

Setting the Scene: Medicines Value Programme and Biosimilar Medicines Commissioning Framework

Steve Brown

Regional Pharmacist
NHS England
NHS Improvement

South West Clinical Senate

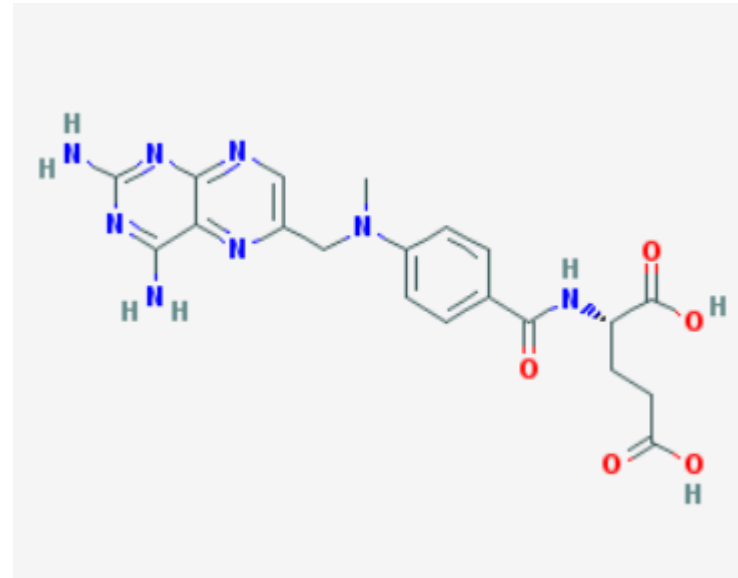
Wednesday 6th December 2017

The Context: 'Biosimilar medicines' / 'Best value care'

- A brief history of Pharmacy!
 - From plants to chemicals to biologicals (and beyond, to ATMPs)



Salix alba



We need to stop taking medicines for granted



Medicines help a lot of people to get well but:

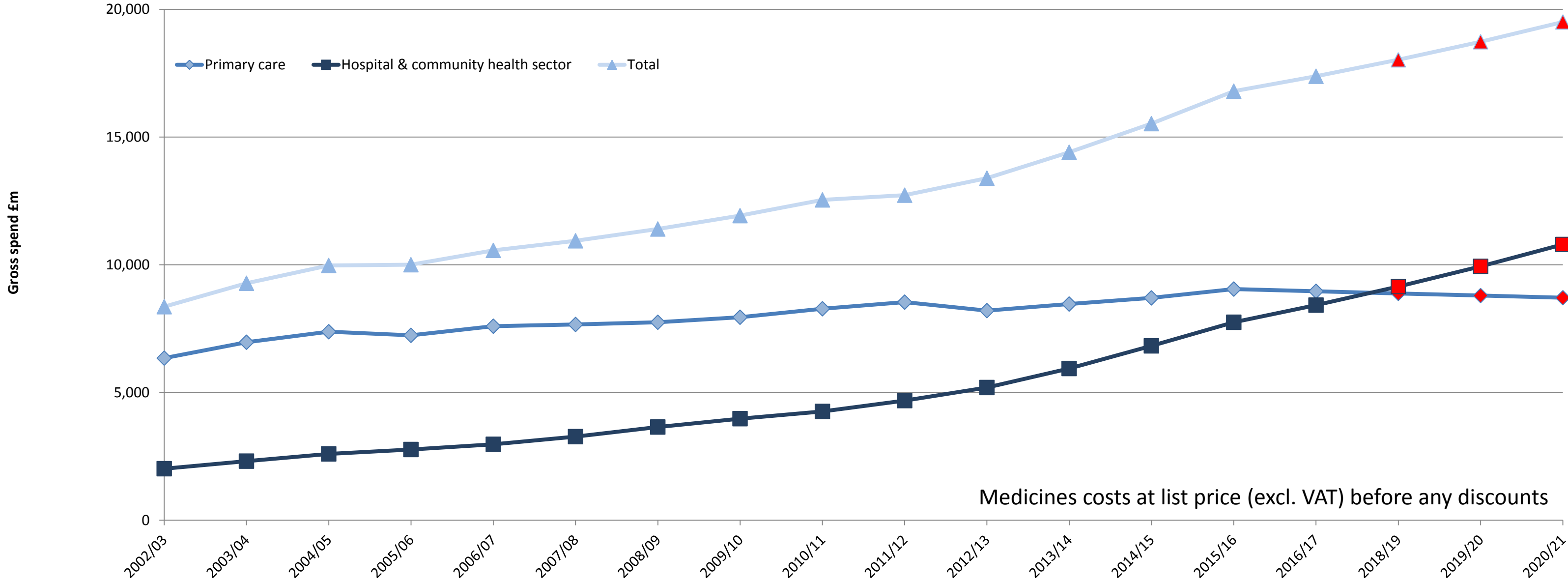
- Medication safety continues to be a serious issue
- **Around 5-8% of hospital admissions are medicines related, many of which are preventable**
- Bacteria are becoming resistant to antibiotics through overuse which is a global issue
- **Up to 50% of patients don't take their medicines as intended meaning their health is affected**
- Use of multiple medicines is increasing – over 1 million people now take 8 or more medicines a day

The NHS spends £17.4 billion a year on medicines (£1 in every £7 that the NHS spends) and they are the most common treatments offered to patients in the NHS

The Medicines Value Programme

How do we help people to get the best results from their medicines – while also achieving best value for the taxpayer?

The NHS drugs bill continues to grow



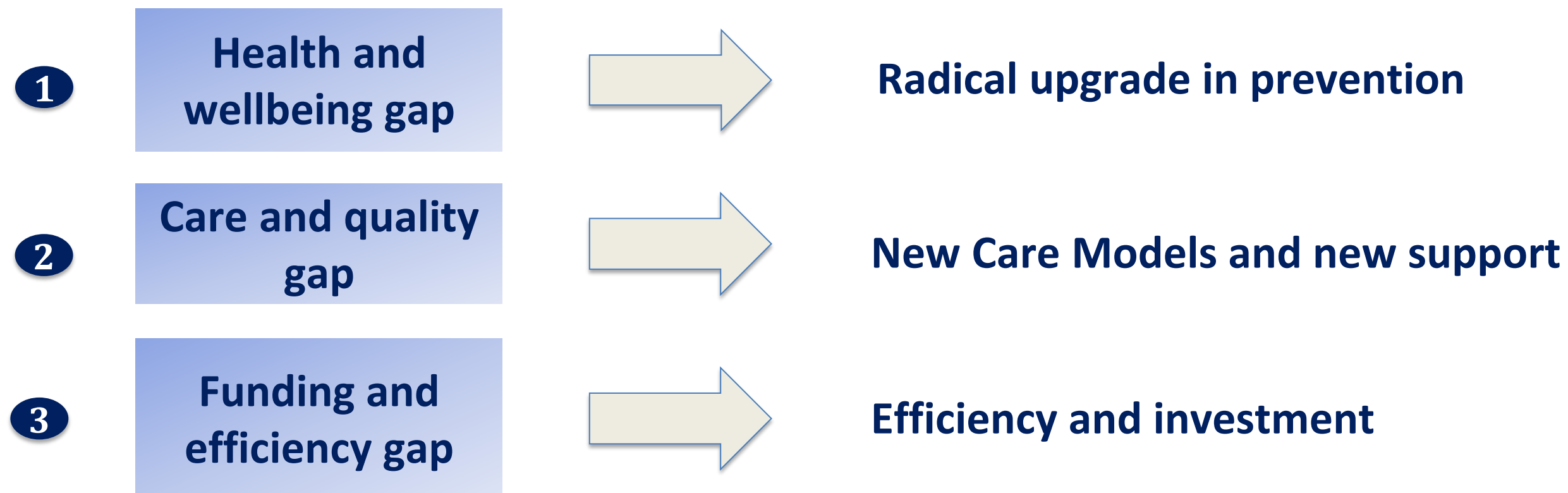
Drivers:

- Uptake of new medicines
- Increasing numbers of medicines used
- Ageing population

Data source: NHS Digital: Hospital Prescribing: England, 2016-17

Achieving the Five Year Forward View

October 2014: For the NHS to meet the needs of future patients in a sustainable way, we need to close all three gaps:



March 2017: Next Steps on the NHS Five Year Forward View:

Strengthening access to high quality GP services and primary care:

- GP surgeries in networks, sharing community nursing, mental health, and clinical pharmacy teams, expand diagnostic facilities, and pool responsibility for urgent care and extended access
- Working more closely with community pharmacists, make fuller use of their contribution

Getting the best value from medicines and pharmacy:

NHS funding is to be used on those things that have the most impact on outcomes for patients

Medicines Value Programme:

Next Steps on the NHS Five Year Forward View and Carter Report

The NHS wants to help people to get the best results from their medicines – while also achieving best value for the taxpayer

- Partnership between NHS England, NHS Improvement, NHS Digital and Health Education England
- It is about using medicines better - savings will be reinvested in improving patient care and providing new treatments to grow the NHS for the future
- Through the regional offices, linking with STPs and ACOs, and nationally coordinated with AHSNs, Getting It Right First Time and NHS Right Care and NHS Clinical Commissioners to create a single voice
- Four Regional Medicines Optimisation Committees are connecting CCGs and providers with the national programme to take coordinated action

1 The NHS policy framework that governs access to and pricing of medicines

2 The commercial arrangements that influence price

3 Optimising the use of medicines

4 Developing the infrastructure to support an efficient supply chain

It is a strategic priority of the NHS for medicines and pharmacy, as outlined in the 'Five Year Forward View next steps' to deliver the 'Medicines Value Programme'

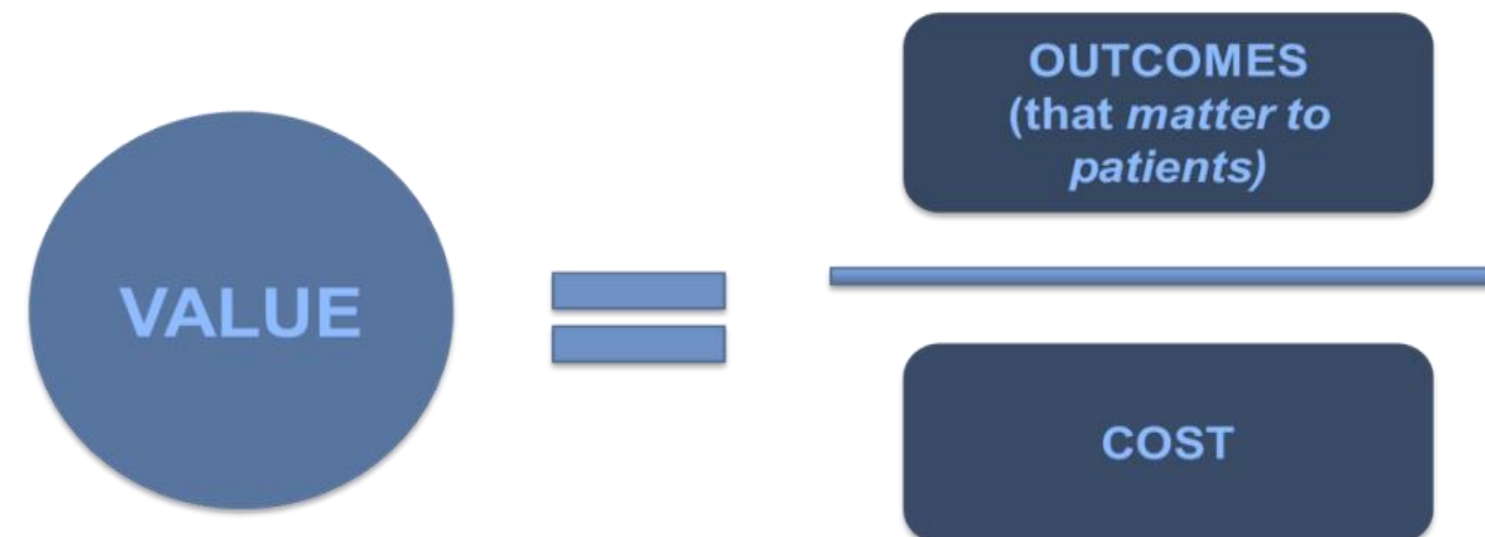
What does medicines value mean?

Measurable improvement in patient outcomes while maintaining an affordable medicines bill

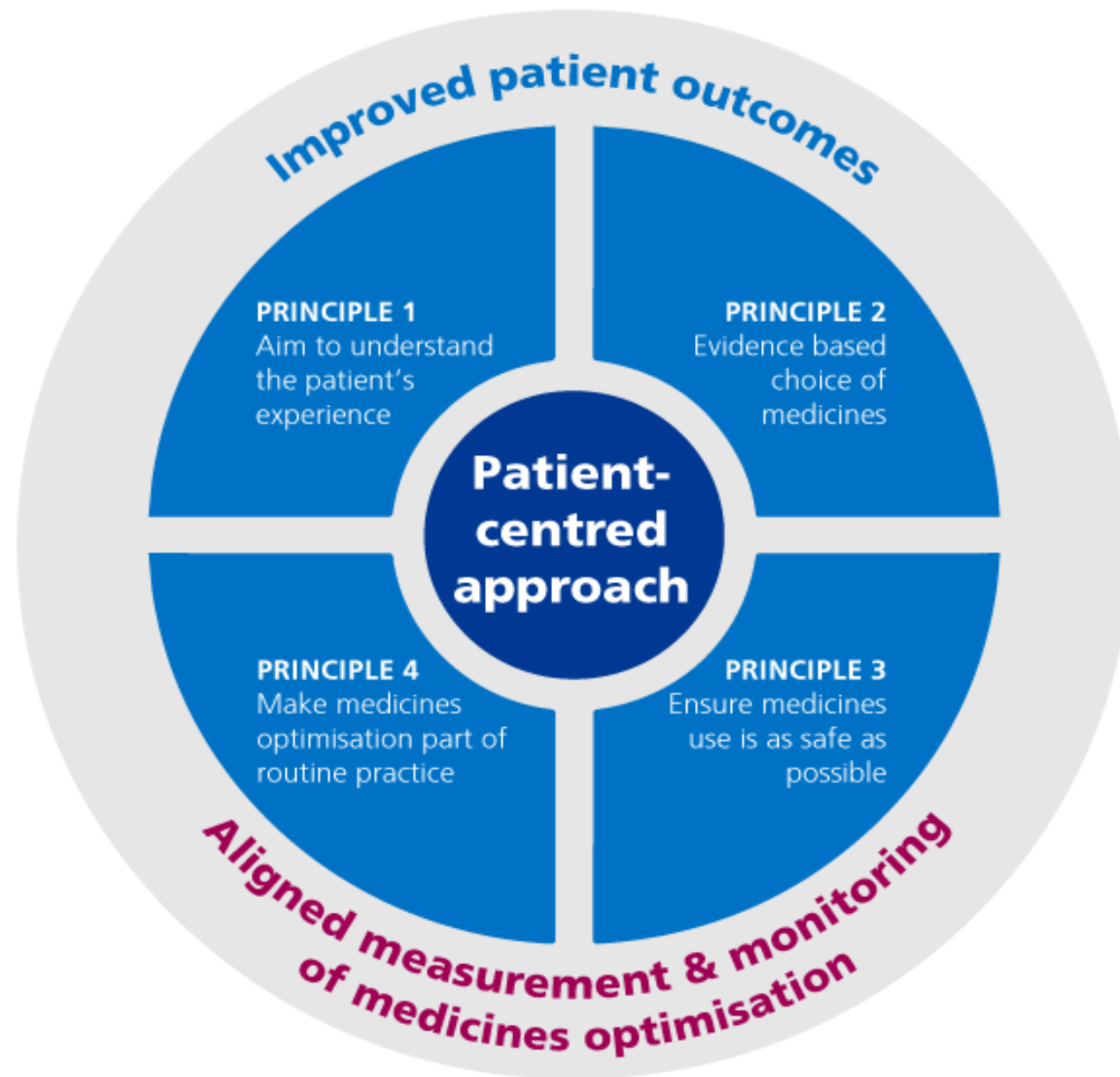
Making how we purchase and supply medicines more efficient

Making sure patients get the right choice of medicine

Improving the quality (safety, effectiveness, patient experience) of prescribing and medicines use



Focus on Medicines Optimisation



To help patients to:

- improve their outcomes
- take their medicines correctly
- avoid taking unnecessary medicines
- reduce wastage of medicines
- improve medicines safety

Regional Medicines Optimisation Committees: Purpose and Scope



- Monitor and support implementation of national advice and guidance
- Provide and disseminate resources to support and accelerate implementation
- Consider the implications of new ways of working and technological innovations
- Provide consistent advice on medicines optimisation
- Reduce duplication at local level
- Horizon scan to identify challenges and emerging issues that would benefit from a system-wide approach

Initial priorities:

- Uptake of biosimilars
- Inappropriate polypharmacy
- Care homes medicines optimisation
- Antimicrobial resistance
- Personalised medicines

To what extent and how should the transition to use of biosimilar medicines be prioritised to enable the provision of best value care in the NHS?

Does the Clinical Senate support the uptake of biosimilar medicines at pace and how can their best practice use be maximised?

NHS England – What is a Biosimilar Medicine?

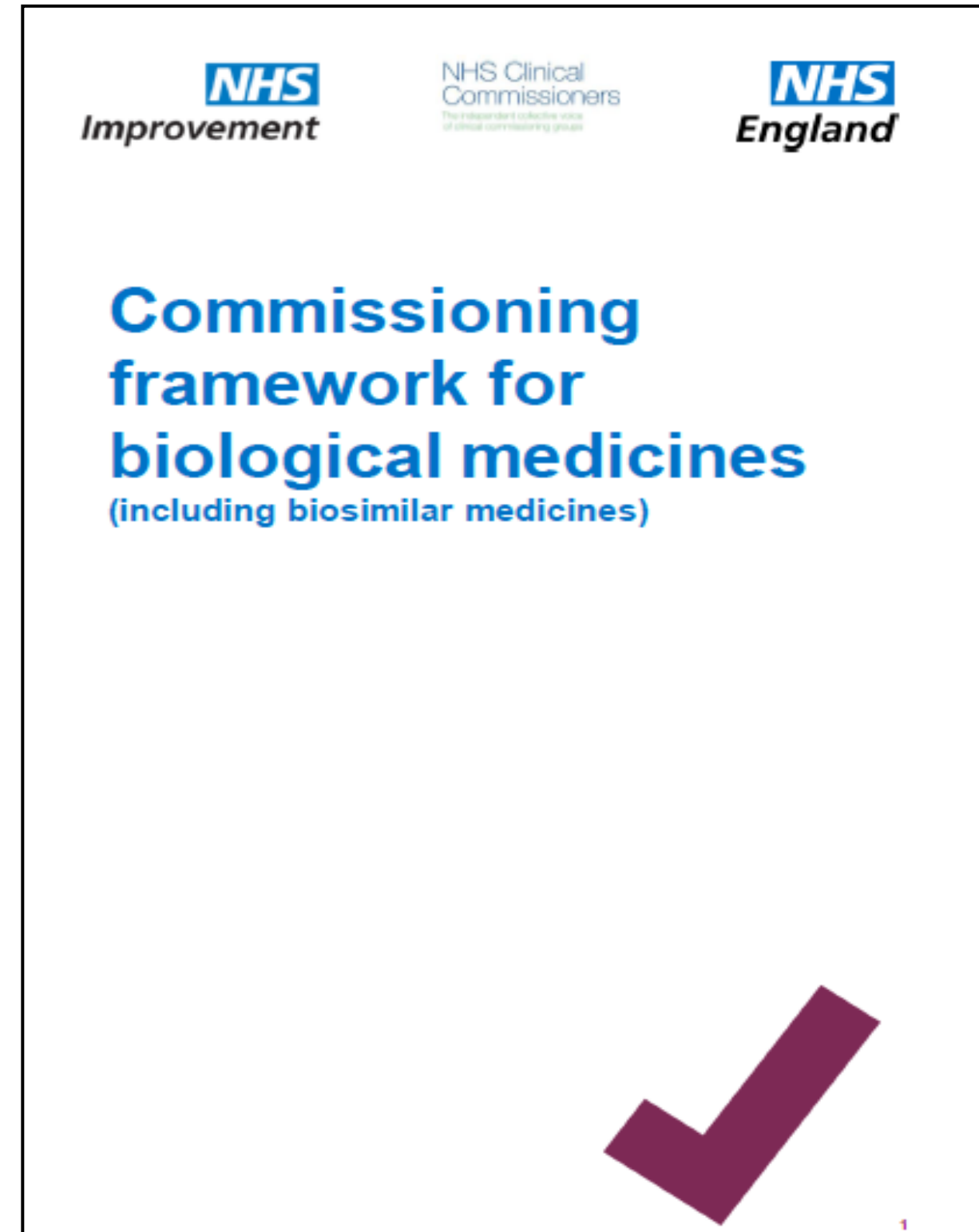
- Biological medicines are made or derived from a biological source ... complex, with inherent variability in their structure.
- A biosimilar medicine is
 - a biological medicine which is highly similar to another biological medicine already licensed for use has been shown not to have any clinically meaningful differences from the originator biological medicine in terms of quality, safety and efficacy.
 - not considered generic equivalents to their originator biological medicine because the two products are similar but not identical. However, they will have met regulatory requirements in terms of comparative quality, safety and efficacy
 - should not be automatically substituted for the originator by the pharmacist.
 - must be prescribed by brand name to support on-going pharmacovigilance of the individual products.
- Where NICE has already recommended the originator biological medicine, the same guidance will normally apply to a biosimilar.
- creates increased choice for patients and clinicians, increased commercial competition and enhanced value propositions for individual medicines.
- The decision to prescribe a biological medicine for an individual patient ... rests with the responsible clinician in consultation with the patient.
- NHS England supports the appropriate use of biosimilars which will drive greater competition to release cost efficiencies to support the treatment of an increasing number of patients and the uptake of new and innovative medicines.

Commissioning Framework for Biological Medicines

Published September 2017

In partnership with industry

- To support commissioners to act promptly to make the most of the opportunity presented by increased competition in biological medicines, including biosimilar medicines
- Sets out actions which can be taken by patients, prescribing clinicians, care providers and commissioners to realise the therapeutic and economic opportunities of biological and biosimilar medicines
- In particular, seeks to set out the importance of a collaborative approach



Commissioning framework for biological medicines

(including biosimilar medicines)



Patients

- Talk to your doctor about your medicines, so you understand them and what the different options are.
- Ask them if there is a biosimilar medicine that would be appropriate for you.

Prescribers

- Consider whether a biosimilar medicine may be appropriate for new patients.
- Consider whether it would be appropriate to switch existing patients to a biosimilar medicine.
- Keep up to date with news from your CCG about biosimilar medicines becoming available.

Providers

- Put in place policies and support for clinicians to enable them to make clinically and cost effective choices in prescribing biological medicines.
- Have a communication and implementation plan in place to alert prescribers to new and better value biological and biosimilar medicines that become available, and engage patients affected

Commissioners

- Ensure that your providers have in place policies to encourage clinically and cost effective prescribing of biological medicines.
- Have a communication and implementation plan in place to alert providers to new and better value biological and biosimilar medicines that become available, and to engage patients.
- Liaise with your NHS England Regional Pharmacist to understand whether there are framework agreements for the biological and biosimilar medicines that you pay for.

Medicines optimisation priority: The importance of biosimilars

11 biosimilar medicines were authorised in the NHS up to 2014.

2014



2015

March 2015: Biosimilar **Infliximab**, for rheumatoid arthritis, comes onto the market. Currently used by 80% of patients.

April 2016: Biosimilar **Etanercept**, also for rheumatoid arthritis, became available. Currently used by 58% of patients.

2016

Switching to these two drugs has already saved the NHS approx. £160 million p.a.



2017

April 2017: biosimilar **Rituximab**, for cancer, became available.

In 2018, biosimilar **Adalimumab** will become available, which is the medicine on which we spend most in our hospitals (over £333 million in 2016/17).

2018



A new generation of biosimilar medicines is coming onto the market, as more biological medicines lose patent exclusivity.

This offers the NHS an additional £200-300 million per year savings opportunity by 2020/21.



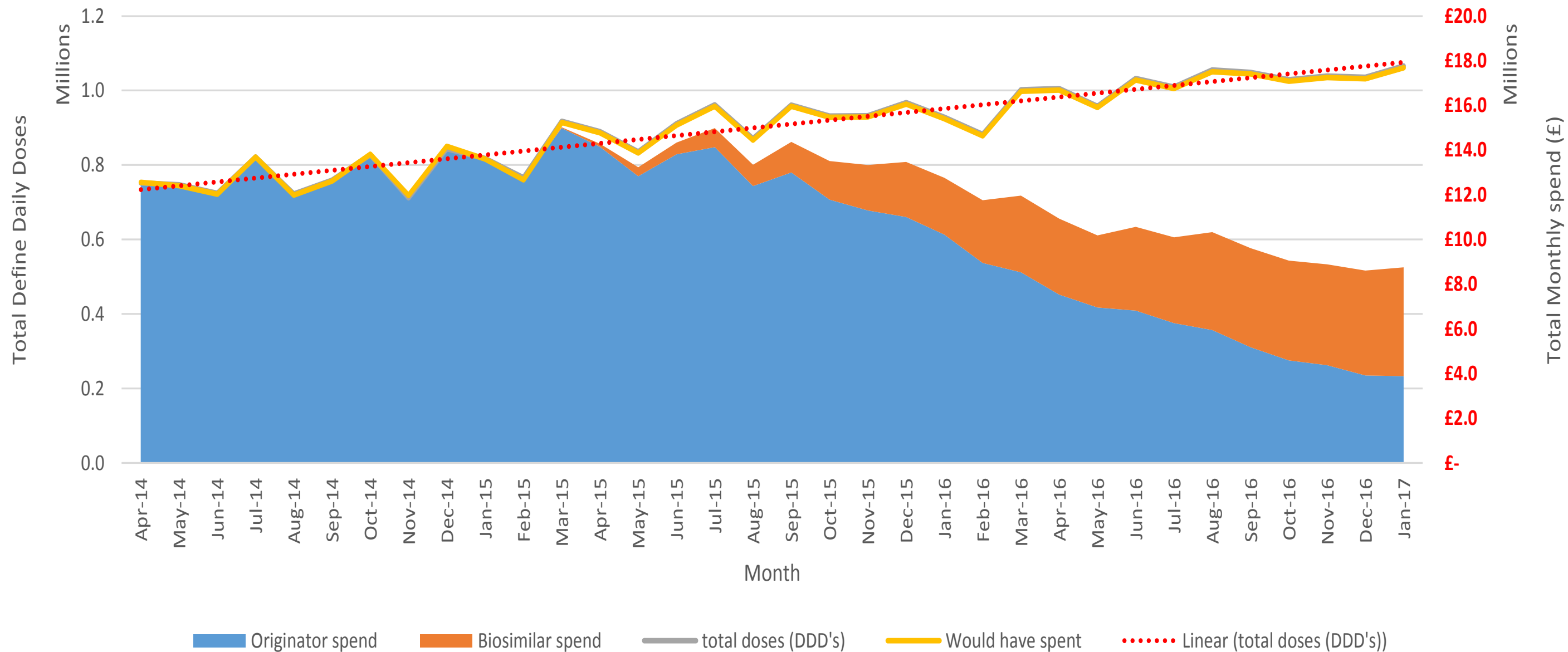
Biosimilar medicines are biological medicines which are highly similar to another biological medicine already licensed for use

To be licensed, a biosimilar medicine must be shown to have no clinically meaningful differences from the originator medicine in terms of quality, safety and efficacy

Where NICE has already recommended the originator biological medicine, the same guidance will normally apply to a biosimilar

Increasing uptake of biosimilars

Infliximab spend - Biosimilar vs. originator PLUS total doses & what spend WOULD have been at original price



Drugs such as Infliximab have significant beneficial impact on patients and slow disease progression

Analysis shows more patients are accessing Infliximab (increase from 0.75 million doses/month to 1.1 million)

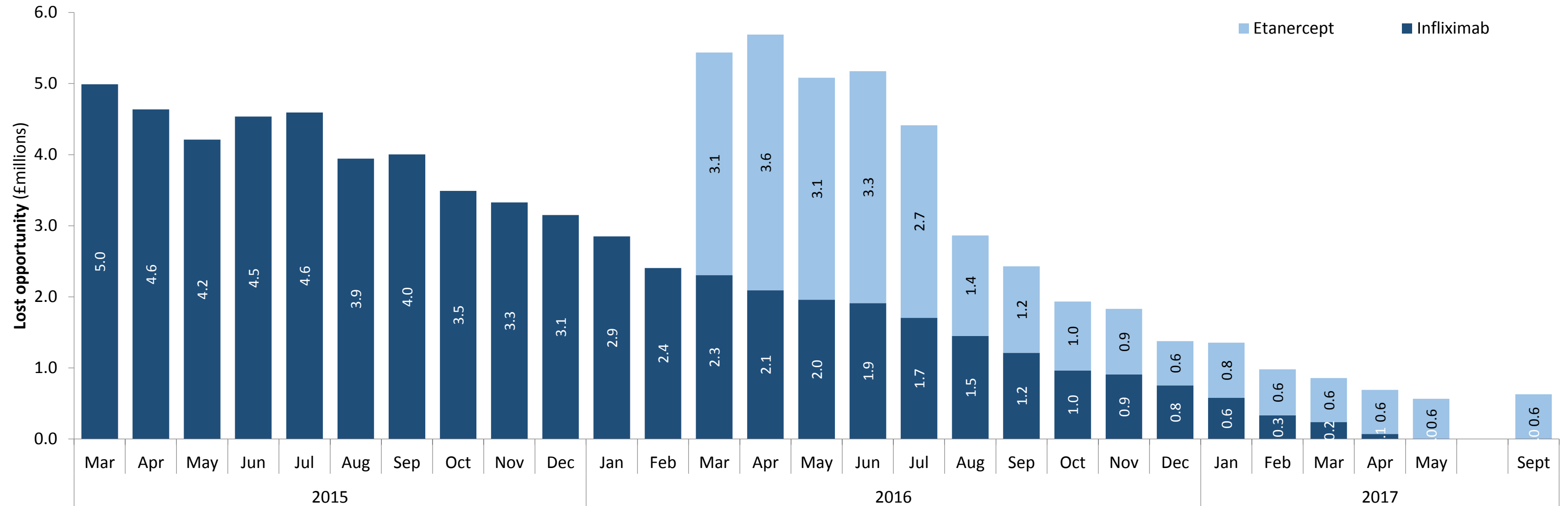
NHS costs would have been £18 million/month and now actually £9 million

Lost opportunities

	Since biosimilar launch up to and including May 2017	2016/17	Sept 2017
Infliximab	£62.6m	£14.10m	£0
Etanercept	£24.2m	£19.8m	£0.6m

Lost cost avoidance opportunity for Infliximab and Etanercept, nationally by month since launch

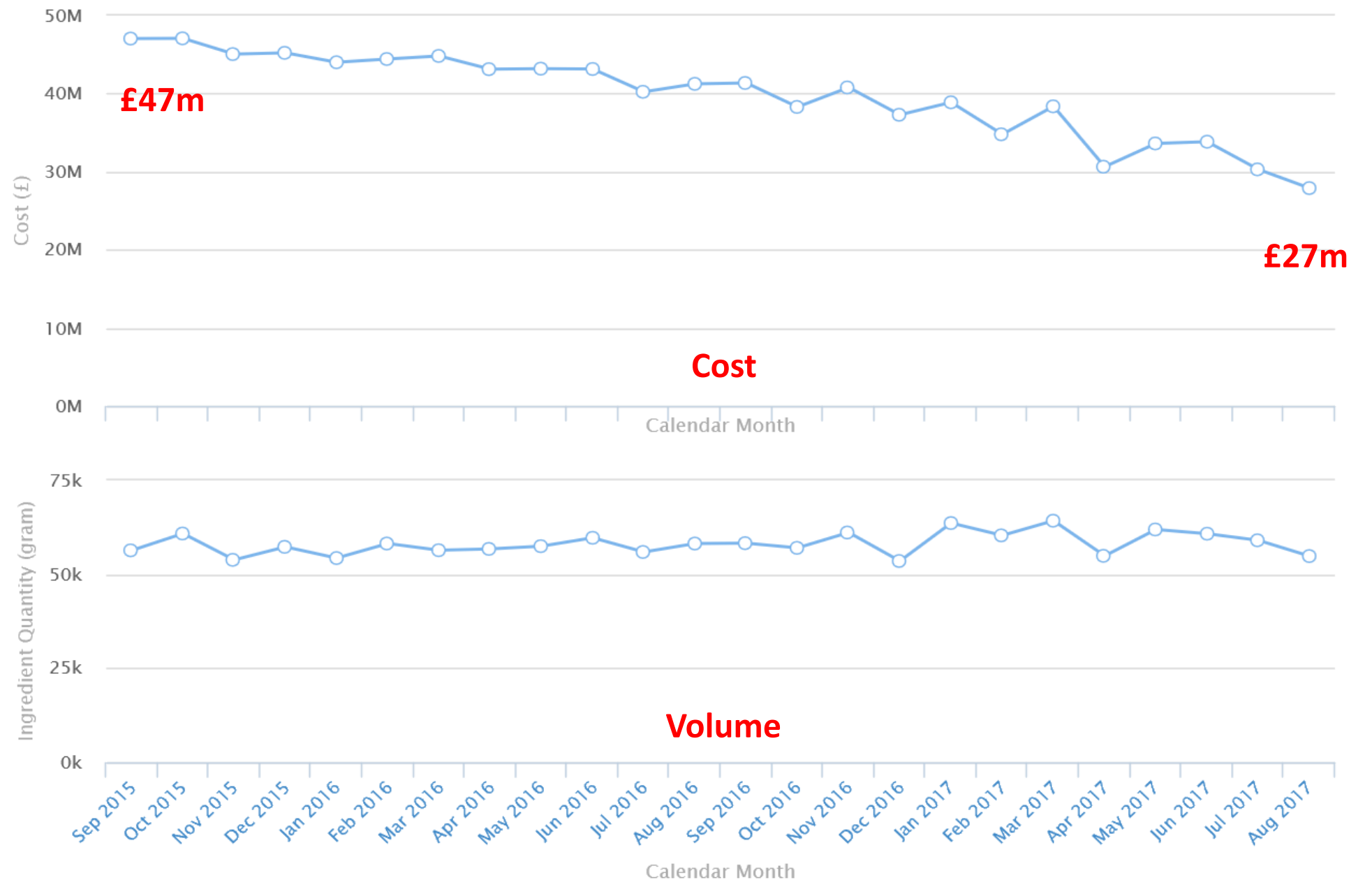
Lost opportunity = Difference in savings accrued by actual uptake of biosimilars each month and those that could have been made had uptake been 80% in each month. Savings are calculated comparing prevailing biosimilar price to the originator price prior to biosimilar becoming available.



Improving Value – Biosimilar Medicines

- Monthly spend on 4 high cost medicines can be shown to be reducing due to moves to biosimilars/generics
- The 4 drugs (Infliximab, Etanercept, Rituximab and Imatinib) show a reduced spend but increased usage
- Reduction from circa £47million to £27million per month
- Volume of product same/higher

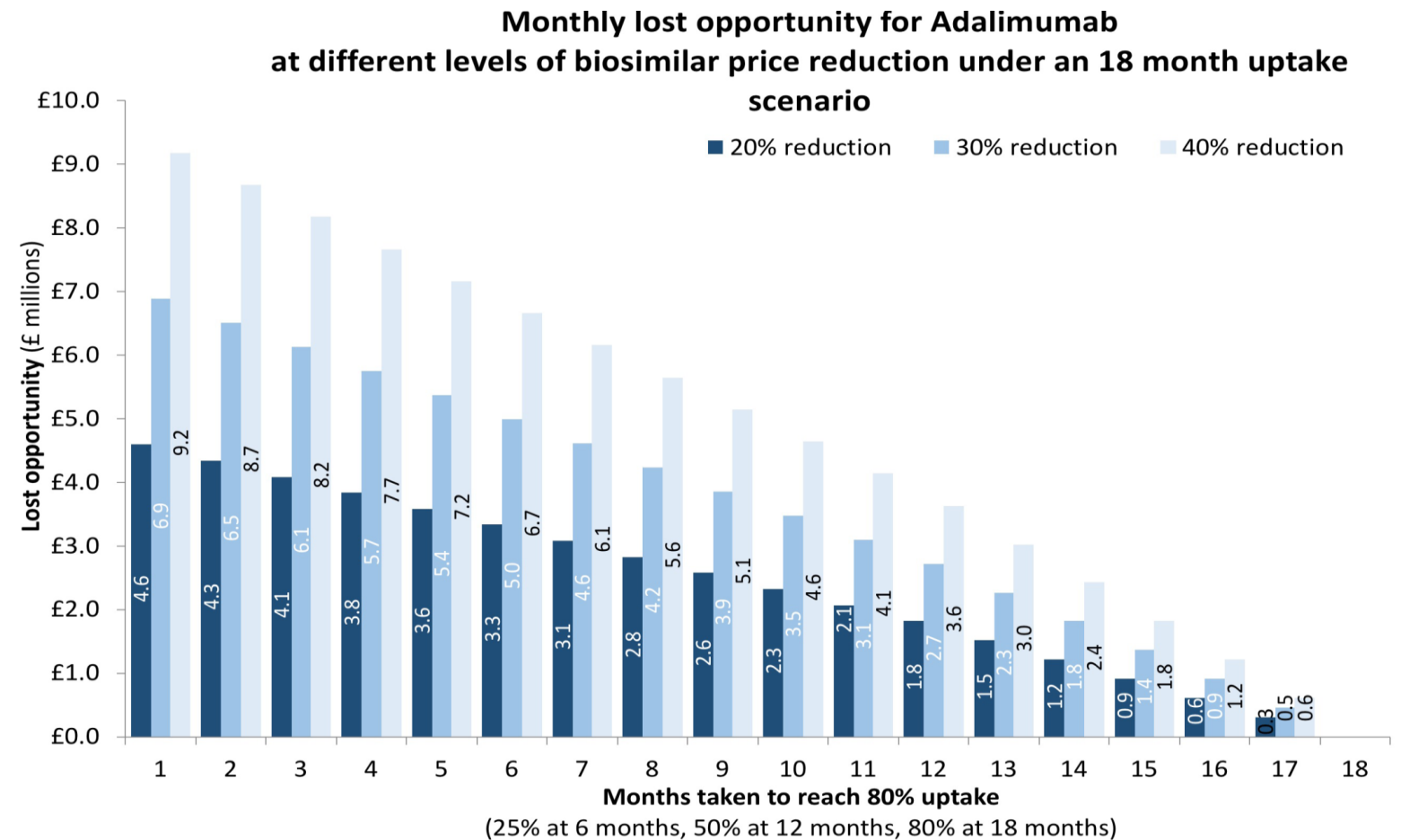
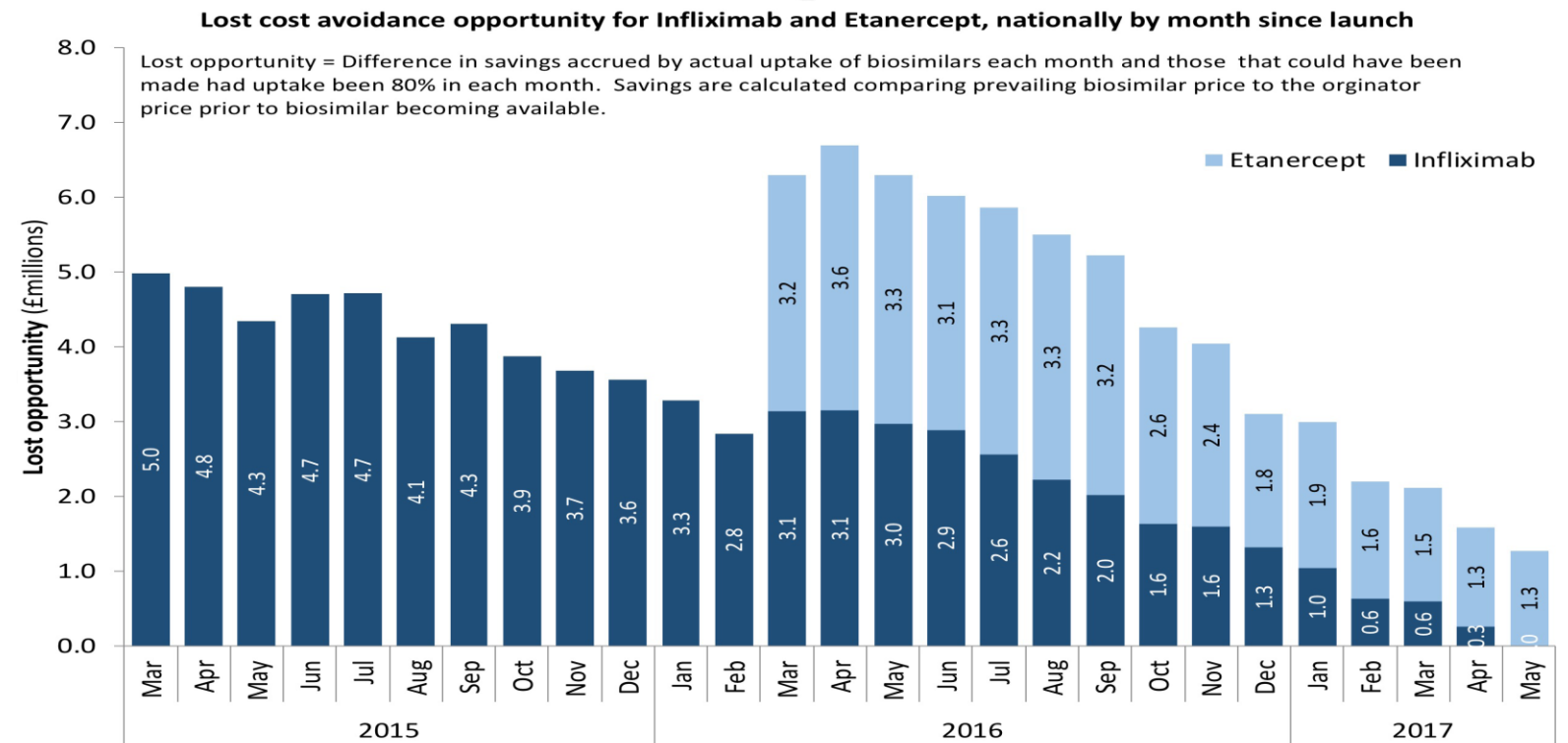
Drugs: ATC: L01XC02 - Rituximab, L01XE01 - Imatinib, L04AB01 - Etanercept, L04AB02 - Infliximab. **Specialties:** Internal (exc. Stock, Sales) (225 of 230). **Prescription Types:** All



Opportunity Costs

- Complex clinical changes involving medicines such as biosimilars require better planning
- Tools have been developed to identify how much the NHS lost monthly before delivering to 80% uptake
- Support information & communication under development to implement at scale & pace

See <http://cancervanguard.nhs.uk/biosimilars-adoption/>



South of England Approach to Best-Value Biologicals

Where to look

- Biosimilar commissioning framework – September 2017
- Regional Biosimilar Implementation Group – December 2017
- CCG planning template through STPs – by 22nd December 2017
- NHS Improvement Model Hospital - uptake and top 10 medicines - ongoing

What to change

- Increase uptake of existing biosimilars – etanercept, infliximab, rituximab
- Support five health economies with lowest uptake of CCG-commissioned medicines
- Horizon-scanning and system readiness for new products - adalimumab (autumn 2018)

How to change

- Support from Commissioning Support Units
- Regional Medicines Optimisation Committee

‘Best value biologicals’ – some of the issues

Evidence:

- **Comparable safety / Immunogenicity / Sustained efficacy?**

Practical issues:

- **Workload eg communication and organisation?**
- **Switching confusion and switching fatigue?**

Procurement:

- **Contracting and sustainability of supply?**

Process:

- **Imposed or flexible?**

Financial pressure:

- **Inappropriate to use a more expensive agent when a cheaper alternative is just as good?**

Setting the Scene: Medicines Value Programme and Biosimilar Medicines Commissioning Framework

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Stephen.Brown17@nhs.net

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