

A world-first to incentivise antimicrobial development: moving from pilot to routine practice in the UK

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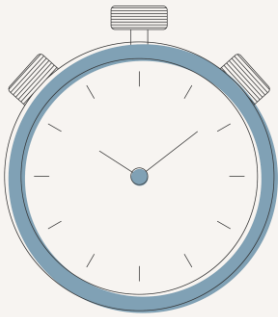
With thanks to colleagues at NICE (James Koh and Nick Crabb)
and NHS England (David Glover and Mark Perkins)

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How we're transforming...

While preserving our core principles of transparency, rigour and independence, we're focussed on developing guidance that is...

More timely and easy
to use



...by providing timely and useable advice.

More relevant



...by focusing on what matters most.

Greater demonstrable
impact



...by learning from data and implementation.



The need for action



Why things need to change

- Antimicrobial resistance (AMR) is a major and growing threat to global public health
- 1.27 million deaths caused by drug-resistant infections globally in 2019¹
- Commercially unattractive to invest in developing new products
 - Only 77 antibacterial agents in phase 1 to 3 clinical trials (2021 data)²
 - Versus 1800 immuno-oncology agents (2020 data)³
- ‘Market failure’ for antimicrobials
 - Low sales due to strict stewardship during parent period
- World Health Organization (WHO): “If we leave it to market forces alone, the new antibiotics we most urgently need are not going to be developed in time.”⁴

1. UK 5-year action plan for AMR 2024-2029 <https://www.gov.uk/government/publications/uk-5-year-action-plan-for-antimicrobial-resistance-2024-to-2029>
2. WHO (2022) <https://www.who.int/activities/coordinating-r-and-d-on-antimicrobial-resistance>
3. Cancer Research Institute (2020) <https://www.cancerresearch.org/immuno-oncology-landscape>
4. WHO (2017) <https://www.who.int/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed>

How the UK has responded

- 2014** UK Government and Wellcome Trust commissioned [Lord O'Neill's independent review on global AMR](#)
- 2015** Joint Government-Industry AMR working group established
- sub-group focussing on reimbursement and evaluation
 - agreed principle of innovative payment model
- 2016** Lord O'Neill published [final recommendations](#)
- 2017** UK Government commissioned its Policy Research Unit in Economic Methods of Evaluation in Health & Care Interventions ([EEPRU](#)) to consider how to capture value of antimicrobials
- 2018** [EEPRU report](#) (Rothery et al.) concludes scope for evaluation informed by health economic modelling and expert opinion
- 2019** UK government [5-year national action plan for AMR](#) commits to test a new model that de-links price paid for antimicrobials from volumes sold





Piloting a solution



The pilot – a NICE assessment with a twist

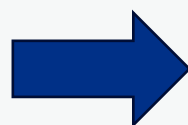
- A fully delinked payment model
 - Pays for antibiotics based on value to patients and the NHS, not volumes used
 - Long-term contracts with fixed annual fee, paid once a quarter
- Contract value determined by NICE-led health technology assessment (HTA)
 - Estimated population-level health gain
 - Incremental net health benefit in quality-adjusted life years (QALYs)
- Captured public health benefits of antimicrobials not normally included in HTA ('STEDI' values)
 - Spectrum value: reducing problems associated with over-use of broad-spectrum antimicrobials that cause collateral damage to the microbiota
 - Transmission value: reducing the spread of resistant infections to other people.
 - Enablement value: ensuring that chemotherapy, surgery and other medical procedures can go ahead
 - Diversity value: providing a range of treatment options to reduce the risk of resistance developing through selection pressure
 - Insurance value: preparing for existing antimicrobials becoming ineffective



Learning from the pilot

Translating QALYs to a globally scalable approach

- Pilot produced the most comprehensive health economic case studies of evaluating antimicrobial products
- Health economic modelling is subject to high uncertainty and resource intensive
- Net health benefit estimates (QALYs) for both products justify payments at UK's "fair share" levels



Can use more pragmatic approach to determine the value of the contract payments:
points-based scoring system
(multi-criteria decision analysis, MCDA)

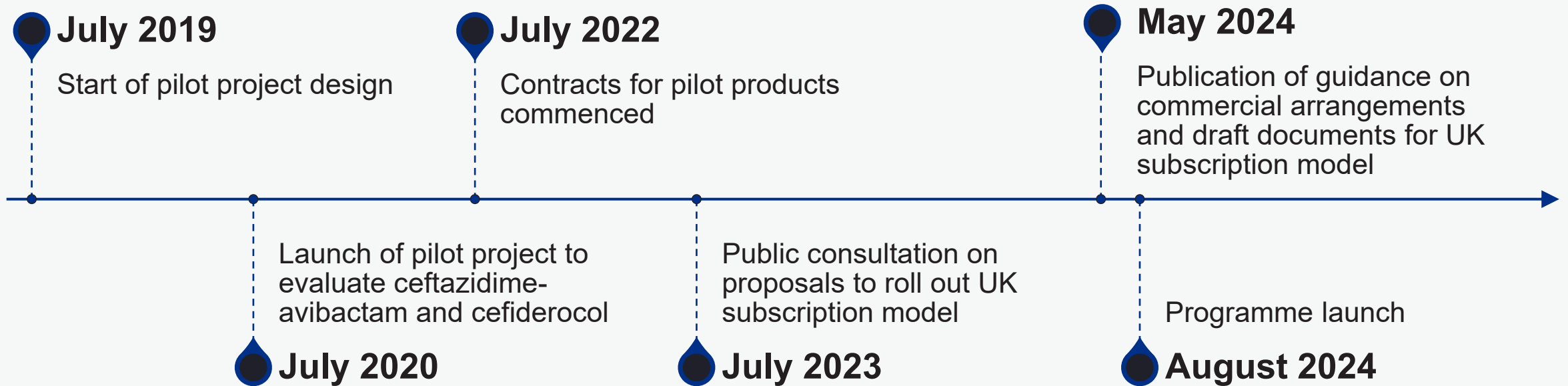
- Anchored in pilot learnings
- Negates need for product-by-product quantitative health economic analyses
- Shortens time between product launch and contract set up

	Ceftazidime-avibactam	Cefiderocol
Value to the NHS over 20-year modelled period	8,880 QALYs	16,200 QALYs
Proportion of value NHS 10-year contract should reward	≥530 QALYs per year	≥970 QALYs per year



From pilot into routine practice

Progress



Evaluation criteria

	Categories	Criteria	Weights
	Relative effectiveness & unmet clinical need 45%	1A: Activity against WHO bacterial priority pathogens	12.2%
		1B: Activity against resistance mechanisms	10.4%
		1C: Activity against UK unmet needs	11.2%
		1D: Effectiveness compared with current UK best standard care	11.2%
		2A: Chemical entity novelty	4.5%
	Pharmacological benefit 25%	2B: Target site novelty	4.0%
		2C: Drug exposure at the site of infection	4.5%
		2D: Absence of cross-resistance	4.5%
		2E: Absence of rapidly emerging resistance	4.0%
		2F: Impact on gut microbiome	3.5%
		3A: Adverse events	5.4%
		3B: Drug-drug interactions	3.9%
	Health system benefit 30%	3C: Formulation or delivery of therapy	4.5%
		3D: Dose frequency	4.5%
		3E: Product stability and storage	2.7%
		3F: Monitoring requirements	3.6%
		3G: Reduced hospital-led care	5.4%

Contract value bands

	Band 1: Breakthrough antimicrobials	Band 2: Critical antimicrobial	Band 3: Priority antimicrobial	Band 4: Important antimicrobial
Product score threshold	Achieves $\geq 80\%$ of max score against evaluation criteria	Achieves 70–79% of max score against evaluation criteria	Achieves 60–69% of max score against evaluation criteria	Achieves 50–59% of max score against evaluation criteria
Annual contract values				
England	£20m	£15m	£10m	£5m
Scotland	£1.92m	£1.44m	£0.96m	£0.48m
Wales	£1.11m	£0.84m	£0.56m	£0.28m
Northern Ireland	£0.66m	£0.5m	£0.33m	£0.17m
Total	£23.7m	£17.77m	£11.85m	£5.92m

- Single procurement process across all 4 UK nations
- One nation runs procurement process
- One assessment against the evaluation criteria



Resources

- Current UK subscription model

<https://www.england.nhs.uk/publication/antimicrobial-products-subscription-model-guidance-on-commercial-arrangements/>

- Evaluation criteria for UK subscription model:

<https://www.nice.org.uk/Media/Default/About/what-we-do/Life-sciences/models-for-the-evaluation-and-purchase-of-antimicrobials/evaluation-criteria.docx>

- England pilot project:

<https://www.nice.org.uk/about/what-we-do/life-sciences/nice-advice-service/models-for-the-evaluation-and-purchase-of-antimicrobials>

- Outterson (2021) Estimating The Appropriate Size Of Global Pull Incentives For Antibacterial Medicines

<https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.00688>

- WHO priority pathogen list:

<https://www.who.int/publications/i/item/9789240093461>

- UK government 5-year national action plan for AMR

<https://www.gov.uk/government/publications/uk-5-year-action-plan-for-antimicrobial-resistance-2024-to-2029>

<https://www.gov.uk/government/publications/uk-5-year-action-plan-for-antimicrobial-resistance-2019-to-2024>