

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SPECIAL HEALTH AUTHORITY

CENTRE FOR HEALTH TECHNOLOGY EVALUATION

PROGRESS REPORT

The Board is asked to note this progress report.

Dr Carole Longson

Director
Centre for Health Technology Evaluation

January 2007

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SPECIAL HEALTH AUTHORITY

CENTRE FOR HEALTH TECHNOLOGY EVALUATION (CHTE)

PROGRESS REPORT

1 Highlights

- The Interventional Procedures Programme published its 200th piece of guidance in December
- Minded referrals for the fourteenth wave of Appraisals have been received from the Department of Health
- The first Single Technology Appraisal information meetings have been held.

2 Progress against business plan objectives

2.1 Technology Appraisals Guidance

The following appraisals have not achieved their quarterly target for publication (please see appendix 1 for further details):

- Colorectal cancer – bevacizumab & cetuximab
- Gemcitabine – metastatic breast cancer
- Fludarabine – chronic lymphocytic leukaemia
- Erlotinib – non small cell lung cancer
- Pemetrexed - non small cell lung cancer

2.2 Technology Appraisal Guidance Consultations

The following Appraisal Consultation Documents (ACDs) have been issued for consultation since the last Board Report in November, and will contribute to meeting future guidance production targets:

- non small cell lung cancer - erlotinib
- non small cell lung cancer - pemetrexed
- Heart failure – biventricular pacing
- Ankylosing spondylitis – adalimumab, etanercept and infliximab
- Glioma (newly diagnosed) carmustine implants and temozolomide

2.3 Consultation on the 14th wave minded referral

The 14th wave minded referral received in December 2006 included the following topics:

- breast cancer – bevacizumab
- metastatic renal cell carcinoma – bevacizumab
- advanced renal cell carcinoma - sorafenib tosylate
- chronic hepatitis C - taribavirin hydrochloride
- chronic hepatitis B - telbivudine and entecavir
- clostridium difficile and associated diarrhoea - tolevamer
- hyperuricaemia in patients with gout - febuxostat
- juvenile idiopathic arthritis - tocilizumab
- moderate to severe chronic plaque psoriasis - adalimumab

Work has already begun and all topics will have completed a 4 week consultation period on the draft remit and scope by the end of January. By the middle of February eight scoping workshops will also have been held. A report on the workshops will be prepared for submission to the Department of Health.

2.3 Interventional Procedures Guidance

Business plan target: Publish approximately five Interventional Procedures Consultation Documents and five Guidance Documents each month.¹ Publish at least 12 pieces of guidance per quarter.

Progress: Ten pieces of IP guidance were published in Q3, including the Programme's 200th piece of guidance in December. Thirteen pieces of guidance are scheduled for publication in Q4.

2.4 Advisory Committee on Borderline Substances (ACBS)

Business plan target: Clarify with the Department of Health the future direction of the management of the work of the Advisory Committee on Borderline Substances and agree a strategy for taking this work forward with the Institute's Board.

Progress: The Minister of State for Health, Andy Burnham, has agreed to transfer formal responsibility for the ACBS from NICE to NHS Purchasing and Supplies Agency (or the new NHS Commercial Agency) from 1 April 2007. The team are working with PASA to ensure a smooth transfer. This issue is covered in more detail in a separate briefing for the Board.

3 Other developments

3.1 Recent appeal ruling on the Appraisals Programme

The Institute Guidance Executive has requested that the Board be updated on the implications for the Appraisals Programme of a recent appeal ruling at which it was considered unfair to the appellant that NICE had failed to disclose a written perspective prepared by a clinical specialist who attended the meetings of the Appraisal Committee. The reason for not disclosing the statement was that it was not provided by the expert despite repeated requests.

¹ 11 Interventional Procedures Advisory Committees meetings per year consider approximately 55 consultations and issue 55 guidance documents per year

The Technology Appraisal Process does not have a mandatory requirement for experts to submit a written statement in order to attend Appraisal Committee meetings. However, given the decision of the appeal panel, we will need to introduce further process steps including:

- amendment of standard letters to explain the new requirements
- the development of templates for written expert submissions
- enhanced liaison with experts to increase the probability that we receive a written statement from them
- development of contingency plans for all appraisals to ensure that meetings are attended by appropriate experts in the event that statements are not received by the experts initially selected.

The estimated resource implications of this are ten days of project management time for start-up (requirement estimated across the whole of the Appraisals Programme), as well as an ongoing requirement for on average two days per appraisal topic of project management time². The required resources will be absorbed within the Programme's current establishment.

3.2 Committee C

The newly formed third Appraisal Committee (C) has met twice in Manchester to discuss three STA topics.

3.3 STA introduction meetings

Two successful information meetings were held for consultees and commentators participating in STA. Approximately 100 people from a mix of backgrounds attended these meetings in Manchester and feedback has been extremely positive. We are planning to hold further information meetings throughout 2007 in both Manchester and London.

3.4 STA review

A review of the STA process by the Research and Development programme of NICE was started in December 2006.

3.5 CHTE and the NICE conference

A number of sessions were hosted by the CHTE team: an away day for Appraisal Committee members, academic groups and staff; a master class on STA and speed meetings at the conference; and a workshop on the Interventional Procedures Programme.

² This figure is based on the assumption that when an expert fails to submit, considerable time may be needed trying to get replacement experts to attend the meeting.

3.6 Request for removal from work programme

The manufacturer of ximelagatran (AstraZeneca) have advised the Institute that they have withdrawn regulatory applications in relation to this product following receipt of trial data, and do not intend to apply for marketing authorisation in the future.

We have appraisals of ximelagatran for the treatment of venous thromboembolism and for the treatment and prevention of stroke and other thromboembolic complications associated with atrial fibrillation on our work programme.

We have written to the Department of Health to request that both these technology appraisals be removed from the Institute's work programme.

4 Centre Recruitment and Staff

4.1 Technology Appraisals

Helen Chung (Technical Analyst) was appointed as Technical Advisor with effect from January 2007, to be based in the NICE Manchester office. Ruth McAllister joins the Manchester team as a Technology Appraisals Analyst in mid-January.

4.2 Interventional Procedures

Sarah Willett, Project Manager, has been appointed as a Guidelines Commissioning Manager in the Centre for Clinical Practice. Emma Gibbs (Administrator) has been appointed as Co-ordinator in the Patient and Public Involvement Programme.

Sally Hamilton has been appointed as a part-time Analyst in the Interventional Procedures Programme for nine months to cover Sally Wortley's maternity leave. Georgina Ronalds has been appointed as a full-time Analyst for one year to enhance Interventional Procedures Programme technical capacity. Sally joins us from the University of Auckland, and Georgina previously held research jobs at the London Borough of Newham and the London School of Hygiene & Tropical Medicine.

Dr Carole Longson
Director, Centre for Health Technology Evaluation
January 2007

Appendix 1: Technology Appraisal Programme - Planned guidance for 2006/07 publication (changes to timelines in bold)

Planned publication of guidance	Progress	Process
Q1 2006/07		
Colorectal cancer – oxaliplatin and capecitabine (adjuvant)	Published on target in Q1 (April 2006) – our 100 th piece of guidance	MTA
Renal transplantation (children and adolescents) – immunosuppressant regimes	Published on target in Q1 (April 2006)	MTA
Breast cancer (early) – docetaxel	Published in Q2 of 2006/07 (Sept 2006) following a consultation on the guidance	STA
Breast cancer (early) – paclitaxel	Published in Q2 of 2006/07 (Sept 2006) following a consultation on the guidance	STA
Q2 2006/07		
Psoriasis - etanercept & efalizimab	Published in Q2 of 2006/07 following the outcome of an appeal hearing	MTA
Psoriatic arthritis - etanercept & infliximab	Published in Q2 of 2006/07 following the outcome of an appeal hearing	MTA
Conduct disorders in children - parent-training/education programmes	Published in Q2 of 2006/07 following the outcome of an appeal hearing	MTA
Anaemia (cancer-treatment induced) - epoetin (alfa & beta) & darbepoetin alfa	Following appeal hearing, appraisal is being referred back to the appraisal committee and additional analysis is being undertaken. Earliest publication anticipated Q3 2007/08.	MTA
Alzheimer's disease – donepezil, rivastigmine, galantamine and memantine (review of existing guidance)	Published simultaneously with the Dementia Guideline in Q3 (Nov 2006) following an appeal hearing.	MTA
Hepatitis C (mild to moderate) - pegylated interferons, ribavarin & alpha interferon	Published on target in Q2 (Aug 2006)	MTA
Prostate cancer (hormone refractory) – docetaxel	Published on target in Q2 (Jun 2006)	MTA

Planned publication of guidance	Progress	Process
Glioma (newly diagnosed) – carmustine implants and temozolomide	The Institute has asked the Appraisal Committee to consider revised analysis. Earliest anticipated publication anticipated Q1 2007/08	MTA
Ischaemic heart disease – coronary artery stents	Appraisal on hold – awaiting further information regarding safety and efficacy of drug eluting stents	MTA
Colorectal cancer – laparoscopic surgery (review of existing guidance)	Published in on target in Q2 (Aug 2006)	MTA
Non-Hodgkin's lymphoma – rituximab	Published on target in Q2 (Sept 2006)	STA
Multiple myeloma – bortezomib	Appeal hearing arranged for 8 February 2007.	STA
Early breast cancer – trastuzumab	Published on target in Q2 (Aug 2006)	STA
Q3 2006/07		
Mesothelioma – pemetrexed disodium	Following appeal hearing, appraisal is being referred back to the appraisal committee. Earliest publication anticipated Q2 2007/08.	MTA
Diabetes type I and II – inhaled insulins	Published on target in Q3 (Dec 2006)	MTA
Breast cancer (early) – hormonal treatments	Published on target in Q3 (Nov 2006)	MTA
Colorectal cancer – bevacizumab and cetuximab	Due to publish in Q4 following an appeal hearing.	MTA
Hyperparathyroidism – cinacalcet HCl	Timelines extended to allow for two rounds of consultation. Earliest anticipated publication in Q4.	MTA
Advanced/metastatic breast cancer - gemcitabine	Draft guidance issued for consultation. Earliest anticipated publication in Q4	STA
Leukaemia (lymphocytic) - fludarabine	Draft guidance issued for consultation. Earliest anticipated publication in Q4	STA

Planned publication of guidance	Progress	Process
Non small cell lung cancer – erlotonib	Draft guidance issued for consultation. Earliest anticipated publication in Q1 2007/08	STA
Non small cell lung cancer - pemetrexed	Draft guidance issued for consultation. Earliest anticipated publication in Q1 2007/08	STA
Q4 2006/07		
Osteoporosis – primary prevention	Development of this appraisal is linked to the development of the osteoporosis guideline. The Appraisal Committee met recently to discuss responses to consultation on a second ACD. The earliest anticipated publication date is estimated at Q2 2007/08	MTA
Osteoporosis – secondary prevention	Development of this appraisal is linked to the development of the osteoporosis guideline. The appraisal committee met recently to discuss responses to consultation on a second ACD. The earliest anticipated publication date is estimated at Q2 2007/08	MTA
Drug misuse – methadone and buprenorphine	Expected to publish, on target, Q4	MTA
Drug misuse – naltrexone	Expected to publish, on target, Q4	MTA
Rheumatoid arthritis - adalimumab, etanercept and infliximab	Appeal hearing being organised, publication date tbc	MTA
Ankylosing spondylitis – adalimumab, etanercept and infliximab	Subject to appeal, now expected to publish Q1 2007/08	MTA
Locally advanced recurrent metastatic head and neck cancer - cetuximab	Timelines extended to allow for second Committee discussion in January 07. Earliest anticipated publication in Q1 2007/08.	STA

Appendix 2: Schedule of Interventional Procedures Guidance 2006/7

Dates in **bold** are past or fixed. Dates in *italics* are targets.

Name of procedure	Disease area	Consultation	Guidance
Stapled transanal rectal resection procedure for obstructed defecation syndrome	Gastrointestinal	Jan-06	April-06
Balloon kyphoplasty for vertebral compression fractures	Musculo-skeletal	Jan-06	April-06
Retrograde urethral sphincterometry	Renal & urinary	Jan-06	April-06
Radiofrequency catheter ablation for atrial fibrillation	Cardiovascular	Jan-06	April-06
High dose rate brachytherapy for localised prostate cancer	Cancer	Feb-06	May-06
Endovascular closure of perimembranous ventricular septal defect	Cardiovascular	Feb-06	May-06
Percutaneous fetal aortic balloon valvuloplasty	Gynae, pregnancy & birth	Feb-06	May-06
Percutaneous fetal pulmonary balloon valvuloplasty	Gynae, pregnancy & birth	Feb-06	May-06
Laparoscopic helium plasma coagulation of endometriosis	Gynae, pregnancy & birth	Feb-06	May-06
Percutaneous disc decompression using coblation for low back pain	Musculo-skeletal	June-04	May -06
Live donor lung transplant for end stage lung disease	Respiratory	Jan-05	May-06
Ultrasound guided foam sclerotherapy for varicose veins (interim guidance)	Cardiovascular	Dec-05	June-06
Non-rigid stabilisation techniques for the treatment of low back pain	Musculo-skeletal	Dec-05	June-06
Percutaneous Cementoplasty	Musculo-skeletal	March-06	June-06
Intrafetal interstitial laser for the ablation of vessels within fetal tumours	Gynae, pregnancy & birth	March-06	June-06
Balloon occlusion of left atrial appendage (PLAATO)	Cardiovascular	March-06	June-06
Harmonic scalpel for tonsillectomy	ENT	March-06	June-06

Name of procedure	Disease area	Consultation	Guidance
Left ventricular assist devices as a bridge to transplant or recovery	Cardiovascular	March-06	June-06
Catheterless oesophageal PH monitoring	Gastrointestinal	April-06	July-06
Tonsillectomy using laser	ENT	April-06	July-06
HIFU for atrial fibrillation as an associated procedure with other cardiac surgery	Cardiovascular	Jan-05	July-06
Percutaneous radiofrequency ablation for primary and secondary lung cancers	Respiratory	April-06	July-06
Deep brain stimulation for tremor and dystonia (excluding Parkinson's disease)	Neurological	May-06	August-06
Thoracoscopically assisted oesophagectomy	Gastrointestinal	May-06	August-06
Insertion of pleuro-amniotic shunt for fetal pleural effusion	Gynae, pregnancy & birth	June-06	Sept-06
Carotid artery stent placement for carotid stenosis	Cardiovascular	Aug-04	Sept-06
Selective dorsal rhizotomy for spasticity in cerebral palsy	Central Nervous System	June-06	Nov-06
Transobturator foramen procedures for stress urinary incontinence	Gynae, pregnancy & birth	July-06	Now incorporated into Clinical Guideline no. 40 Urinary Incontinence
Therapeutic amnioinfusion for oligohydramnios during pregnancy (excluding labour)	Gynae, pregnancy & birth	July-06	Nov-06
Laparoscopic radical prostatectomy including robotically assisted	Cancer	July-06	Nov-06
Living-donor liver transplantation	Gastrointestinal	Aug-06	Nov-06
Intramedullary skeletal kinetic distractor for femoral and tibial lengthening	Musculo-skeletal	July-06	Dec-06

Name of procedure	Disease area	Consultation	Guidance
Fetal vesico-amniotic shunt for bladder for lower urinary tract outflow obstruction	Gynae, pregnancy & birth	July-06	Dec-06
Photodynamic therapy for early stage oesophageal cancer	Cancer	Aug-06	Dec-06
Preoperative high dose rate brachytherapy for rectal cancer	Cancer	Aug-06	Dec-06
Cryotherapy for renal tumours	Cancer	June-06	Dec-06
Intrauterine laser ablation of placental vessels for the treatment of twin to twin transfusion syndrome	Gynae, pregnancy & birth	Sep-06	Dec-06
Amnioreduction using septostomy with or without amniodrainage for the treatment of twin to twin transfusion syndrome	Gynae, pregnancy & birth	Sep-06	Dec-06
Open femoro-acetabular surgery for impingement syndrome	Musculo-skeletal	Oct-06	<i>Jan-07</i>
Laparoscopic distal pancreatectomy	Gastrointestinal	Oct-06	<i>Jan-07</i>
Fetal cystoscopy for diagnosis and treatment of lower urinary outflow tract obstruction	Gynae, pregnancy & birth	Oct-06	<i>Jan-07</i>
Palliative photodynamic therapy for advanced oesophageal cancer	Cancer	Aug-06	<i>Jan-07</i>
Cryotherapy for renal tumours	Cancer	June-06	<i>Jan-07</i>
Laparoscopic insertion of peritoneal dialysis catheter	Gastrointestinal	<i>Nov-06</i>	<i>Feb-07</i>
Implantation of accommodating intraocular lenses during cataract surgery	Eye	<i>Nov-06</i>	<i>Feb-07</i>
Injectable bulking agents for faecal incontinence	Gastrointestinal	<i>Nov-06</i>	<i>Feb-07</i>
Radiofrequency-assisted liver resection	Gastrointestinal	<i>Nov-06</i>	<i>Feb-07</i>
Mesh sacrocolpopexy for pelvic organ prolapse	Gynae, pregnancy & birth	<i>Dec-06</i>	<i>Mar-06</i>
Laparoscopic nephrolithotomy and pyelolithotomy	Renal & urinary	<i>Dec-06</i>	<i>Mar-06</i>
Arthroscopic femoro-acetabular surgery for hip impingement syndrome	Musculo-skeletal	<i>Dec-06</i>	<i>Mar-06</i>

ITEM 12

Name of procedure	Disease area	Consultation	Guidance
Microwave ablation for primary liver cancers	Cancer	<i>Dec-06</i>	<i>Mar-06</i>