health issue from both a public health and clinical point of view.

Liz Biggs is Hertfordshire's Healthy Schools Co-coordinator and provided input from the schools' perspective to the NICE obesity guideline. She said, 'I'm responsible for supporting the schools in my area to take a "whole school approach" to health issues – meaning that there are consistent messages about being healthy in the classroom, in the dining room and in the playground. The NICE guidance helps to reinforce the messages in a "whole schools" way.'

Schools probably wouldn't describe themselves as working within public health, but they have an important role in improving the health of their pupils. Those working in education won't be used to getting advice and information from NICE, but now that NICE has a remit to produce public health guidance, I look forward to seeing other NICE recommendations that can help support the work that schools are doing.'

Case study 2

Stepping in on substance misuse

With 70,000 people aged 15–24 classed as problematic drug users, substance misuse is an issue for everyone who works with young people. In March 2007 NICE made recommendations calling for anyone working with young people to identify those who are vulnerable to drug problems and intervene at the earliest opportunity, before they start using drugs at all, or before they get into more difficulties if they are already misusing drugs.

The guidance, which was based on the best available evidence, gave advice on how to step in and help young people access the right support and services, as well as outlining just what those services might be.

Professor Peter Littlejohns, Clinical and Public Health Director at NICE and Executive Lead for this guidance, said, 'This guidance will help practitioners working with young people to understand which interventions are effective and how they should be used with those at high risk of substance misuse.'

Dr Catherine Law, Institute of Child Health, University College London and chair of the Public Health Interventions Advisory Committee at NICE, added, 'The good thing about these recommendations is that they can be implemented by any individual whose role involves interacting with young people in their daily work.'



Public health intervention guidance published in 2006/7

Title	Publication date
Prevention of sexually transmitted infections and under 18 conceptions (PHI 003)	February 2007
Interventions to reduce substance misuse among vulnerable young people (PHI 004)	March 2007

Public health intervention guidance in development

Title	Publication date*
Workplace interventions to promote smoking cessation	April 2007
Alcohol and schools intervention	November 2007
Mental wellbeing of children in primary education	February 2008
Mental health and older people	March 2008
Proactive case finding and retention and improving access to services in disadvantaged areas	April 2008
Workplace physical activity	May 2008
Prevention of smoking by children and young people	June 2008
Workplace mental health	August 2008

Public health programme guidance in development

Title	Publication date*
Behaviour change	October 2007
Smoking cessation services	November 2007
Physical activity and the environment	January 2008
Community engagement	February 2008
Maternal and child nutrition	February 2008
Management of long-term sickness and incapacity	December 2008
Promotion of physical activity in children	December 2008
Health promotion in schools and colleges of further education	July 2009

* at time of going to press

Health Development Agency publications produced in 2006/7

NICE took over the functions of the Health Development Agency in April 2005, taking on a wider role in public health and inheriting a publications programme. The last of the inherited publications were issued this year.

Title	Publication date
Health and social inequalities in English adolescents: exploring the importance of school, family and neighbourhood	April 2006
Healthier planning: spatial strategies and beyond	April 2006
Review of grey literature on drug prevention among young people	May 2006
The NHS and local transport planning: a briefing	May 2006
Promotion of breastfeeding initiation and duration: evidence into practice briefing	July 2006
Food-support programmes for low-income and socially disadvantaged childbearing women in developed countries: systematic review of the evidence	July 2006
Interventions to prevent accidental injury to young people aged 15–24: evidence briefing	July 2006
Transport interventions promoting safe cycling and walking: evidence briefing	July 2006
Interventions that use the environment to encourage physical activity: evidence review	September 2006
Smoking and public health: a compendium of smoking behaviour initiatives that address socially disadvantaged populations: evidence review	January 2007
Public health interventions to promote positive mental health and prevent mental health disorders among adults: evidence briefing	January 2007



Technology appraisals

Technology appraisals make recommendations on the use of new and existing medicines and treatments within the NHS. This year NICE produced its first rapid appraisal under the new single technology appraisal process. In total, 21 technology appraisals were published on topics ranging from Alzheimer's disease and anti-cancer drugs to the management of children with conduct disorders

First single technology appraisals delivered on schedule

In August 2006 NICE published a technology appraisal on the use of trastuzumab (Herceptin) in treating early breast cancer, just as promised a year earlier. This was the first technology appraisal to be developed using the new single technology appraisal (STA) process launched with the Department of Health in 2005. Others on breast cancer drugs docetaxel (Taxotere) and paclitaxel (Taxol) came just a month later.

The new STA process was designed to sit alongside NICE's existing processes to produce faster guidance on life-saving drugs that have already been licensed and on new medicines close to when they first become available. NICE consulted with organisations representing patients, healthcare professionals and healthcare industries on details of the new process.

In 2006/7 NICE recruited new members to its independent Appraisal Committees to support this work. Andrew Dillon, Chief Executive of NICE, welcomed them saying, 'Last year we announced our new rapid appraisal process which will allow us to issue guidance to the NHS on new drugs and treatments more quickly. In order to deliver this new programme of work we needed to increase the capacity of our Appraisal Committees. We looked to recruit individuals who have the experience and

commitment to help the Institute take some of the most difficult decisions in public life, and in doing so contribute to improving the quality and consistency of care provided by the NHS.'

In August 2006 the Department of Health asked NICE to transfer a range of existing topics to the STA process. These were:

- erlotinib (Tarceva) for non-small-cell lung cancer
- irinotecan (Campto) for adjuvant treatment of advanced colorectal cancer (subject to licensing)
- pemetrexed (Alimta) for non-small-cell lung cancer
- cetuximab (Erbitux) for locally advanced recurrent metastatic head and neck cancer (subject to licensing)
- atrasentan (Xinlay) for hormone refractory prostate cancer (subject to licensing)
- omalizumab (Xolair) for asthma
- lerdelimumab (CAT-152) for glaucoma
- carmustine implants (Gliadel implants) for recurrent glioma
- nesiritide (Natrecor) for acute heart failure
- natalizumab (Tysabri) for multiple sclerosis
- infliximab (Remicade) for psoriasis.

New appraisal topics referred to NICE

In August 2006 the Secretary of State for Health referred a range of new topics for technology appraisal. They were:

- idraparinux sodium for the prevention of stroke in patients with atrial fibrillation
- idraparinux sodium for the prevention of recurrent venous thromboembolism
- varenicline for smoking cessation
- alteplase for acute ischaemic stroke
- drugs for refractory rheumatoid arthritis
- adalimumab and leflunomide for the treatment of psoriatic arthritis
- ruboxistaurin for the treatment of diabetic eye disease
- drugs for the treatment of sleep apnoea
- neuro-imaging in identification of first episode psychosis
- cochlear implants.

In February 2007 a further five topics were referred under the STA programme, namely:

- bevacizumab for non-small-cell lung cancer
- certolizumab pegol for rheumatoid arthritis
- infliximab for ulcerative colitis
- lapatinib for advanced or metastatic breast cancer
- rimonabant for the treatment of obese and overweight patients.

Three more were added to NICE's multiple technology appraisal programme. They were:

- endovascular stents for abdominal aortic aneurysms
- machine versus cold (static) storage of donated kidneys
- spinal cord stimulation for chronic pain.

In addition, NICE was asked to appraise adalimumab for moderate to severely active Crohn's disease. This will be appraised as part of the multiple technology appraisal (MTA) programme, along with infliximab (review of existing guidance), certolizumab pegol and natalizumab.

Case study 3

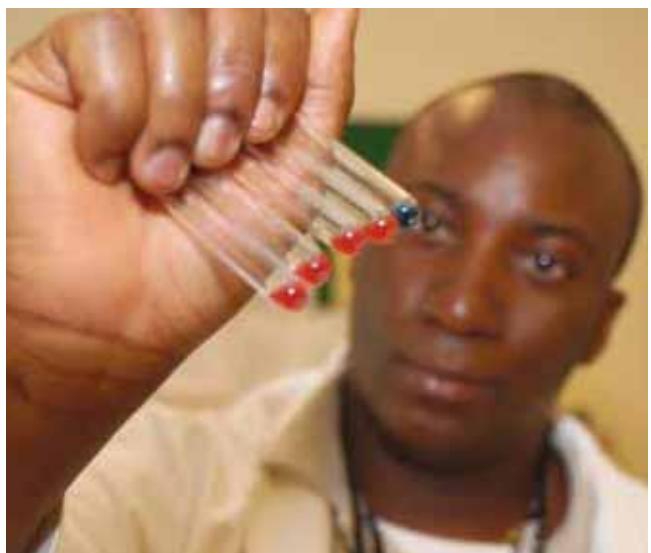
Why cost effective doesn't always mean cheaper

Professor David Barnett co-chairs the Institute's three appraisal committees which help develop technology appraisals. One aspect of the committees' role is to look at cost effectiveness.

'The treatments provided by the NHS are normally designed to improve quality of life or to extend life and sometimes both. They all have a cost, of course, and it's part of our job to decide whether new treatments offer enough benefit to patients, compared to current standard treatments, to justify what the NHS is being asked to pay for them. To help us do this, we use a measurement called a "quality adjusted life year", or QALY. QALYs allow us to take account of the extent to which new treatments offer improvements in quality of life as well as extending life. Using QALYs in all our assessments means that we avoid regarding one disease or condition as more important than another.'

Making sure new treatments offer real benefits for patients and provide good value for money for the NHS is important because we have a fixed amount of money to spend on the NHS and it's not possible to buy everything that might have even the smallest benefit for everyone. Put simply, we can't afford to buy treatments that don't work well enough. Spending money on treatments with little or no value for one group of patients means that money can't be spent on treatments that are effective for another group.

It's not just about price, though. A very expensive treatment might well be cost effective if it offers sufficient benefits for patients. Conversely, a treatment that might not cost very much could still be poor value for money if it doesn't offer enough improvement in quality or length of life.'



Case study 4

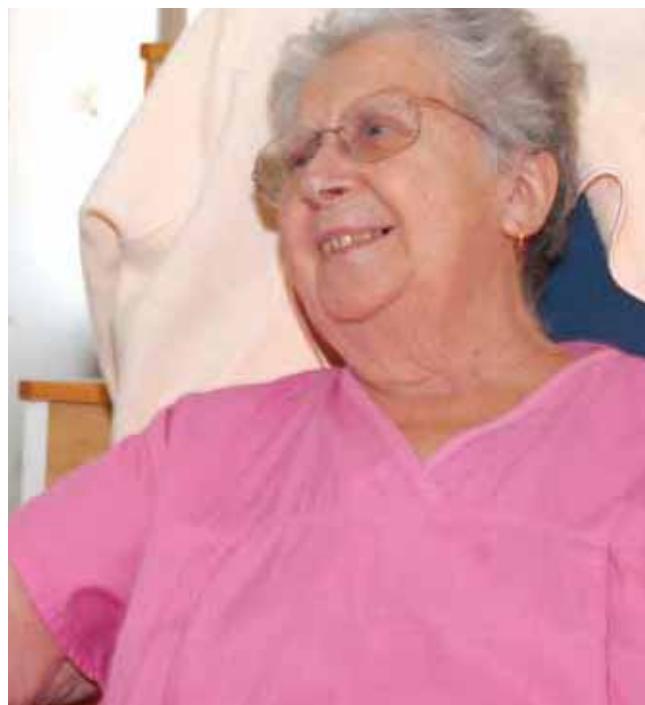
Bringing technology appraisals and guidelines together

Technology appraisals assess individual treatments, like drugs, used in the NHS. In 2006/7 NICE worked in partnership with its counterpart in social care, the Social Care Institute for Excellence, to incorporate a technology appraisal into a guideline for both health and social care staff.

The topic was dementia and the joint NICE/SCIE guidance covered the treatment and care of people with dementia in health and social care. It not only incorporated the latest technology appraisal of drugs for Alzheimer's disease but also called for a coordinated and integrated approach from health and social care staff to provide treatment and care for patients with dementia and support for their carers. The guideline emphasised that memory assessment centres should be the single point of referral for all people with a possible diagnosis of dementia. People diagnosed with dementia should not be excluded from other services.

Andrew Dillon, NICE Chief Executive, said, 'This is a very important guideline not only for people with dementia but also their carers. This is the first time that a clinical guideline has been produced in conjunction with SCIE, demonstrating the real importance of health and social care professionals working together closely to drive forward improved standards of care for people with dementia.'

The clinical guideline incorporates our appraisal guidance on the use of drugs for people with Alzheimer's disease, but it also sets wider standards for the care of people with all types of dementia which clinicians and commissioners alike in the NHS are expected to implement.'



Technology appraisals published in 2006/7

Title	Publication date
Renal transplantation – immunosuppressive regimens for children and adolescents (TA99)	April 2006
Colon cancer (adjuvant) – capecitabine and oxaliplatin (TA100)	April 2006
Prostate cancer (hormone-refractory) – docetaxel (TA101)	June 2006
Conduct disorder in children – parent-training/education programmes (TA102)	July 2006
Psoriasis – efalizumab and etanercept (TA103)	July 2006
Psoriatic arthritis – etanercept and infliximab (TA104)	July 2006
Colorectal cancer – laparoscopic surgery (review) (TA105)	August 2006
Hepatitis C – peginterferon alfa and ribavirin (TA106)	August 2006
Breast cancer (early) – trastuzumab (TA107)	August 2006
Breast cancer (early) – paclitaxel (TA108)	September 2006
Breast cancer (early) – docetaxel (TA109)	September 2006
Follicular lymphoma – rituximab (TA110)	September 2006
Alzheimer's disease – donepezil, galantamine, rivastigmine (review) and memantine (TA111)	November 2006
Breast cancer (early) – hormonal treatments (TA112)	November 2006
Diabetes (type 1 and 2) – inhaled insulin (TA113)	December 2006
Drug misuse – methadone and buprenorphine (TA114)	January 2007
Drug misuse – naltrexone (TA115)	January 2007
Breast cancer – gemcitabine (TA116)	January 2007
Hyperparathyroidism – cinacalcet (TA117)	January 2007
Colorectal cancer (metastatic) – bevacizumab and cetuximab (TA118)	January 2007
Leukaemia (lymphocytic) – fludarabine (TA119)	February 2007

Technology appraisal guidance under development

Title	Publication date*
Glioma (newly diagnosed and high grade) – carmustine implants and temozolomide	June 2007
Ischaemic stroke (acute) – alteplase (STA)	June 2007
Heart failure – biventricular pacing (cardiac resynchronisation)	July 2007
Smoking cessation – varenicline (STA)	July 2007
Heart failure (acute decompensated) – nesiritide (STA)	August 2007
Hypercholesterolemia – ezetimibe	August 2007
Osteoporosis – primary prevention	August 2007
Osteoporosis – secondary prevention including strontium ranelate	August 2007
Haemorrhoid – stapled haemorrhoidectomy	September 2007
Macular degeneration (age-related) – pegaptanib and ranibizumab	September 2007
Mesothelioma – pemetrexed disodium	September 2007
Anaemia (cancer-treatment induced) – erythropoietin (alpha and beta) and darbepoetin	November 2007
Asthma (in adults) – corticosteroids	November 2007
Asthma (in children) – corticosteroids	November 2007
Follicular lymphoma – rituximab (STA)	December 2007
Dementia (non-Alzheimer's) – new pharmaceutical treatments (suspended)	January 2008
Glioma (recurrent) – carmustine implants (STA)	January 2008
Ischaemic heart disease – coronary artery stents (review)	January 2008
Lung cancer (non-small-cell) – bevacizumab (STA)	January 2008
Sleep apnoea – continuous positive airways pressure (CPAP)	January 2008
Thrombophilia	January 2008
Atypical psychosis (first onset) – neuro-imaging	February 2008
Pulmonary arterial hypertension (adults) – drugs	April 2008
Diabetes – insulin pump therapy	May 2008
Hearing impairment – cochlear implants	May 2008
Crohn's disease – infliximab (review), certolizumab pegol, natalizumab and adalimumab	July 2008
Abdominal aortic aneurysm – endovascular stent-grafts	November 2008
Ankylosing spondylitis – adalimumab, etanercept and infliximab	To be confirmed

Title	Publication date*
Asthma (uncontrolled) – omalizumab (STA)	To be confirmed
Atrial fibrillation – idraparinix sodium (STA)	To be confirmed
Atrial fibrillation – ximelagatran (suspended)	To be confirmed
Breast cancer (advanced or metastatic) – lapatinib (STA)	To be confirmed
Colitis (ulcerative) – infliximab (STA)	To be confirmed
Colon cancer (adjuvant) – irinotecan (STA)	To be confirmed
Diabetic retinopathy – ruboxistaurin (STA) (suspended)	To be confirmed
Falls – fallers' clinics (suspended)	To be confirmed
Glaucoma – lerdelimumab (CAT-152) (STA) (suspended)	To be confirmed
Growth failure (in children) – human growth hormone (HGH) (suspended)	To be confirmed
Head and neck cancer – cetuximab (STA)	To be confirmed
Lung cancer (non-small-cell) – erlotinib (STA)	To be confirmed
Lung cancer (non-small-cell) – gefitinib (suspended)	To be confirmed
Lung cancer (non-small-cell) – pemetrexed (STA)	To be confirmed
Multiple myeloma – bortezomib (STA)	To be confirmed
Multiple sclerosis – cannabinoids (STA) (suspended)	To be confirmed
Multiple sclerosis – natalizumab (STA)	To be confirmed
Osteoarthritis and rheumatoid arthritis – cox II inhibitors (review) (suspended)	To be confirmed
Pancreatic cancer – gemcitabine (suspended)	To be confirmed
Prostate cancer (hormone refractory) – atrasentan (STA) (suspended)	To be confirmed
Psoriasis – infliximab (STA)	To be confirmed
Psoriatic arthritis (moderate to severe) – adalimumab (STA)	To be confirmed
Psoriatic arthritis (moderate to severe) – leflunomide (STA)	To be confirmed
Rheumatoid arthritis – adalimumab, etanercept and infliximab	To be confirmed
Rheumatoid arthritis (refractory) – abatacept (STA)	To be confirmed
Rheumatoid arthritis (refractory) – rituximab (STA)	To be confirmed
Venous thromboembolism (recurrent) – idraparinix sodium (STA)	To be confirmed
Venous thromboembolism (VTE) – ximelagatran (suspended)	To be confirmed

*at time of going to press

STA; single technology appraisal





Clinical guidelines

NICE clinical guidelines provide advice on the appropriate treatment and care of people with specific diseases and conditions. Atrial fibrillation, postnatal care and bipolar disorder were among the 13 guidelines produced by the Institute this year

International experts review clinical guidelines programme

This year saw five international experts from the World Health Organization (WHO), the United Nations' health agency, undertake an independent peer review of the Institute's clinical guidelines programme. They analysed the methodology and process used for developing NICE guidelines and reviewed a series of recently published guidelines, one from each of the National Collaborating Centres (NCCs) that NICE commissions to develop them.

The WHO panel identified many strengths, such as the programme's overall organisation, its links with the Royal Colleges, the use of a respected methodology and its excellent work on patient and stakeholder involvement.

The WHO made a number of recommendations to help us improve our process and methodology for guideline development. We have already made substantial progress with implementation of these recommendations and will continue to do so throughout 2007/8.

NICE to help NHS reduce spending on treatments that do not improve patient care

In September 2006 Health Minister Andy Burnham asked NICE to launch a new programme of work to help the NHS identify interventions that are not effective or do not improve patient care. In response to this request, NICE developed three new types of product:

- Clinical guidelines and technology appraisals aimed at reducing optimal practice. For example, NICE is looking at when it is appropriate to use grommets to treat glue ear. This technique has its place in treating this condition, but we need to make sure that it is not being over-used. Between 10 and 30% of children will experience glue ear before the age of 3 and they can be treated using grommets or with other techniques, including 'watchful waiting', which means keeping a careful eye on the child to see whether the condition resolves itself without further intervention. NICE expects to issue guidance on this topic in 2008.

- Reminders highlighting recommendations from existing NICE guidance to advise the NHS to stop an intervention that is ineffective or poor value for money. To date, NICE has issued online reminders on drugs for the treatment of eczema, long-acting reversible contraception and treatments for post-traumatic stress disorder.
- Guides offering practical web-based advice for NHS commissioners on how to commission routine services in line with NICE recommendations. The first commissioning guide on upper gastrointestinal endoscopy services was published in October 2006, underpinned by NICE guidelines on dyspepsia and referral for suspected cancer. Four further commissioning guides have been published, covering anticoagulation therapy services, pulmonary rehabilitation for chronic obstructive pulmonary disease (COPD), assisted discharge scheme for COPD and diabetes foot care services.

Gillian Leng, NICE Implementation Director commented, 'NICE already advises the NHS on when it should invest in new drugs and treatments that work well for patients. It's common sense for us to also advise the NHS on when it is appropriate to stop using treatments that don't benefit patients or do not represent good value for money where there are better alternatives available.'

New guideline topics welcomed

In August 2006, the Secretary of State for Health referred two new clinical guideline topics to NICE. These were the diagnosis and management of metastatic spinal cord compression and the diagnosis and management of irritable bowel syndrome. A further two topics were referred in February 2007. These were rheumatoid arthritis in adults and diarrhoea and vomiting in children. In addition, in December 2006 prophylaxis for infective endocarditis was referred for development under the new short guideline process.



Case study 5

New guideline for bipolar disorder

It takes an average of 8 years from a person experiencing the first symptoms of bipolar disorder to receiving a diagnosis. 'This is far too long,' said Stephen Pilling, consultant clinical psychologist and joint director of the National Collaborating Centre for Mental Health. Speaking at the launch of a new guideline on the identification, treatment and management of bipolar disorder in children and adults, he said, 'More needs to be done to improve awareness, identification and recognition of this problem so that appropriate treatments are prescribed and symptoms can be better controlled.'

Bipolar disorder (formerly known as manic depression) is a serious mental health condition characterised by the presence of episodes of mania and depression. The guideline calls for more to be done to ensure that bipolar disorder is correctly identified and recognised by health professionals. It sets out the criteria for when patients need to be referred on for specialist psychiatric assessment and treatment, and the drug treatment options for people with bipolar disorder, and emphasises the need to involve service users in treatment decisions.

Professor Richard Morris, Professor of Psychiatry, University of Nottingham and Guideline Development Group member said, 'Bipolar disorder is a lifelong condition that requires continuity of care. Too often patients do not have access to the medical help they require. The guideline should clarify the assessment and treatment needed and give hope to people with bipolar that with proper continuing treatment they can lead a relatively normal and fulfilled life.'



Case study 6

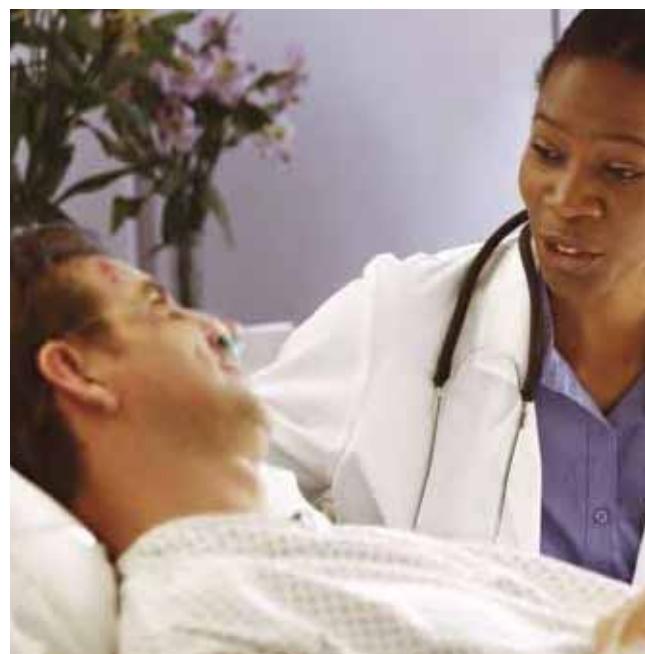
Gold standard for hypertension endorsed

June 2006 saw publication of the keenly awaited updated clinical guideline on the management of hypertension, published jointly with the British Hypertension Society (BHS).

Around four in ten adults in England and Wales have hypertension – a risk factor for cardiovascular diseases such as stroke and coronary heart disease and for chronic renal failure. In 2001, the NHS paid for 90 million prescriptions for drugs that lower blood pressure, accounting for nearly 15% of the total annual cost of all primary care drugs. Nonetheless, hypertension is often inadequately treated.

The new guideline is the gold standard for the optimum pharmacological management of hypertension, seeking to decrease the morbidity and mortality of diseases for which hypertension is a significant risk factor.

Professor Morris Brown, President of the BHS and member of the Guideline Development Group said, 'The British Hypertension Society is pleased to be a partner in the first joint guideline between NICE and a specialist society. I hope that the new guideline will both stimulate and enable doctors to review treatment of all their patients with hypertension.'





Clinical guidelines and cancer service guidance published during 2006/7

NICE has established seven National Collaborating Centres (NCCs) to help develop the clinical guidelines. Each is a professionally led group harnessing the expertise of the royal medical colleges, professional bodies and patient/carer organisations. The NCCs are:

- National Collaborating Centre for Acute Care
- National Collaborating Centre for Cancer
- National Collaborating Centre for Chronic Conditions
- National Collaborating Centre for Mental Health
- National Collaborating Centre for Nursing and Supportive Care
- National Collaborating Centre for Primary Care
- National Collaborating Centre for Women's and Children's Health

In 2006/7 they published 12 new guidelines and the last in NICE's cancer service guidance series.

Title	Publication date
Brain tumours (cancer service guidance)	June 2006
Hypertension (CG34)	June 2006
Parkinson's disease (CG35)	June 2006
Atrial fibrillation (CG36)	June 2006
Postnatal care (CG37)	July 2006
Bipolar disorder (CG38)	July 2006
Anaemia management in chronic kidney disease (CG39)	September 2006
Urinary incontinence (CG40)	October 2006
Familial breast cancer (CG41)	October 2006
Dementia (CG42)	November 2006
Obesity (CG43)	December 2006
Heavy menstrual bleeding (CG44)	January 2007
Antenatal and postnatal mental health (CG45)	February 2007

Clinical guidelines under development

Title	Publication date*
Anxiety (amendment)	April 2007
Depression (amendment)	April 2007
Venous thromboembolism	April 2007
Feverish illness in children	May 2007
MI: secondary prevention	May 2007
Faecal incontinence	June 2007
Acutely ill patients in hospital (SCG)	July 2007
Drug misuse – opioid detoxification	July 2007
Drug misuse – psychosocial interventions	July 2007
Chronic fatigue syndrome/myalgic encephalomyelitis	August 2007
Urinary tract infection in children	August 2007
Head injury (update)	September 2007
Intrapartum care	September 2007
Atopic eczema in children	December 2007
Lipid modification	January 2008
Osteoarthritis	January 2008
Prostate cancer	January 2008
Irritable bowel syndrome	February 2008
Ventilation tubes	Februry 2008
Antenatal care	March 2008
Diabetes in pregnancy	March 2008
Diabetes – type 2 (update)	March 2008
Prophylaxis for infective endocarditis (SCG)	March 2008
Perioperative hypothermia (inadvertent)	April 2008
Osteoporosis	To be confirmed
Induction of labour (update)	June 2008
Respiratory tract infection (SCG)	June 2008
Attention deficit hyperactivity disorder	July 2008
Stroke – acute management	July 2008
Familial hypercholesterolaemia	August 2008
Surgical site infection	August 2008
Chronic kidney disease	September 2008
Metastatic spinal cord compression	November 2008
Suspected child abuse	November 2008 (TBC)
Antisocial personality disorders	December 2008
Medicines concordance	December 2008
Personality disorders – borderline	December 2008
Breast cancer (advanced)	January 2009
Breast cancer (early)	January 2009
Schizophrenia (update)	January 2009
Rheumatoid arthritis in adults	February 2009
Depression in primary and secondary care (update)	March 2009 (TBC)
Depression with chronic physical health problems (update)	March 2009 (TBC)
Low back pain	March 2009
Diarrhoea and vomiting in children	April 2009
Glaucoma	April 2009
Venous thromboembolism – prevention in patients admitted to hospital	June 2009 (TBC)
Acute chest pain	September 2009 (TBC)
Benign prostatic hyperplasia	September 2009 (TBC)
Substance misuse in pregnant women	September 2009 (TBC)
Meningococcal disease and meningitis in children and adolescents	October 2009

*at time of going to press

SCG; short clinical guideline



Interventional procedures

NICE guidance on interventional procedures determines not only whether a procedure is safe enough but also whether it works well enough for routine use in the diagnosis and treatment of NHS patients. The Institute published guidance on 50 such procedures last year, on topics such as using lasers or ultrasonic scalpels to remove tonsils, removing kidney tumours with frozen nitrogen, living-donor liver transplants and surgical techniques on the unborn fetus

Case study 7

Introducing IPAC

Professor Bruce Campbell is a vascular surgeon. He chairs NICE's Interventional Procedures Advisory Committee (IPAC), which was set up as a result of the Bristol Royal Infirmary Enquiry to help ensure the safety of NHS patients undergoing new procedures.

He said, 'IPAC reviews the evidence on how well new procedures work and whether they are sufficiently safe. As well as information from clinical trials, IPAC takes into account the views of specialist advisors, who are doctors, and other health professionals with knowledge of the procedure, as well as the views of patients who have undergone the procedure. Our guidance then sets out what (if any) special arrangements should be put in place by NHS trusts in order for them to offer the procedure to patients.'

These special arrangements usually involve making sure the patient knows that the procedure is new and making sure the outcomes of the procedure are accurately recorded. We also provide information for patients about the procedure.

So far NICE has issued guidance on over 200 procedures, including guidance on treatments for cancer, heart disease, and spinal and eye problems. We have also issued important guidance on reducing the risk of transmission of CJD through surgical instruments.

By providing guidance on how safe procedures are and how well they work, we make it possible for new treatments and tests to be introduced into the NHS in a responsible way, which helps ensure patients are kept safe without stifling innovation.'

Interventional procedures published during 2006/7

Title	Publication date
Balloon kyphoplasty for vertebral compression fractures (IPG166)	April 2006
Retrograde urethral sphincterometry (IPG167)	April 2006
Percutaneous radiofrequency catheter ablation for atrial fibrillation (IPG168)	April 2006
Stapled transanal rectal resection for obstructed defaecation syndrome (IPG169)	April 2006
Living donor lung transplantation for end-stage lung disease (IPG170)	May 2006
Laparoscopic helium plasma coagulation for the treatment of endometriosis (IPG171)	May 2006
Endovascular closure of perimembranous ventricular septal defect (IPG172)	May 2006
Percutaneous disc decompression using coblation for lower back pain (IPG173)	May 2006
High dose rate brachytherapy for prostate cancer (IPG174)	May 2006
Percutaneous fetal balloon valvuloplasty for aortic stenosis (IPG175)	May 2006
Percutaneous fetal balloon valvuloplasty for pulmonary atresia with intact ventricular septum (IPG176)	May 2006
Short-term circulatory support with left ventricular assist devices as a bridge to cardiac transplantation or recovery (IPG177)	June 2006
Tonsillectomy using ultrasonic scalpel (IPG178)	June 2006
Percutaneous cementoplasty for palliative treatment of bony malignancies (IPG179)	June 2006
Percutaneous laser therapy for fetal tumours (IPG180)	June 2006
Percutaneous occlusion of left atrial appendage (IPG181)	June 2006
Ultrasound guided foam sclerotherapy for varicose veins (IPG182)	June 2006
Non-rigid stabilisation techniques for the treatment of low back pain (IPG183)	June 2006

