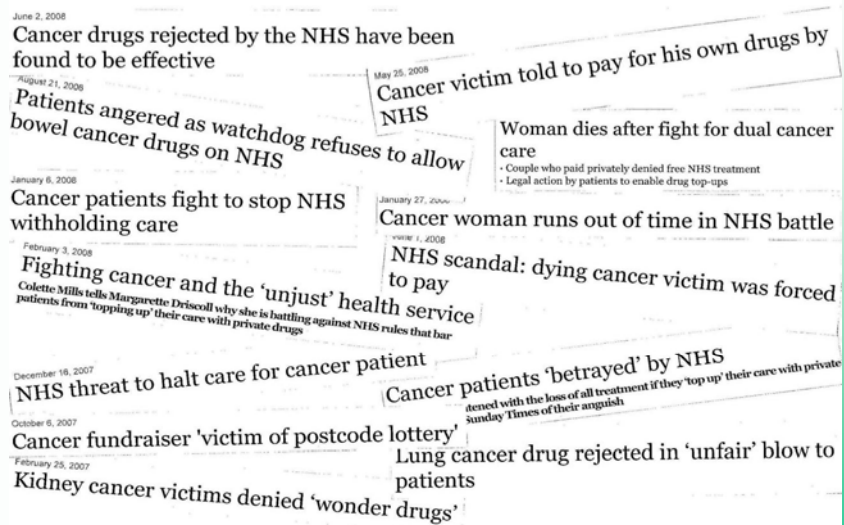


CANCER MEDICINE APPROVAL IN NHS NORTH EAST

Ken Bremner
Chief Executive
City Hospitals Sunderland NHS
Foundation Trust
Chair of NECDAG



INTRODUCING NEW CANCER DRUGS - HOW TO GET IT RIGHT

- Resources limited, money, staff to make & give chemo
- Cancer drugs have readily identifiable costs and benefits
- Can't have everything, decisions have to be made
 - **Is the drug clinically effective?**
 - **Is the drug cost effective?**
 - **Can the local healthcare economy afford the budget impact?**
- Balance tensions between efficiency and equity
- Must ensure consistency of approach
- Must assess each drugs case on its own merits
- Have a clear and transparent process that's defensible in public –
NECDAG

NORTH OF ENGLAND CANCER DRUG APPROVAL GROUP (NE CDAG)

Purpose

- To ensure that all patients with cancer in the North East Cancer Networks receive **equitable access** to a clinically defined appropriate range of cancer medicines
- Acts as an expert body within the North East
- Make decisions about availability of new and existing cancer drugs

NORTH OF ENGLAND CANCER DRUG APPROVAL GROUP (NE CDAG)

- Accept all NICE recommended drugs
 - Advise PCTs of financial and service impact
- Final NICE guidance due within 3 months = not considered
- Prioritise:
 - non NICE recommended potentially curative drug
 - non NICE Palliative (non curative)
- 'Horizon Scan' – looking ahead over next 12 months
- Audit, evaluate, support implementation
- Make dis-investment decisions where appropriate
- Encourage the use of new drug therapies in clinical Trials
- Serves 3.2 million population

NORTH OF ENGLAND CANCER DRUG APPROVAL GROUP (NE CDAG)

- NECDAG Considers
 - New drugs for cancer
 - New indications for old drugs
 - New combinations of drugs
 - Hormonal, supportive and other licensed new / novel treatments
 - 'Off-label' medicines
 - Unlicensed medicines only in exceptional circumstances
 - Currently developing our role in paediatric cancer medicines (new in 2009/10)

North Of England Cancer Drug Approval Group (NE CDAG)

- Meets 4 to 6 times per year
- Quorum = 3 out of the 5 PCT cluster representatives
- Decisions must have agreement from at least 3 out of the 5 PCT representatives
- In event of lack of unity Final Voting rests with PCT commissioners
- Submissions sent electronically on the 'New Product Request' form by set deadlines
- Supported by Gateway Subgroup
- Network Pharmacists provide cost analysis & support
- Requests presented by a nominated member of the Tumour Specific Group

AUTHORITY OF NE CDAG

- NECDAG has delegated authority from strategic commissioners to financially approve or reject drugs
 - Cost Less than £200,000 for Network (£20,000 per PCT)
 - QALY less than £25,000
- Commissioners within the group have delegated authority from host CTs to approve or reject requests within agreed criteria and timescales
- Decisions on affordability will be made by PCTs representatives on the day of the meeting and endorsed within seven days of the meeting for drugs with very high financial impact
- PCTs and trusts will be informed in writing of decisions within 7 days of the NECDAG meeting

APPROVAL GROUP MEMBERSHIP:



- Chair (CEO)
- Network Director
- 4 Clinical Reps
- 2 Network Medical Directors
- 2 Network Pharmacists
- SHA Executive Director
- Network Communications Lead
- 2 Network Patient Reps
- 5 PCT Executive Directors
- (1 Cumbria, 4 from joint SHA area)
- 2 Public Health Reps

NE CDAG – EARLY SUCCESS STORIES



- Herceptin for early breast cancer
 - NE approval Jan 2006: NICE Aug 06
- Pemetrexed for Mesothelioma
 - NE approved Dec 2005: NICE Aug 07
- Temozolamide for adjuvant glioma
 - NECDAG Nov 06: NICE Aug 07
- Erlotinib for NSCLC
 - NECDAG approved Nov 07
 - Alternative to 2nd line docetaxel
 - Using a 'risk share' scheme to match price of docetaxel
 - NICE rejected but following appeal approved 'provided pricing deal used to ensure costs not greater than docetaxel'
 - NICE Approval Nov 08

RECENT NE CDAG DECISIONS

Drug(s)	Indication	Date	Decision
Cetuximab (Erbix [®])	3rd Line KRAS wild-type metastatic colorectal	November 09	Approved
Lapatinib (Tyverb)	Breast cancer	September 09	Not Approved
Plerixafor (Mozobil [®])	stem cell mobilisation in multiple myeloma & lymphoma	September 09	Approved
Bevacizumab (Avastin [®])	Metastatic colorectal cancer patients with unresectable liver only metastases	July 2009	Not Approved
Cisplatin and Etoposide	chemoradiotherapy to superior sulcus carcinomas of lung	June 2009	Approved
Ritixumab (CLL)	1 st line CLL with FC Chemotherapy.	April 2009	Approved
Oral Topotecan (Hycamtin [®])	Relapsed Small Cell Lung Cancer (SCLC)	February 2009	Approved

LESSONS LEARNT

- Look to NICE to set the standards
- Have to work with QALYS, but accept that
 - QALYs not perfect, best tool we've got
 - Health economist expertise rare, so keep it simple
- Must critically appraise industry's economic models
- Must understand assumptions behind economic models
- Why have we been a success?
 - Action at Chief Executive level and SHA backing
 - PCT and Commissioner 'buy in' so funds follow decisions
 - Make tough decisions, i.e. We do say **No**
 - Strong leadership, respected experts and patient presence

STILL LEARNING!

- Want to offer North East patients best medicines
- Have to keep commissioners happy
- Learn to deal with Phase II evidence & Lack of survival data
- Need good intelligence e.g. ASCO etc
- Need credibility with clinicians
- Learn to work with industry on prices
 - NECN early adopter of 'Risk Share Schemes'
- Need to manage the media – Press officer vital
- We need to encourage NICE to go faster!

NE CDAG USE OF PATIENT ACCESS SCHEMES

- Drugs initially rejected due to cost
 - 2nd line sunitinib/sorafenib in RCC
 - Erlotinib in NSCLC Feb 07
- Pfizer - sunitinib scheme = NE approved July 07 (NICE 18 months later)
- Roche - erlotinib TAP scheme NE approved Nov 07 (NICE 12 months later)
- Not all schemes workable...
- Goal Achieved, getting North East patients access to drugs they want... But have to manage workload with schemes
- Most recently Cetuximab 1st line and 3rd line

ONGOING CHALLENGES

- Saying no – dealing with appeals
- Marginal benefit of new drugs
- Patient and public pressure
- Exceptional circumstance pathway
 - Helping PCTs develop policies on treatments
 - Trying to ensure constancy of decision making
- Applying NICE end of life ruling
- Co-payment/ additional private care
 - Developed Policy for North East
 - Integrated DH guidance into practice
 - Monitor and manage demand as needed

NICE AND END OF LIFE RULING

- Pressure on NICE to approve more medicines
- 'We' place increased value on life near end
- New rules for **'life-extending, end of life treatments'**
 - ICER exceeds the £30,000
 - Less than 2 years life expectancy
 - at least an additional 3 months survival
 - Small numbers of people
 - Does extra time in remission = longer survival?
- Doing the Maths
 - using the assumption that the extended survival period is experienced at the full quality of life
 - ? Need to wait and see figures
 - Lower HU value = lower QALY

(NE CDAG) – THE FUTURE

- Recognition in DH guidance
- Recommended as model
- ... collaborative processes already developed North East for cancer drugs could be used as a model...
- Already copied for Non cancer drugs NETAG!!

Improving access to medicines for NHS patients

A report for the Secretary of State for Health by Professor Mike Richards CBE
November 2008

CONCLUSIONS FACTS & FIGURES

Over Last four years NECDAG has

- Reviewed 53 new drugs/ regimens
 - 33 Approved
 - 8 Restricted Approval
 - 12 Not approved
- Estimated budget impact of £5 million

CONCLUSIONS 2

- North East Group effective and credible
- Can be done elsewhere
- Needs regional approach... SHA involvement
- Equity within North East but differences elsewhere – regional postcode prescribing
- Higher profile = more scrutiny
- Model adopted for non-cancer medicines
NETAG
- Would be happy to not exist (Fast NICE!)