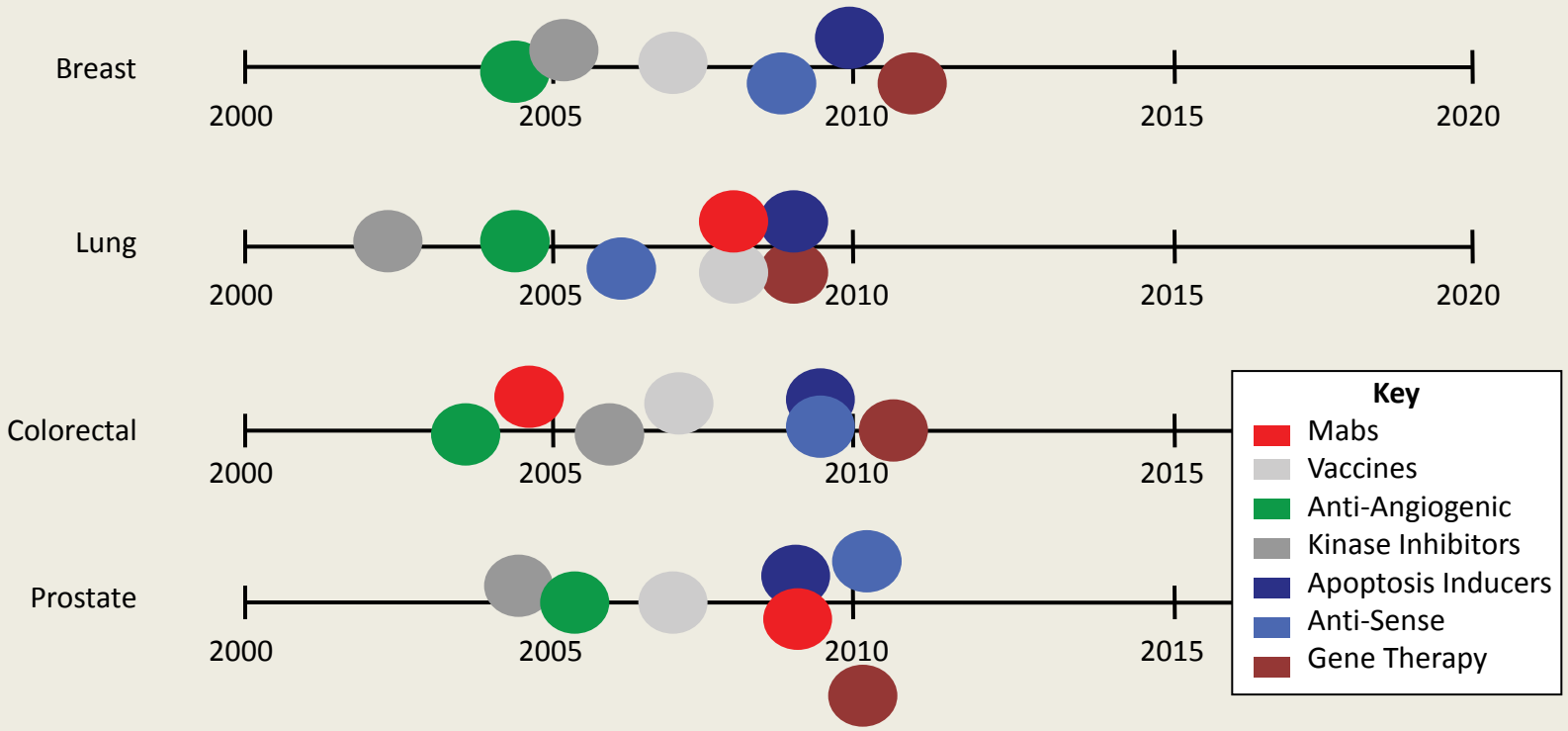
# Key Issues in Haematology Commissioning

Professor Adrian Newland

Chair, The London Cancer New Drugs Group

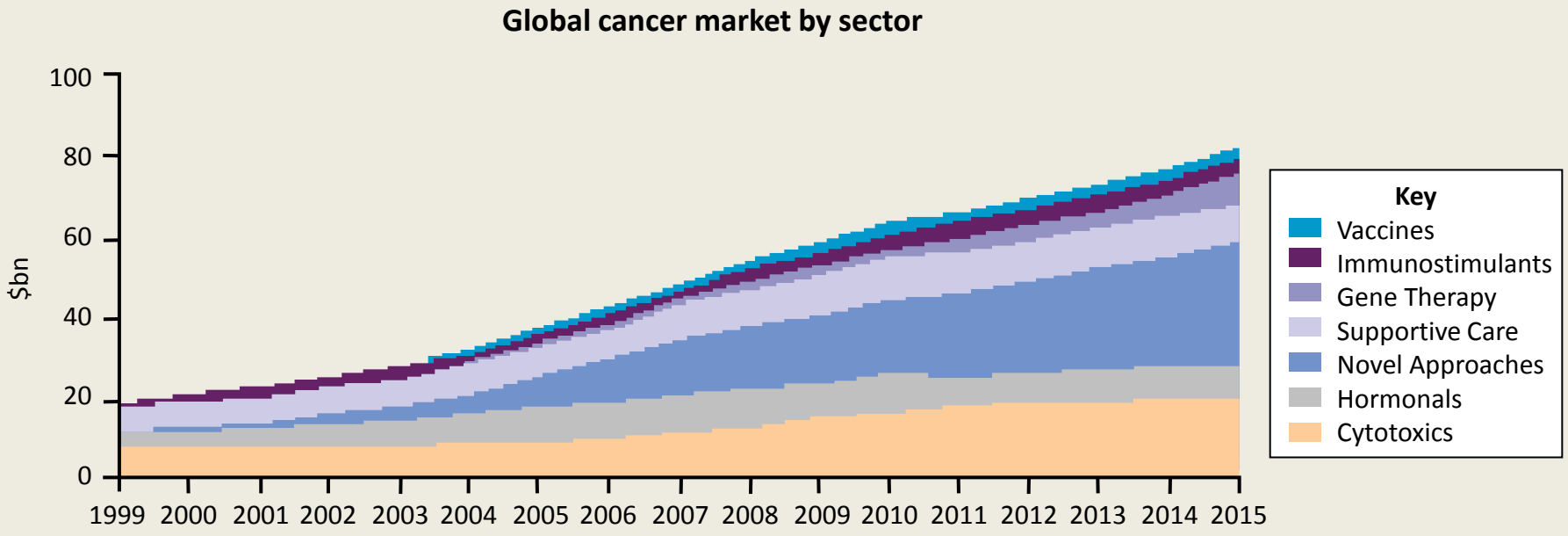
# Launch date for molecular therapies in the USA




McKinsey Consulting, New York

# Cancer market tripled over last decade

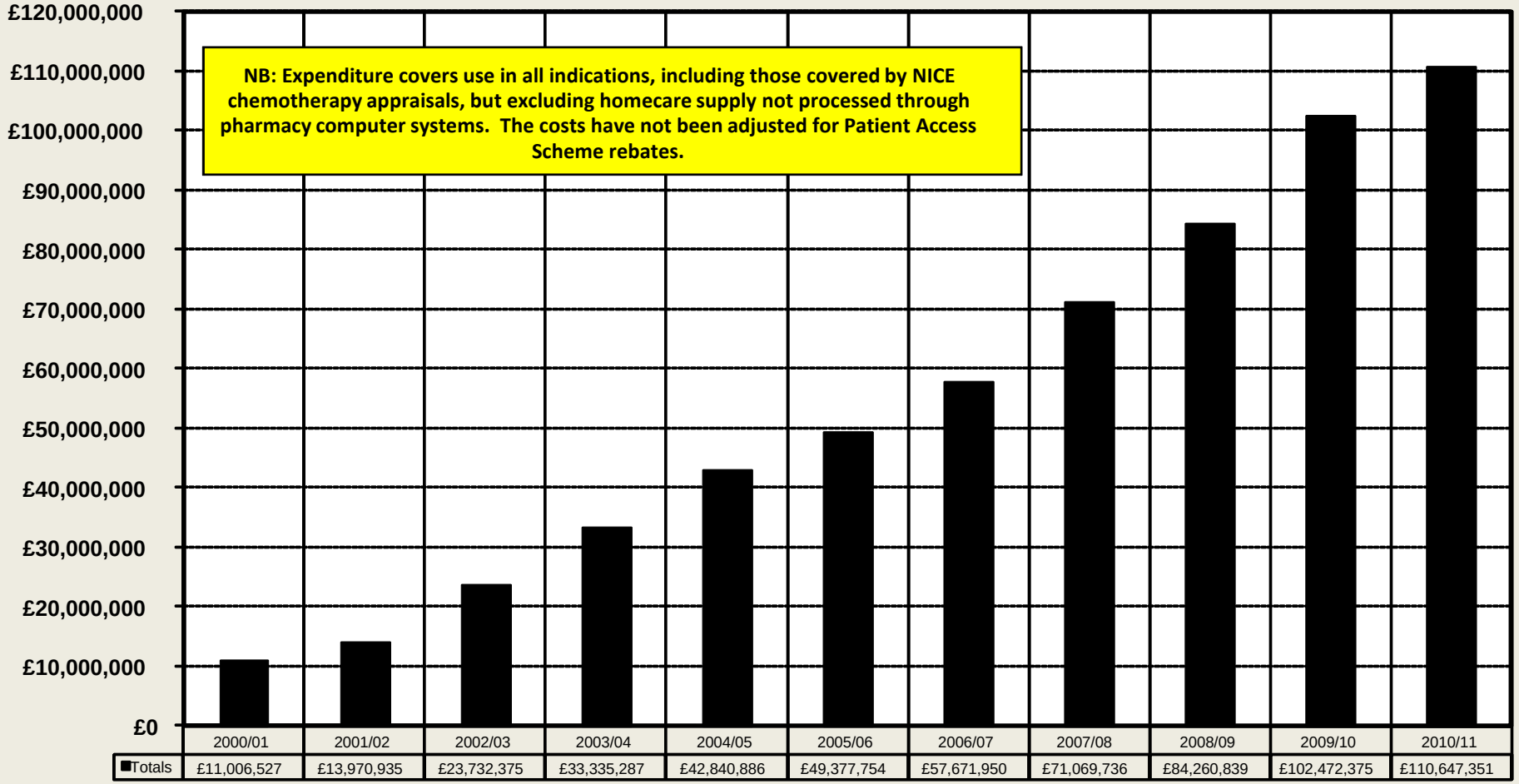
McKinsey Consulting, New York




2010 sales $64bn, CAGR 12% driven by:

- New technology – targeted therapies
- Earlier intervention
- Patient numbers (ageing population – other diseases controlled)

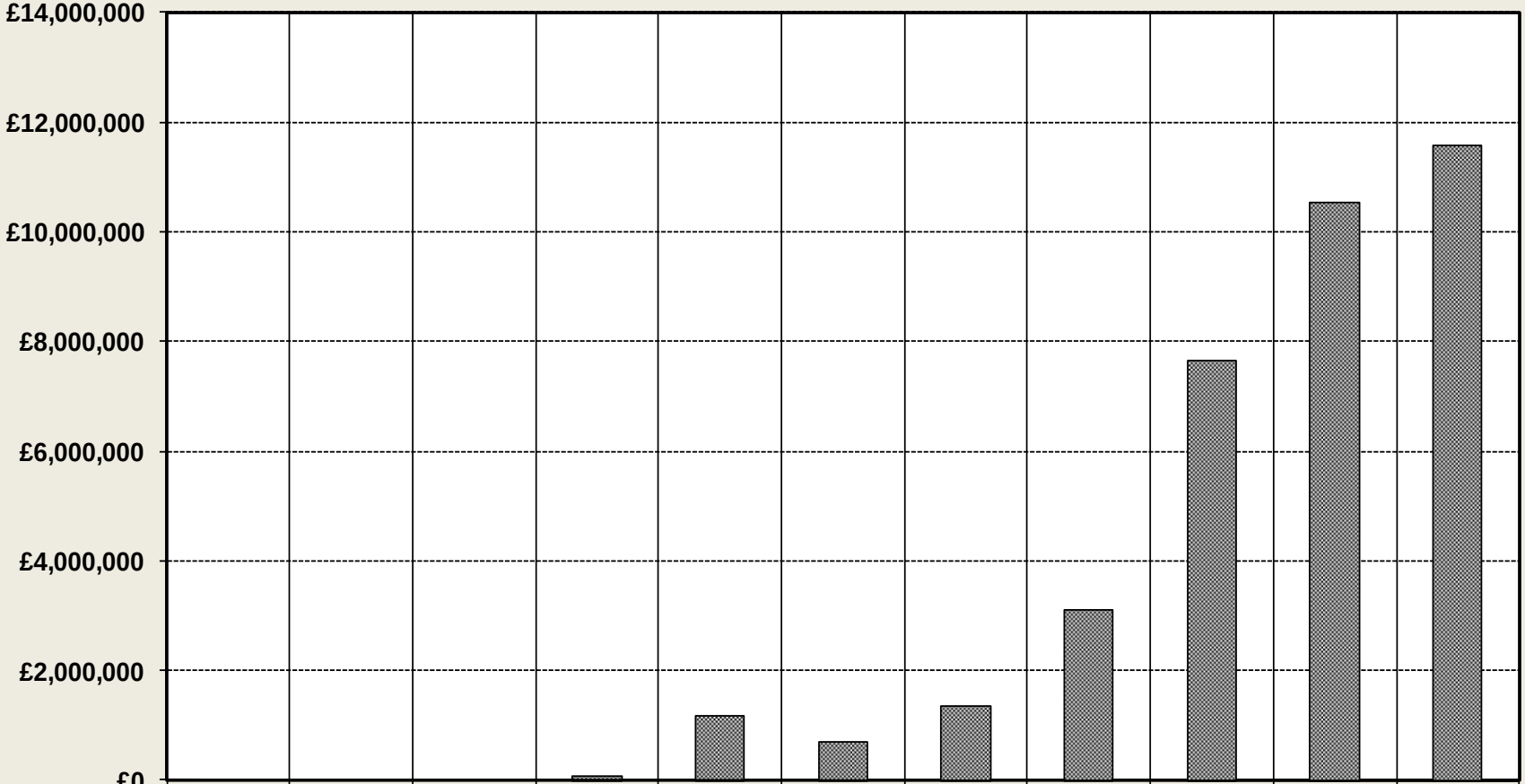
# London Cancer Drugs Annual Expenditure Trends - Drugs Covered by NICE Chemotherapy Appraisals




| | 2000/01 | 2001/02 | 2002/03 | 2003/04 | 2004/05 | 2005/06 | 2006/07 | 2007/08 | 2008/09 | 2009/10 | 2010/11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Totals | £11,006,527 | £13,970,935 | £23,732,375 | £33,335,287 | £42,840,886 | £49,377,754 | £57,671,950 | £71,069,736 | £84,260,839 | £102,472,375 | £110,647,351 |

Produced for the LCNDG by the London Specialist Pharmacy Service

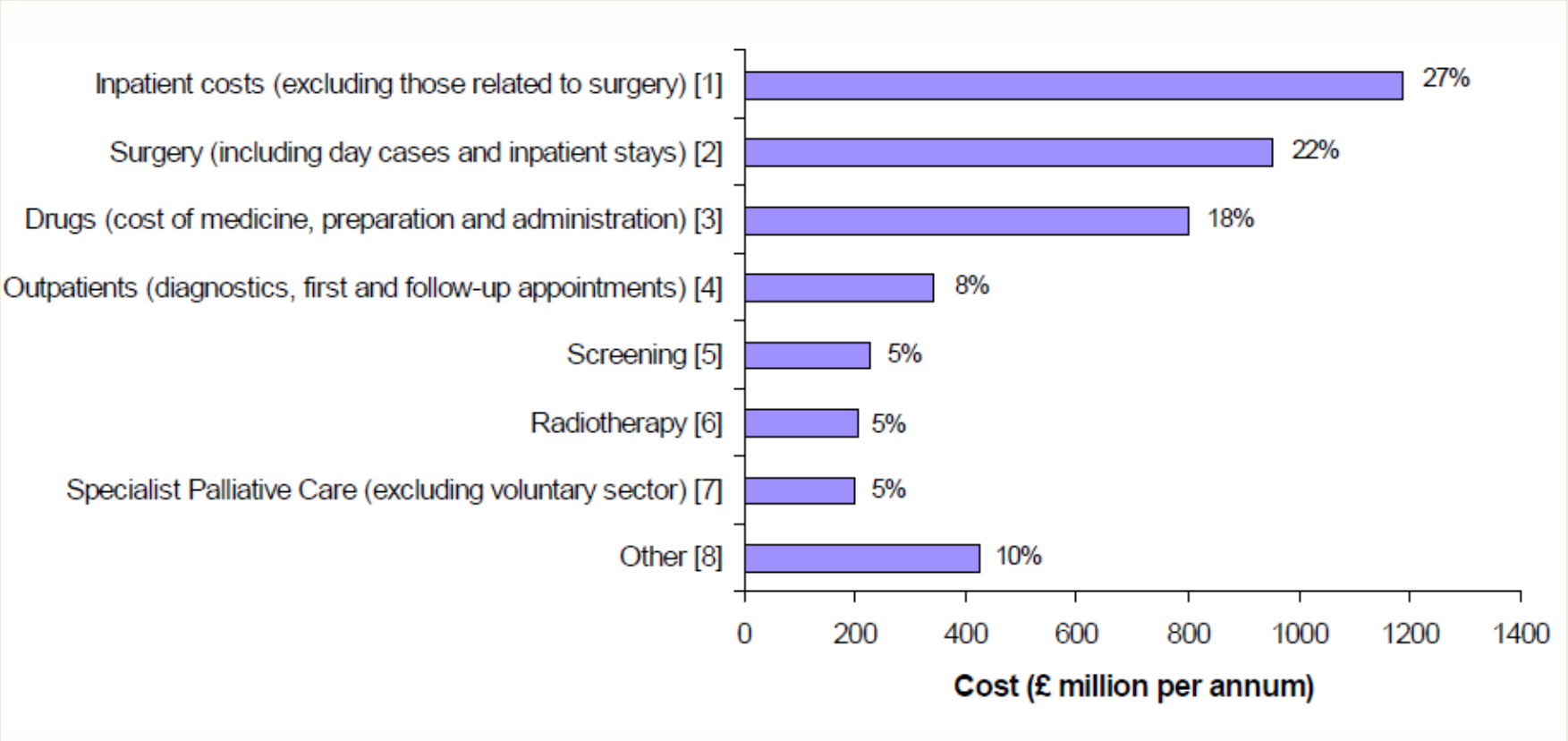
## London Cancer Drugs Annual Expenditure Trends - Recently Licensed Drugs not covered by NICE Chemotherapy Appraisals




| | 2000/01 | 2001/02 | 2002/03 | 2003/04 | 2004/05 | 2005/06 | 2006/07 | 2007/08 | 2008/09 | 2009/10 | 2010/11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Totals | £0 | £0 | £0 | £61,594 | £1,175,752 | £697,171 | £1,342,633 | £3,098,485 | £7,651,760 | £10,535,56 | £11,573,31 |

Produced for the LCNDG by the London Specialist Pharmacy Service

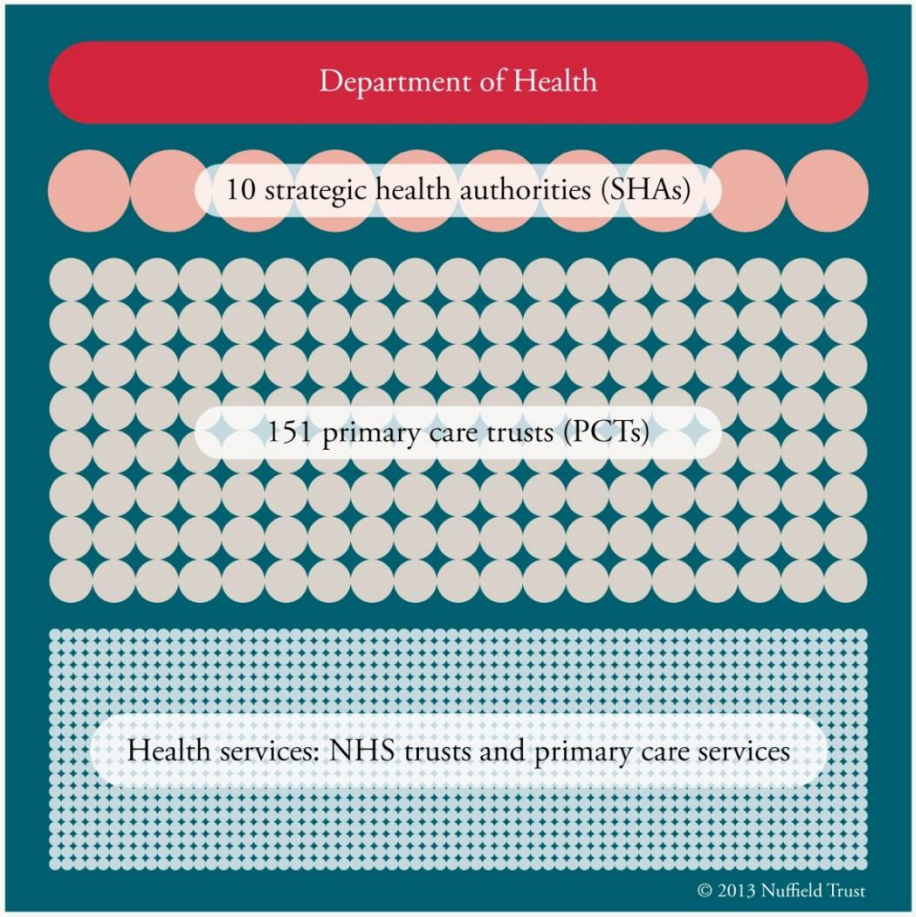
# Cancer expenditure in England



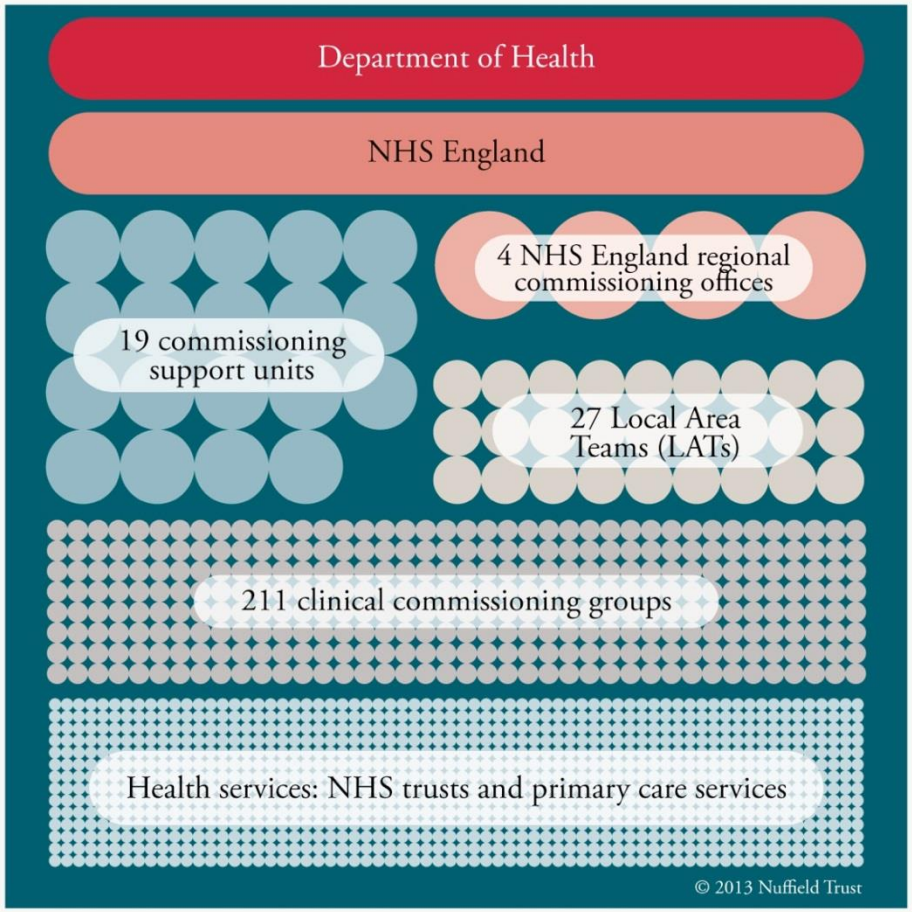

Total expenditure: around £4.35bn pa in England
Expenditure per head of population = £80
(compared with £121 in France and £143 in Germany)

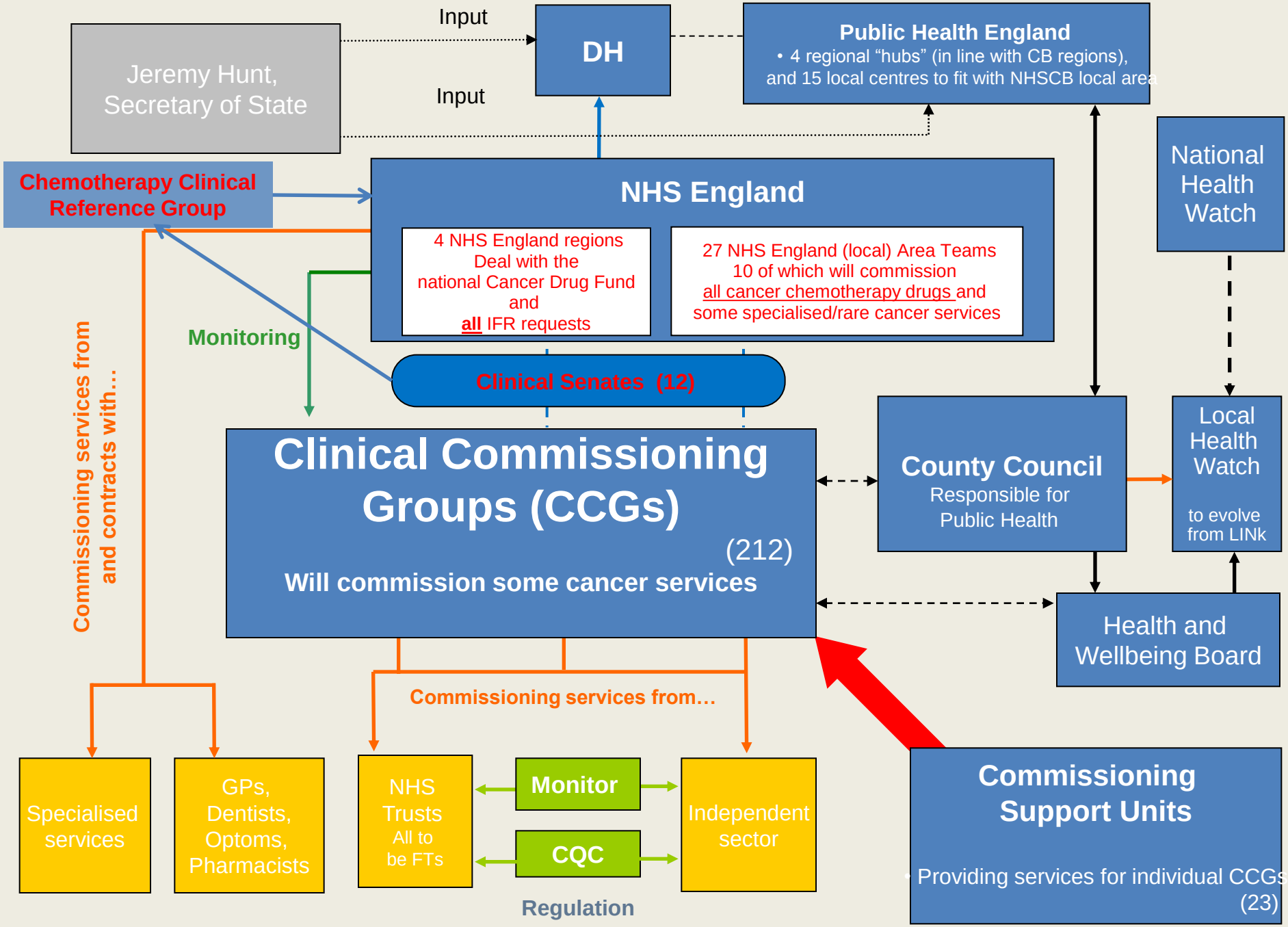
Richards, Mike, “Transforming Inpatient Care”, July 2009

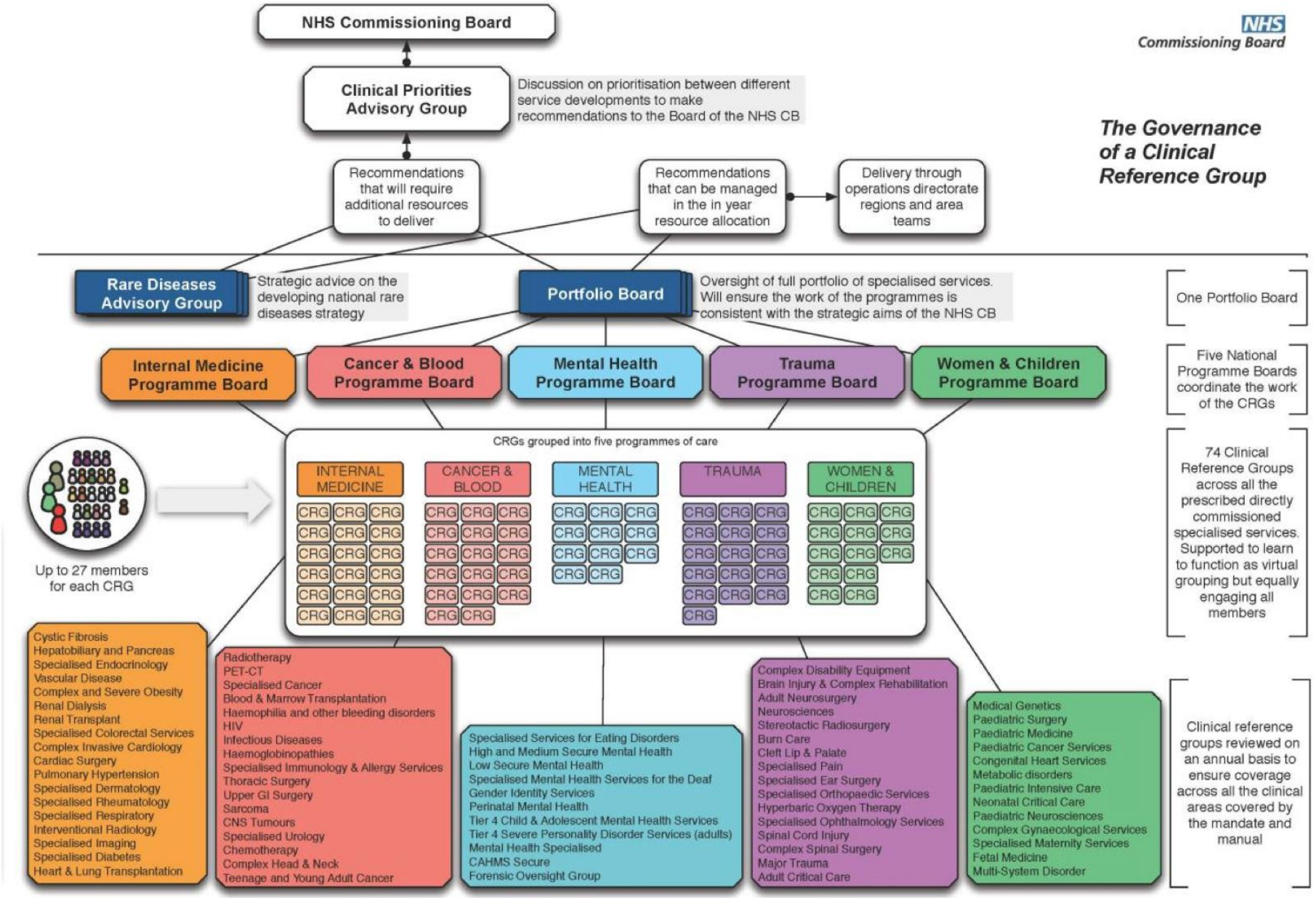
# The NHS in England before the reforms



# NHS April 2013 onwards




Jeremy Hunt, Secretary of State
Input
Input
DH
Public Health England
• 4 regional "hubs" (in line with CB regions), and 15 local centres to fit with NHSCB local area
National Health Watch
Chemotherapy Clinical Reference Group
NHS England
4 NHS England regions Deal with the national Cancer Drug Fund and all IFR requests
27 NHS England (local) Area Teams 10 of which will commission all cancer chemotherapy drugs and some specialised/rare cancer services
Monitoring
Clinical Senates (12)
Commissioning services from and contracts with…
Clinical Commissioning Groups (CCGs)
(212)
Will commission some cancer services
County Council
Responsible for Public Health
Local Health Watch
to evolve from LINk
Health and Wellbeing Board
Commissioning services from…
Specialised services
GPs, Dentists, Optoms, Pharmacists
NHS Trusts
All to be FTs
Monitor
CQC
Independent sector
Regulation
Commissioning Support Units
Providing services for individual CCGs (23)


NHS Commissioning Board
NHS Commissioning Board
Clinical Priorities Advisory Group
Discussion on prioritisation between different service developments to make recommendations to the Board of the NHS CB
The Governance of a Clinical Reference Group
Recommendations that will require additional resources to deliver
Recommendations that can be managed in the in year resource allocation
Delivery through operations directorate regions and area teams
Rare Diseases Advisory Group
Strategic advice on the developing national rare diseases strategy
Portfolio Board
Oversight of full portfolio of specialised services. Will ensure the work of the programmes is consistent with the strategic aims of the NHS CB
One Portfolio Board
Internal Medicine Programme Board
Cancer & Blood Programme Board
Mental Health Programme Board
Trauma Programme Board
Women & Children Programme Board
Five National Programme Boards coordinate the work of the CRGs
CRGs grouped into five programmes of care
INTERNAL MEDICINE
CANCER & BLOOD
MENTAL HEALTH
TRAUMA
WOMEN & CHILDREN
CRG
74 Clinical Reference Groups across all the prescribed directly commissioned specialised services. Supported to learn to function as virtual grouping but equally engaging all members
Up to 27 members for each CRG
Cystic Fibrosis
Hepatobiliary and Pancreas
Specialised Endocrinology
Vascular Disease
Complex and Severe Obesity
Renal Dialysis
Renal Transplant
Specialised Colorectal Services
Complex Invasive Cardiology
Cardiac Surgery
Pulmonary Hypertension
Specialised Dermatology
Specialised Rheumatology
Specialised Respiratory
Interventional Radiology
Specialised Imaging
Specialised Diabetes
Heart & Lung Transplantation
Radiotherapy
PET-CT
Specialised Cancer
Blood & Marrow Transplantation
Haemophilia and other bleeding disorders
HIV
Infectious Diseases
Haemoglobinopathies
Specialised Immunology & Allergy Services
Thoracic Surgery
Upper GI Surgery
Sarcoma
CNS Tumours
Specialised Urology
Chemotherapy
Complex Head & Neck
Teenage and Young Adult Cancer
Specialised Services for Eating Disorders
High and Medium Secure Mental Health
Low Secure Mental Health
Specialised Mental Health Services for the Deaf
Gender Identity Services
Perinatal Mental Health
Tier 4 Child & Adolescent Mental Health Services
Tier 4 Severe Personality Disorder Services (adults)
Mental Health Specialised
CAHMS Secure
Forensic Oversight Group
Complex Disability Equipment
Brain Injury & Complex Rehabilitation
Adult Neurosurgery
Neurosciences
Stereotactic Radiosurgery
Burn Care
Cleft Lip & Palate
Specialised Pain
Specialised Ear Surgery
Specialised Orthopaedic Services
Hyperbaric Oxygen Therapy
Specialised Ophthalmology Services
Spinal Cord Injury
Complex Spinal Surgery
Major Trauma
Adult Critical Care
Medical Genetics
Paediatric Surgery
Paediatric Medicine
Paediatric Cancer Services
Congenital Heart Services
Metabolic disorders
Paediatric Intensive Care
Neonatal Critical Care
Paediatric Neurosciences
Complex Gynaecological Services
Specialised Maternity Services
Fetal Medicine
Multi-System Disorder
Clinical reference groups reviewed on an annual basis to ensure coverage across all the clinical areas covered by the mandate and manual

| Pathway | Old Arrangement | New Arrangement | Notes |
|---|---|---|---|
| Awareness raising | PCT | Public Health | Although commissioned by PH, **CCGs** and NHS England are expected to support awareness campaigns as appropriate |
| Early detection (GP Referral) | PCT | NHS England | **CCGs** expected to manage and improve GP referrals as appropriate |
| Screening | PCT | Public Health through NHS England | GPs directly provide cervical screening (sample taking) and can support programmes in general by endorsing them , working with PH and encouraging patients to attend |
| Diagnostics | Mostly PCT, some Specialised Commissioning | **CCG** | |
| Surgery | Mostly PCT, some Specialised Commissioning | Mostly **CCG**, some NHS England | **CCGs** responsible for common cancers such as breast and colorectal. NHS England responsible for rare cancers such as brain and anal. |
| Chemotherapy | Mostly PCT, some Specialised Commissioning | NHS England | |
| Radiotherapy | Mostly PCT, some Specialised Commissioning | NHS England | |
| Living with and beyond cancer | PCT | **CCG** / NHS England collaboratively | Commissioning arrangements for this area need to be worked through with NHS England. |

# NHS Commissioning Board (2)

- **Specific functions**
- **CDF**
- **Chemotherapy**
- **Management of IFRs**
- **Oversight and Performance Management of High Secure Hospitals and Services**
- **Safe and Sustainable Programme**.
  - paediatric congenital heart surgery
  - paediatric neurosurgery services
- **Safeguarding Rarity and Highly Specialised Services**.

http://www.commissioningboard.nhs.uk/files/2012/11/op-model.pdf

# Convergence

- 2012-13- transition year
  - To finalise future commissioning of chemotherapy
- Single prioritisation tool
- Convergence of CDF processes
- National audit & outcome data
- National list

# Convergence….National list

**National Cancer Action Team**

**List of Drugs & Indications for Cancer Drug Fund at April 2012**

**Drug list and indications compiled from data available on SHA websites in April 2012**

Key

- Routinely funded via CDF
- Considered but not routinely CDF funded
- Not yet considered or no requests received
- In base line commissioning
- Individual basis by CDF

NB

1. The data above is based on the CDF indications as listed in April 2012.
2. There may be some changes required as some of the indications overlap, and will be reviewed in time.
3. A limitation is that there is variation in commissioning of the drugs within the cancer networks that fall within an SHA.
4. Some agents such as denosumab and plerixafor do not have direct anti cancer activity, and although are on some CDF lists, are not on all as they are funded out with the CDF.
5. The London position related to decisions taken from April 2011.

| Drug | Indication | North West | North East | York & Humber | West Midlands | East Midlands | East of England | London | South East Coast | South Central | South West | % of total CDF applications for 11/12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Oncology drugs with the Highest Number of Applications (70.2% of the total CDF applications)** | | | | | | | | | | | | |
| Abiraterone | Metastatic prostrate cancer. 2nd line. Castrate-resistant with previous docetaxel-containing chemotherapy. | | | | | | | | | | | 11.8 |
| Bevacizumab | Metastatic colorectal cancer. 1st line. | | | | | | | | | | | 21.9 |
| | Metastatic colorectal cancer. 2nd or 3rd line. | 2nd | 2nd | 2nd | | 2nd | | 2nd | | | | |
| Cabazitaxel | Metastatic hormone-refractory prostate cancer. 2nd line treatment following docetaxel-based therapy | | | | | | | | | | | 1.7 |
| Cetuximab | Metastatic colorectal cancer (KRAS wild-type). 1st line treatment with chemotherapy including continuation of treatment for patients receiving cetuximab according to NICE TA176, but have failed to become operable at 16 weeks, but who have not progressed. | | | | | | | | | | | 11.6 |
| | Metastatic colorectal cancer (KRAS wild type). 2nd line. | | | | | | | | | | | |
| | Metastatic colorectal cancer (KRAS wild type). 3rd line treatment and beyond (as monotherapy) in advanced disease. | | | | | 3rd only | | | | | | |
| Cetuximab | Non-Metastatic colorectal cancer (KRAS wild type). Neo-adjuvant chemotherapy with an irinotecan based combination for inoperable and locally advanced non metastatic bowel cancer in patients with wild type KRAS and no previous treatment with Cetuximab. | | | | | | | | | | | |
| Everolimus | Renal cell carcinoma. 2nd line treatment. Previous treatment must have been VEGF-targeted. | | | | | | | | | | | 5 |
| Everolimus | Advanced pancreatic neuroendocrine tumours (NET). | | | | | | | | | | | |
| Eribulin | Locally advanced or metastatic breast cancer. In patients who have been previously treated with, or unsuitable for, an anthracycline, taxane and capecitabine | | | | | | | | | | | 3.1 |
| Fulvestrant | Locally advanced or metastatic breast cancer. 3rd or 4th line hormone antagonist therapy. | | | | | | | | | | | 3.6 |
| Ipilimumab | Advanced melanoma. 2nd line therapy | | | | | | | | | | | 1.8 |
| Lapatinib | Advanced or metastatic breast cancer. In patients with progression following prior therapy, which must have included anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting. | | | | | | | | | | | 5.2 |
| | Advanced breast cancer progressing with CNS disease on trastuzumab. Single agent or in combination with Capecitibine | | | | | | | | | | | |
| | Advanced breast cancer. In patients who have poor venous access, or have had a previous reaction to trastuzumab, or have cardiac toxicity as a result of trastuzumab. | | | | | | | | | | | |
| | Advanced breast cancer. In patients who have had a sustained response to trastuzumab followed by progression | | | | | | | | | | | |
| | Metastatic Breast Cancer. 1st line with aromatase inhibitor | | | | | | | | | | | |
| Sorafenib | Advanced hepatocellular carcinoma. 1st line. | | | | | | | | | | | 4.5 |

# Changes to the list (1)

- >150 to around 50 drugs/indications
- standard chemotherapy
  - funded by the NHSCB as a PbR exclusion and will become part of baseline chemotherapy commissioning
- not listed as standard chemotherapy (above) & not explicitly mentioned on the DH PbR exclusions list
  - will be included in tariffs already paid to provider Trusts and will therefore not be funded separately by the NHSCB
- poorly evidenced chemotherapy which will not routinely be funded by the CDF or NHSCB via any mechanism

# Changes to the list (2)

National CDF cohort policy list will be regularly updated by the Clinical Reference Group for Chemotherapy as part of their horizon scanning process

For patients who have already received an approved CDF application, prior to 1st April 2013, they will continue to receive funding from the CDF for as long as their consultant decides they are receiving a clinical benefit

# Application/Notification process

- online, web based notification system
  - TBC in London, paper based in short term
- Form completed by consultant responsible for the patient's care, or a nominated senior doctor in their team.
  - Pt demographic details
  - confirming the clinical criteria for use,
  - Confirmation of patient consent to treatment.
  - The nhs.net details of the specialist cancer pharmacist within the provider Trust
  - NHS.net ONLY

# Chemotherapy Funding

- From April 2013;
  - All chemotherapy commissioned by NHS England via 10 of the 27 (Local) Area Teams
  - Provider-based allocation of funding
  - Delivery Tariffs will be mandatory from April 2013
    - Five bands based on resources required to deliver the drug(s). Reflects nurse & chair time
  - Procurement Tariffs expected in 2014
    - Ten (+?) bands based upon national reference costs. To include pharmacy & preparation costs.

# Chemotherapy Funding

| Status | Adult / Paed | Regimen Name (Dataset short version) | Regimen name (Long version) | Component Drug name | Proc. OPCS | Proc. HRG | Delivery OPCS | Delivery HRG | Usual Cycle Length |
|---|---|---|---|---|---|---|---|---|---|
| Existing | Adult | AC | AC | Cyclophosphamide | X70.2 | SB02Z | X72.3 | SB12Z | 21 days |
| | Adult | AC | AC | Doxorubicin | X70.2 | SB02Z | X72.3 | SB12Z | 21 days |

| HRG Code | HRG Name | Tariff (£) Per Episode |
|---|---|---|
| SB11Z | Deliver exclusively oral chemotherapy | 128 |
| SB12Z | Deliver simple parenteral chemotherapy at first attendance | 161 |
| SB13Z | Deliver complex parenteral chemotherapy at first attendance | 321 |
| SB14Z | Deliver complex parenteral chemotherapy with a prolonged infusion at first attendance | 482 |
| SB15Z | Deliver subsequent elements of a chemotherapy cycle | 321 |
| SB17Z | Deliver Chemotherapy for regimens not on the National List | |

# CDF Post April 2013

- Single national allocation of funding
- Single national list of drugs  (27) & indications (64)
- Provider-based allocation of funding
- National list based on cohort policies
- Access to the CDF for drugs covered by a cohort policy would only be on a registration/notification basis (not an approval basis).
- Individual patient applications would be by exception and handled by a regional CDF clinical panel
- Single web based registration system with four operating points – one in each region

# CDF Post April 2013

- Chemotherapy Clinical Reference Group
  - Many different baseline commissioning positions
  - Regular horizon scanning  using London/North West Scoring Tool
  - Links to Clinical Senates
  - No early adopters?
  - Individual Cancer Drug Fund Requests (ICDFR)
  - ≥ 20 cases = cohort
  - Affordability & removal of existing drugs
  - ……but remember, no activity costs allowed

# CDF Post April 2013

- Drugs removed from CDF
  - Baseline commissioning (including NICE)
  - Included in HRG tariff
  - Removed from CDF altogether
- Audit & Finance
  - ≤ 10% patients never commence treatment
  - Actual spend approximately 60% of predicted

# Future Cancer Drug Commissioning

- Chemotherapy Tariffs
  - Delivery Tariffs 2013
  - Procurement Tariffs 2014
- Chemotherapy Closer to Home
- Centralised Cancer Drug Commissioning
  - NHS England (NCB)
  - Chemotherapy Clinical Reference Group
  - Standard Service Specification B3L – Adult SACT
- Value Based Pricing
  - Not retrospective
  - ‘Blockbusters’ - 18/year maximum
  - Across all therapeutic areas?

# QIPP

- Cancer services need to make a contribution to the £20billion NHS savings required
- Reducing unnecessary admission and reducing length of stay will improve quality and productivity
- While at the same time, improving early diagnosis, reducing premature deaths, improving QoL and enhancing end-of-life care
- Concentrate on prevention and screening

# National QIPP workstreams

| |
|---|
| Urgent and emergency care |
| Primary care |
| Technology and digital vision |
| Procurement |
| End-of-life care |
| Productive care |
| Back office functions |
| Medicines use and procurement |
| Clinical support services |
| Right care |
| Safe care |
| Long term conditions |

# Innovation, Health and Wealth: promoting uptake of NICE guidance

- Support for adoption of NICE guidance
- Compliance regime and uptake metrics
- End to local duplication of NICE evaluation
- Support for the NICE scientific advice programme
- Targeted effort to implement diagnostic and treatment recommendations
- Immediate transfer of DH Innovative Technology Adoption and Procurement Programme (iTAPP) to NICE

# Optimising medicines use will…

1. Improve outcomes
2. Deliver greater productivity
3. Potentially reduce whole system costs

# Repositioning medicines

- Support better outcomes
- Support greater productivity
- Support/require workforce re-design
- Supply chain
- Value-based pricing

# Significant obstacles

- Cultural – Doctor knows best and passive consumers
- Fear of the unknown and belief in current system
- Silos and funding
- Truly cash releasing?
- Scepticism about partnership working

# What are the barriers to adopting innovation?

- Perverse incentives
  - Trusts lose income
  - Solution to share efficiencies across the LHE
    - * Integrated Cancer Systems in London
- UK slow adopters (compared to Europe) of innovation
    - * Thrombolytic therapy in MI

**Why?**

# Why are some people not offered appropriate medicines?

- **People are not diagnosed**
  - 23% of newly diagnosed cancer patients come through A&E
- **Tests required by NICE are not done**
  - The need for EGFR testing outstrips the number done by 1.7
- **Varying access to specialist care**
  - 18% of those with glioma did not receive carmustine as not discussed at an MDM
- **Capacity to deliver is insufficient**
  - The rate of delivery of chemotherapy for lung cancer doubles if seen by a CNS
- **Commissioning is deficient**
  - Commissioners and providers argue over who should pay
- **Policies are variable**
  - The elderly with lung cancer do not receive chemotherapy as often as their condition warrants

# Are there alternative biological therapies?

- Cloning human genetic material and development of *in vitro* biological production systems has allowed development of virtually any recombinant DNA-based biological substance for eventual development of a drug
- Monoclonal antibody technology combined with recombinant DNA technology has paved the way for tailor-made and targeted medicines
- Gene- and cell-based therapies are emerging as new approaches

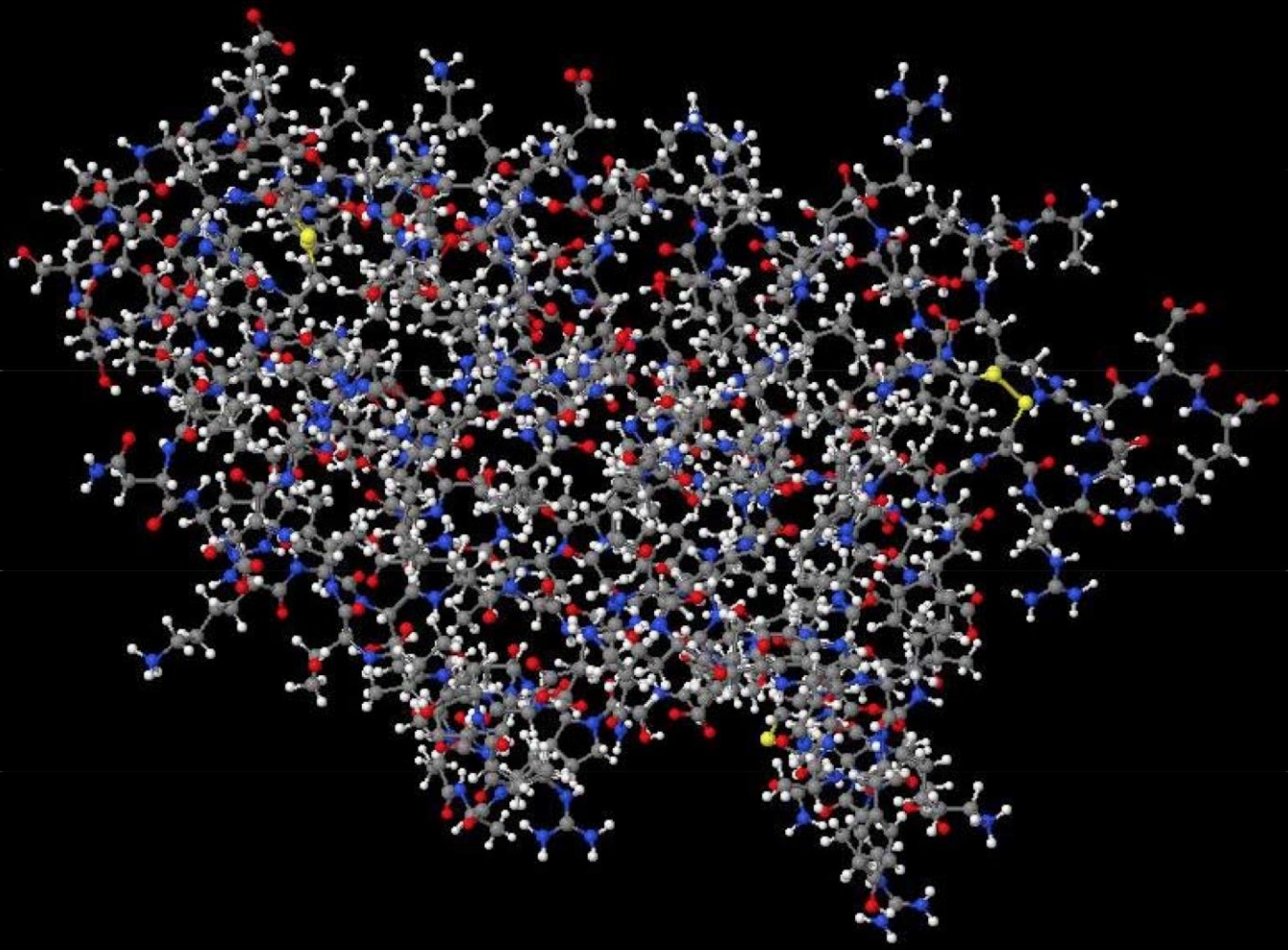
# Biosimilars

- Unlike small molecule drugs, biologics exhibit high molecular complexity
- Follow-on manufacturers do not have access to the original molecular clone or cell line, nor to the exact manufacturing process
- Structurally different – potential for differences in ADE* unlikely to be picked up pre-marketing
- Might therefore perform differently in terms of efficacy and safety

*ADE = Adverse Drug Events

# Biosimilars

- After patent expiry of an approved biological agent any company can ‘copy’ and market these biologics (biosimilars) after regulatory scrutiny
- Biosimilars currently marketed include: –insulin, HGH, interferons, G-CSF, erythropoietins, etc
- Biosimilars are subject to a more detailed approval process than chemical generics but not as rigorous as for the originator product
- Clinical results must show similarity to the referenced biologic



epoetin

ranitidine

# Size & complexity – small molecule drugs and biologics

IgG antibody
~ 25,000 atoms

Human growth hormone (HGH)
~ 3,000 atoms

Aspirin
21 atoms

# Biosimilars

- Complexity in development/manufacturing Rituxan/Mabthera–biosimilar development suspended by both Samsung and Teva/Lonza. First entrant expected 2016
- Patient safety paramount:
  - Careful post-marketing surveillance
  - Further rationale for not considering a follow-on product to be interchangeable with an innovative product
- Traceability required to ensure interchangeability does not compromise safety
- EMA allows extrapolation e.g. data in RA extrapolated to NHL

# Recommendations

- **Diagnosis:**

  Test the quality of MDM decision making

- **Funding:**

  Molecular tests should be commissioned by the CB

  A new system for non-PbR excluded drugs needs to be introduced

- **Delivery:**

  Expand the specialist nursing workforce

  A viable Cancer Network system is needed

# Summary

- There is no choice – greater productivity required to mitigate serious funding issues
- Need to reduce variation and move the mean
- There is a need to **create headroom** for true innovation
- Partnership working required between primary care, interface and secondary care – a serious challenge
- Good information systems and transparency of data
- There are no quick fixes
- Be fully informed about biosimilars and ensure traceability
- None of this happens without high quality medicines management