Dr Nicola Mackie
Imperial College Healthcare NHS Trust, London

<table>
<thead>
<tr>
<th>Speaker Name</th>
<th>Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicola Mackie</td>
<td>has sat on Advisory Boards for ViiV, Gilead and MSD. She has been a speaker at company-sponsored events for ViiV and Gilead. She has been involved with development of educational materials for ViiV and has received sponsorship to attend a conference from BMS.</td>
</tr>
<tr>
<td>Date</td>
<td>October 2014</td>
</tr>
</tbody>
</table>
New drugs, new rules: balancing the books

Dr Nicky Mackie
Imperial College Healthcare NHS Trust
New drugs, new rules: balancing the books

What proportion of your overall budget do ARVs represent?

1. 0-20%  
   - 9%
2. 21-40%  
   - 8%
3. 41-60%  
   - 11%
4. 61-80%  
   - 25%
5. >80%    
   - 20%
6. Don’t know  
   - 28%
New drugs, new rules: balancing the books
Did you balance your drug budget last year?

1. Yes 29%
2. No 14%
3. Don’t know 31%
4. Not my problem/Don’t care 26%
<table>
<thead>
<tr>
<th>Service Sub-code</th>
<th>Description</th>
<th>Comments / reporting method</th>
<th>Payment method</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCBPS14z1</td>
<td><strong>HIV Drugs</strong>&lt;br&gt;   (a) ARVs (adult/Paeds)&lt;br&gt;   (b) PEP/PEPse&lt;br&gt;   (c) Non ARVs (Adult/Paeds)</td>
<td>Excluding Home Delivery Charges, including detail of drugs as per reporting of other specialised drugs&lt;br&gt;SLAM / Bespoke Quarterly Drug &amp; Diagnostic return</td>
<td><strong>Pass through</strong></td>
</tr>
<tr>
<td>NCBPS14z2</td>
<td><strong>HIV Infrastructure/Outpatients Caseload</strong>&lt;br&gt;   (a) Infrastructure&lt;br&gt;   (b) Non ARVs&lt;br&gt;   (c) High cost diagnostics</td>
<td>Including Infrastructure, Fixed Cost Block Element, non-ARVs and High Cost Diagnostics</td>
<td>Fixed cost Block</td>
</tr>
<tr>
<td>NCBPS14z3</td>
<td>HIV Admitted Patient Care&lt;br&gt;   (a) Laboratory&lt;br&gt;   (b) Pharmacy&lt;br&gt;   (c) High cost diagnost...</td>
<td>Providing of ARVs/ Drugs&lt;br&gt;   Quarterly Drug &amp; Diagnostic return</td>
<td>PbR</td>
</tr>
<tr>
<td>NCBPS14z4</td>
<td><strong>HIV Delivery Charges</strong></td>
<td>This should be reported through the bespoke monthly HIV return</td>
<td>Pass through</td>
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<tr>
<td>NCBPS14z5</td>
<td>HIV New Outpatients</td>
<td>This should be reported through the bespoke monthly HIV return</td>
<td>Non demographic growth – Block / annual reconciliation on new patients</td>
</tr>
<tr>
<td>NCBPS14z6</td>
<td>HIV Babies of Indeterminate Status</td>
<td>This should be reported through the bespoke monthly HIV return</td>
<td>Cost and volume – local tariff</td>
</tr>
<tr>
<td>NCBPS14z7</td>
<td>HIV Newfill</td>
<td>Providers are requested to report and recharge Newfill through Chelsea and Westminster Hospital NHS Foundation Trust.</td>
<td>Block through lead provider and for cross charge between providers and lead provider</td>
</tr>
</tbody>
</table>

**Block contract?**

**Pass through costs?**
ARV budget

• Block contract: provider paid an annual fee in instalments by commissioner for providing a defined range of services

• Pass through costs: budget based on out-turn from previous year (+ growth) divided into monthly instalments; quarterly reconciliation against data from provider (over- and under-performance)
Challenges

• No formal training in ‘balancing the books’
  – Increasing financial responsibility in a tough economic climate
  – Contain *and reduce* costs without affecting current high standards of care and treatment outcomes
Challenges

• No formal training in ‘balancing the books’
  – Increasing financial responsibility in a tough economic climate
  – Contain *and reduce* costs without affecting current high standards of care and treatment outcomes

• Constantly evolving commissioning landscape
• Inconsistency in access to drugs across the UK
• Differences in regional prescribing guidelines
• No clear single price
Back in the clinic...

- Drug X
- Single pill
- Statistically superior in all clinical trials
- Fewer side effects than comparators
- More expensive...£££
British HIV Association guidelines for the treatment of HIV-1-positive adults with antiretroviral therapy 2012
(Updated November 2013. All changed text is cast in yellow highlight.)

London Therapeutic Tender Implementation: Guidance for Clinical Use

4th June 2014
FINAL
Therapeutic Tendering

• General principles:
  – The tendering process has realised large savings for the NHS
  – Used to achieve ‘optimal’ pricing for HIV high-cost drugs: aim to ensure equity of access to HIV treatment and care for increasing numbers of patients

• Financial impact* in London:
  – Annual expenditure on ARVs in London= £180 million
  – Since 2011, Therapeutic Tendering saved ~£10.4 million (recurrent annual savings) – equivalent to a reduction of ~5.2% in annual ARV expenditure
  – The new therapeutic contract (April 2014) is expected to save at least £4.8 million (2.5%) on branded ARVs and a further £16 million on use of generics

*branded ARVs
Therapeutic Tendering

• Other regions:
  – Midlands and East: re-tendered and have regional guidelines
  – N England: tender underway: no current guidelines
  – S England: previous tender (due to re-tender Sep 2015): no current guidelines

• Why no national procurement of drugs?
British HIV Association guidelines for the treatment of HIV-1-positive adults with antiretroviral therapy 2012

(Updated November 2012; emphasis and text is cast in yellow highlight.)

London Therapeutic Tender Implementational Guidance for Clinicians

4th June 2014

FINAL
How does drug X reach the clinic?
How is HIV care commissioned?

- Local Authorities: Responsible for prevention services for local populations - including HIV prevention and GU services.
- NHS England: Commission community and acute care for local populations.
- Clinical Commissioning groups: Responsible for commissioning specialised services through provider based commissioning for all eligible England patients – HIV care & treatment and all ARVs, irrespective of use.
NHS England: Specialised Services

NHS England

- Internal Medicine
- Cancer and Blood
- Mental Health
- Trauma
- Women and Children

Clinical Reference Groups

HIV
Clinical Reference Groups (CRGs)

- Comprise:
  - clinicians, commissioners, public health experts, representatives from patient/carer groups and professional organisations

- Roles:
  - review and develop national strategies, service specifications and clinical access policies
  - define quality measures and build quality dashboards
<table>
<thead>
<tr>
<th>HIV CRG</th>
<th>Chair – Simon Barton</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NORTH</strong></td>
<td><strong>MIDLANDS &amp; EAST</strong></td>
</tr>
<tr>
<td>North East (Vice Chair)</td>
<td>Edmund Liang Ong</td>
</tr>
<tr>
<td>Greater Manchester</td>
<td>Edmund Wilkins</td>
</tr>
<tr>
<td>Yorkshire + Humber</td>
<td>Christine Bowman</td>
</tr>
<tr>
<td>Cheshire + Mersey</td>
<td>Mas Chaponda</td>
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<tr>
<td><strong>SOUTH</strong></td>
<td><strong>AFFILIATES</strong></td>
</tr>
<tr>
<td>South West</td>
<td>Mark Gompels</td>
</tr>
<tr>
<td>Thames Valley</td>
<td>Christopher Conlon</td>
</tr>
<tr>
<td>Wessex</td>
<td>Cecilia Priestley</td>
</tr>
<tr>
<td>South East Coast</td>
<td>Martin Fisher</td>
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<tr>
<td><strong>PPE</strong></td>
<td></td>
</tr>
<tr>
<td>Patient rep</td>
<td>Paul Clift</td>
</tr>
<tr>
<td>Patient rep</td>
<td>Memory Sachikonye</td>
</tr>
<tr>
<td>Patient Advocate</td>
<td>Abi Carter</td>
</tr>
<tr>
<td>Patient Advocate</td>
<td>Garry Brough</td>
</tr>
<tr>
<td>Accountable Commissioner</td>
<td>Claire Foreman</td>
</tr>
</tbody>
</table>
Clinical Commissioning Policy Statement: Stribild® for the treatment of HIV-1 infection in adults

September 2013

Reference: NHS ENGLAND BO6/Ps/a

<table>
<thead>
<tr>
<th>Commissioning position:</th>
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</thead>
<tbody>
<tr>
<td>In the context of available effective ARV therapy, Stribild® represents an alternative therapy for patients with HIV infection as per its licensing authorisation. Stribild® will be routinely funded by NHS England in the following scenarios:</td>
</tr>
<tr>
<td>In ARV experienced patients with no prior history of virological failure or drug resistance, and who require a switch from their current regimen where there is a clinical advantage of Stribild® over alternative switch options and where the use of the individual components is not contraindicated.</td>
</tr>
</tbody>
</table>

Or

In ARV-naïve patients with high viral loads who are not suitable for NNRTIs (or others on NNRTIs who need to switch for reasons unrelated to resistance).

And

Where the decision to prescribe Stribild® has been taken after review in a Multidisciplinary HIV specialist treatment meeting and that this will be subject to clinical and commissioner audit.

And

Where Stribild® prescribing is no greater than 5% of the patients in a clinical cohort on treatment.
Why do commissioning policies exist?

BHIVA guidelines

• Limited resources
• Prioritisation of competing needs
• ‘greatest benefit for greatest number’

Commissioning Policy

• No cost-effectiveness analyses in current guidelines
The policy: who decides?

Clinical Reference Group → National Programme of Care Board → Clinical Priorities Advisory Group

CRG Working Group provides an evaluation of the evidence based on clinical efficacy, safety, cost-effectiveness and affordability

Is it a cost pressure? Will it generate savings?

Led by the Accountable Commissioner and involves a finance expert
The policy: who decides?

Clinical Reference Group → National Programme of Care Board → Clinical Priorities Advisory Group

Policy Published → Consultation → Directly Commissioned Services Committee
Commissioning position:

In the context of available effective ARV therapy, Stribild® represents an alternative therapy for patients with HIV infection as per its licensing authorisation. Stribild® will be routinely funded by NHS England in the following scenarios:

In ARV experienced patients with no prior history of virological failure or drug resistance, and who require a switch from their current regimen where there is a clinical advantage of Stribild® over alternative switch options and where the use of the components is not contraindicated.

In ARV-naïve patients with high viral loads who are not suitable for NNRTIs (or others on NNRTI who need to switch for reasons unrelated to resistance).

And

Where the decision to prescribe Stribild® has been taken after review in a Multidisciplinary HIV specialist treatment meeting and that this will be subject to clinical and commissioner audit.

And

Where Stribild® prescribing is no greater than 5% of the patients in a clinical cohort on treatment.
New Drugs Panel

• “ensures that drugs are introduced and managed...in an appropriate, safe and effective manner; a process in line with Trust clinical governance requirements and other national guidelines for maintenance and updating of local formularies”

Ref: NICE guidelines: Developing and Updating Local Formularies
http://www.nice.org.uk/mpc/medicinespracticeguidelines/mpg1.jsp
Back in the clinic...

- Drug X
- Single pill
- Statistically superior in all clinical trials
- Fewer side effects than comparators
- More expensive...£££
Balancing the books: the future

• On-going financial constraint within the NHS
• Commissioning intentions 2015/16

• Cost-effectiveness
• Generics
Cost-effectiveness (1)

- BHIVA guidelines
- Paucity of data comparing different drug regimens
- There is a need to produce and understand cost-effectiveness data
Cost-effectiveness (2)

- What is the additional cost for prescribing drug X compared with a conventional backbone +/- a generic agent?
- How much is reasonable to pay to avoid side effects in some patients?
- What is the true cost of toxicity (more appointments, monitoring etc)?
- Only one of a number of criteria that should be employed in determining whether an intervention should be made available
Generics: Patent expiration dates

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2011</th>
<th>2012</th>
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<tr>
<td>Zidovudine</td>
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<tr>
<td>Lamivudine</td>
<td>Zidovudine</td>
<td>Lamivudine</td>
<td>Nevirapine (IR)</td>
<td>Combivir</td>
<td>Abacavir</td>
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<td>Nevirapine (IR)</td>
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<tr>
<td>Efavirenz</td>
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<thead>
<tr>
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<tr>
<td>Nevirapine (PR)</td>
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<td>Atazanavir</td>
<td>Nevirapine (PR)</td>
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<td>Kivexa</td>
<td>Raltegravir</td>
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<td>Nevirapine (PR)</td>
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<td>Kivexa</td>
<td>Raltegravir</td>
</tr>
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</table>

Discounts range between 60 and 90%
Conclusions

• We should **all** be responsible for ‘balancing the books’
• Collaborative approach with commissioners
• Informed patient choice should remain central to all decisions
• Strive to continue to allow flexibility in our prescribing where appropriate
Thank you

• To all those who offered advice or information:
  – Duncan Churchill
  – Simon Collins
  – Martin Fisher
  – Claire Foreman
  – Linda Greene
  – Nadia Naous
  – Peter Sharott
  – Rosy Weston
  – Ed Wilkins