

# Can we use insurance-based reimbursement models for novel antibiotics?

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# Why is this important?

The lack of financial incentives associated with developing novel antibiotics has resulted in limited innovation in this space, though it is crucially needed. We explore how the principles of insurance can be applied to structure reimbursement models for novel antibiotics, and ultimately stimulate innovation while offering financial protection to payers.

Antibiotics are essential in fighting bacterial infections and helping to prevent infections from occurring. One of the challenges with antibiotics is around conservation. Each time they are used, rightly or wrongly, resistance build-up may occur. Over time, this can lead to the development of multi-drug resistant pathogens. The World Health Organisation (WHO) already reports high prevalence rates of resistance against common bacteria in various countries<sup>1</sup>.

Stewardship programmes can be implemented to curb the use of antibiotics given the threat of resistance. Several factors have contributed to the proliferation of antibiotics in the past. For example:

- Prescribing practices influenced by patient expectations;
- Use of antibiotics to treat viral infections (antibiotics are only effective against bacterial infections);
- Use in animal farming to prevent the risk of infections; and
- Reliance on broad-spectrum antibiotics for additional patient safety.

In the US, the FDA is currently looking into new reimbursement models for antibiotics which can incentivise drug development while also facilitating conservation goals<sup>2</sup>.

Sources:

1. <http://www.who.int/en/news-room/fact-sheets/detail/antimicrobial-resistance>
2. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm610503.htm>
3. [https://amr-review.org/sites/default/files/160525\\_Final%20paper\\_with%20cover.pdf](https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf)

# The players

## Manufacturers

- Currently not incentivised to develop novel antibiotics.
- Use of antibiotics normally characterised by short treatment duration.
- Could act as 'insurer' in insurance-based reimbursement model.



## Payers

- Bear financial risk of antibiotic resistance.
- Exposed to catastrophic scenarios.
- Could act as 'policyholder' in insurance-based reimbursement model

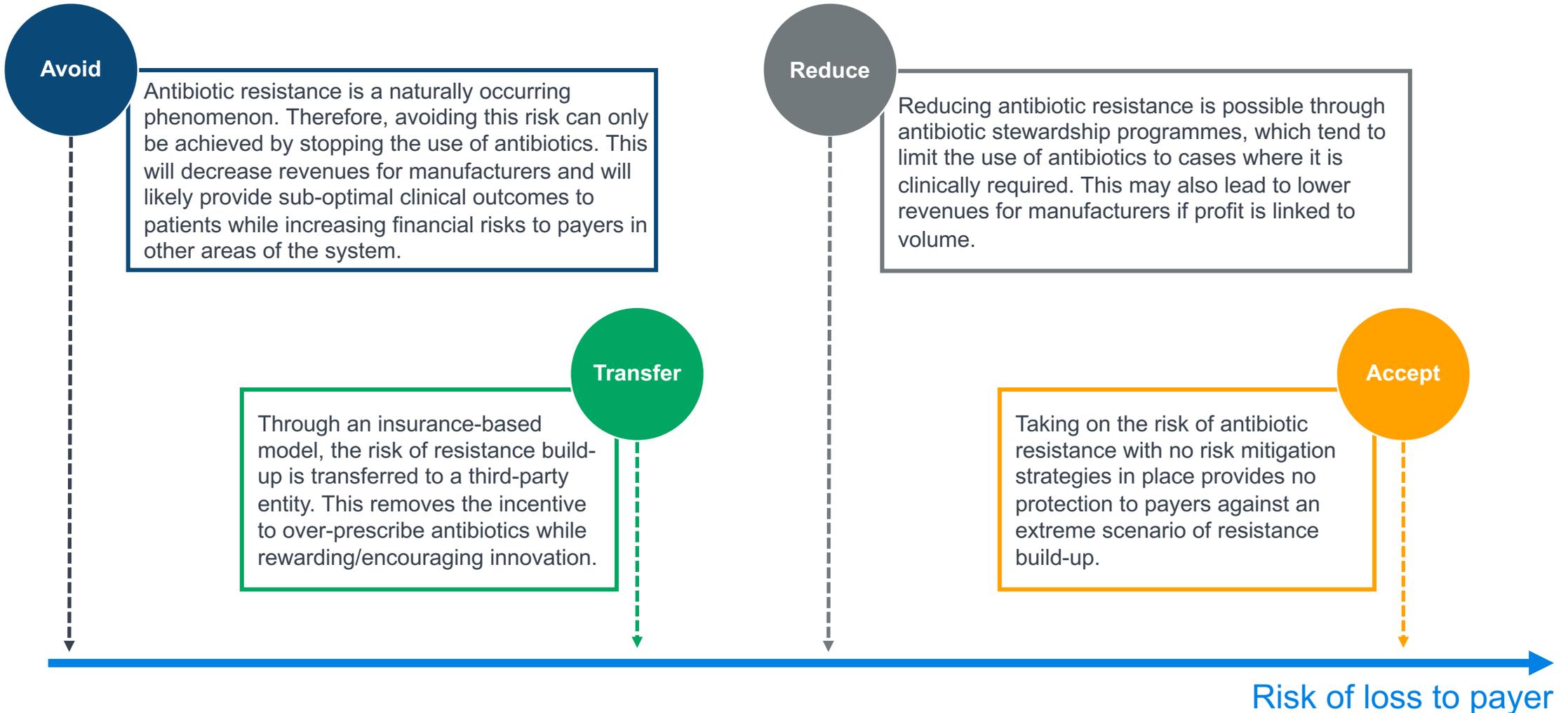


## Patients

- Patients with infections at risk of antibiotic resistance; Further, prophylactic use of antibiotics in routine surgeries may be compromised.
- Inappropriate use of antibiotics sometimes driven by patient expectations.
- The O'Neill Review estimated that deaths attributable to antibiotic resistance are expected to surpass cancer at 10 million lives each year in 2050 (from around 1 million currently) with large potential impacts on the economy and lost productivity<sup>3</sup>.



# Approaches to risk of loss typically reflect potential financial impact and likelihood of loss (i.e. prevalence of antibiotic resistance)



# Insurance-like reimbursement model

Although the approach is described as an “insurance-like” model, many insurance principles do not translate accurately in the analogy and an arrangement of this type would require clear mitigation strategies to limit each parties’ financial exposure.

However, the analogy does help to illustrate how the potential arrangement and risk share/gain share aspect could work and highlights a few key considerations.

## The insurance mechanism

### Insurer (Manufacturer)

*Insurer: an entity that underwrites an insurance risk, in exchange for receiving premiums, and undertakes to pay compensation according to the insurance contract terms.*

- Manufacturer receives lump sum or regular payments.
- Manufacturer partially or fully absorbs risk of higher than expected utilisation while being protected against low utilisation through the predetermined premium.

### Claims

*The claim value is in accordance with the size of loss associated with the insured risk.*

- Claims are equivalent to antibiotics released into the market.
- Resistance to existing antibiotics higher than expected → more antibiotics released into the market than expected.
- Advantageous for manufacturer if resistance is curbed and volume of antibiotics low to gain more profits from the “insurance” arrangement.
- Guidelines would need to be in place to prevent manufacturer from withholding antibiotics inappropriately.

### Claims

### Policyholder (Payer e.g. NHS England)

*Policyholder: an entity that pays premiums to the insurer and holds the insurance contract. The policyholder is insured against the financial risk(s) specified in the insurance contract.*

- Payer makes pre-determined premium payments to the manufacturer based on expected utilisation and cost of resistance.
- This arrangement enables innovation in the antibiotic space and de-links profit and volume.

### Premiums

*Premiums comprise a pure risk cost, a margin for uncertainty and administration expenses. Premium payments received are certain and the value of these is known upfront.*

- Payer makes pre-defined payment(s) to manufacturer based on expected utilisation of the novel antibiotics and cost of resistance within the healthcare system as well as loadings for uncertainty and administration expenses.

### Premiums

# Application of insurance principles

## The “peril”

In insurance terms, the peril refers to the cause of loss. In this context, a key trigger for loss would be an increase in multi-drug resistance.

Traditional insurance risks should be unpredictable but in this case, an increase in multi-drug resistance can be triggered by events that are controllable. Risk triggers should be accompanied by risk mitigation techniques to protect the insurer.

The payer is protected against the cost burden of multi-drug resistance through the pre-determined premium but there are broader implications in that the arrangement:

1. Ensures manufacturers receive a minimum level of revenue for the drug regardless of utilisation.
2. Limits the perverse incentive for over utilisation which could lead to increased resistance over time.
3. Enables the payer to pay a pre-determined premium amount to reduce the risk and cost of resistance by incentivising the development of new antibiotics while having some control over the volumes flowing through the system. The use of typical insurance mechanisms like excesses, deductibles and limits could be applied to antibiotic volumes and used to structure the transfer of risk between stakeholders.

## What if resistance develops against the particular antibiotic being considered?

The incentive for stewardship would help mitigate this risk but decisions and guidelines regarding prescription and reimbursement would have to take place at a national, rather than local, level.

### Effective policies on AMR will consider:

1. The impact of new antibiotics on conservation goals.
2. The importance of aligning incentives among various stakeholders.
3. De-linking profit from volume.

# Key insurance principles to consider



## Long term vs. short term contract

*Health insurance and property and casualty insurance usually have one year terms; life insurance policies usually continue over multiple years, with some ability to revisit the premium on an annual basis.*

- A one year policy would be possible, but unlikely to be optimal since there may be insufficient time for risks to materialise and for manufacturer to be compensated for development and manufacturing costs through the premium payment(s).
- Further, some payers with short term contracts may be less interested in this type of product, given they could struggle to realise the long term benefits. For products where prices are annually adjusted, concerns around the impact of an uptick in costs would be mitigated.
- The time period of such a contract would need to be long enough to address the above factors but short enough that the contract could be terminated/revisited in light of changing experience – notably, a change in resistance.



## Pooling of risk

*Pooling of risk is a fundamental principle of insurance. It provides protection against uncertainty of the insured perils materialising. Large risk pools have similar characteristics which enable the insurer to better quantify and protect against risks that each risk pool poses.*

- No pooling of risk since the payer is the single policyholder.
- There is a potential to aggregate similar risks by grouping similar drugs (provided the drugs exist).
- Manufacturer's risk could be defrayed through capital or reinsurance markets, where it could be aggregated with other, uncorrelated risks.



## Double insurance

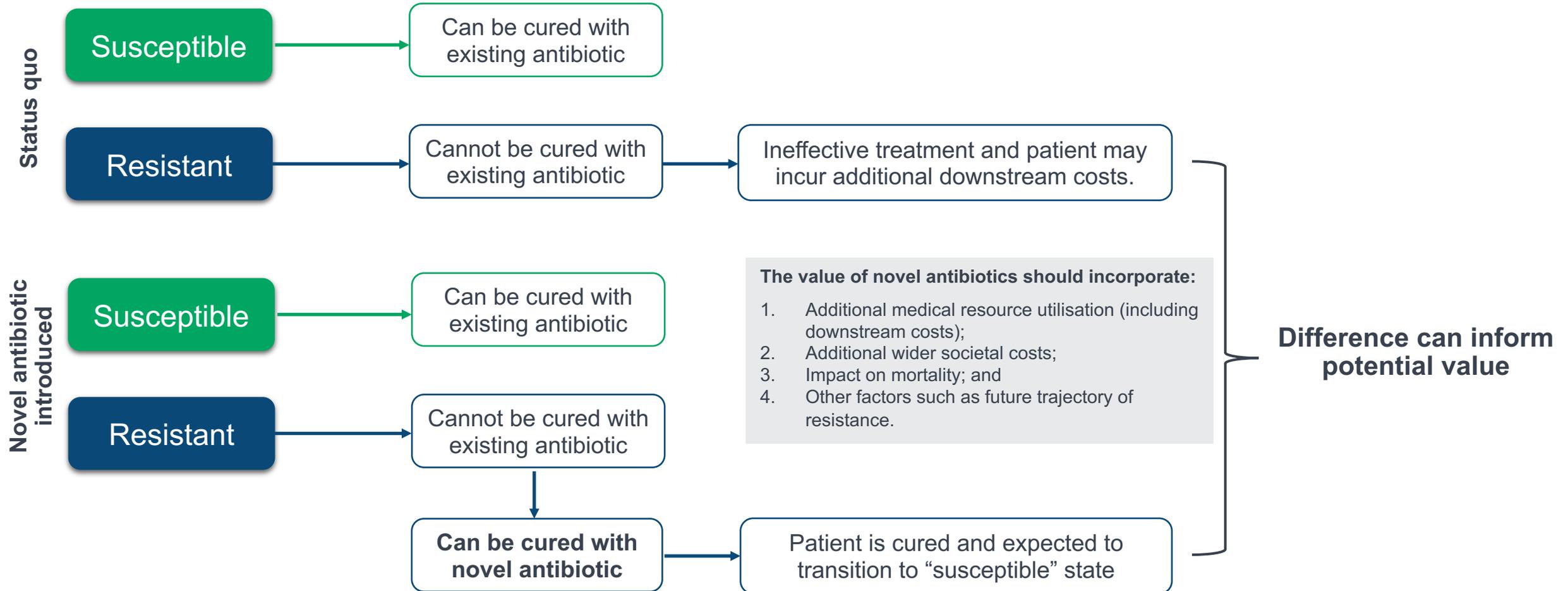
*In typical insurance contracts, the policyholder cannot be insured for more than 100% of the loss incurred. If insurance is provided by multiple insurers, each insurer will pay a proportion of the loss incurred with the sum of the claims not exceeding 100% of the loss incurred.*

- If a new drug enters the market (follow-on or generic), the payer could potentially enter into additional contracts with each insurer entitled to a portion of the premium but this could compromise the feasibility of the arrangement.
- The fact that there is only one policyholder means that the usual competitive elements observed in insurance markets are not at play.
- A possible structure would be to include a single contract for a period of time, analogous to a patent period, with additional competing contracts added at a later stage.

***Although some principles of insurance do not translate directly in this context, it provides us with a framework to assess key considerations and risks to ensure that any agreed structure is fair to all stakeholders and appropriate risk mitigation strategies can be put in place.***

# Once we have a reimbursement model, how do we quantify the value?

- The current direct financial burden of resistance is important to inform the value of antibiotics. However, wider societal costs, the impact on mortality and future trajectory of resistance should be considered too.
- Susceptible pathogens are still responsive to current antibiotics while resistant strains can only be cured if a novel antibiotic is developed.



# How can actuarial approaches help?

- Health technology appraisals (HTA) are typically used to make recommendations on the use of new and existing medicines and treatments within the NHS.
- Actuarial approaches can complement traditional HTA processes and provide further insights into the economic impact a novel antibiotic may have for addressing AMR.

## HTA frameworks have some limitations when used for novel antibiotics:

1. Treatment benefits beyond individual patients rarely captured; yet other positive outcomes and externalities can be linked to antibiotics. E.g. herding.
2. The “insurance” protection which transfers financial risk of extreme scenarios, is applied in some public health areas through stockpiling, however this value is rarely reflected in HTAs.
3. Wider societal costs can be substantial, yet are not currently considered.
4. Antibiotics require a population based approach and for this reason, alternative evaluation techniques are necessary.

## Key actuarial principles that can be applied:

1. Projections of population cohorts over time.
2. Use of real world claims data to parameterise distributions.
3. Assessment of extreme and more volatile scenarios.
4. Benchmarking of actual against expected experience.
5. Scenario testing based on current and projected trends.



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## Why Milliman?

- We are one of the largest actuarial consulting firms in the world and the global market leader in actuarial consulting.
- We work extensively with many of the world's largest pharmaceutical companies, including support for their value-based contracting efforts.
- We combine global expertise and market-leading technical skills with local market presence, leveraging our in-depth knowledge of the regulations and markets in which we operate.

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