Incentivizing antibiotic innovation

Christine Årdal, Norwegian Institute of Public Health
Bottlenecks to antibiotic innovation

**Profitability:** Return on investment from developing a new antibiotic is significantly lower than other competing therapeutic areas. This is due to:

- Many generic antibiotics are still highly effective.
- Desire to preserve activity of new antibiotics leads to slow uptake.
- The costs of current and future resistance and the social value of antibiotics are not factored into reimbursement processes.
- Markets for each of the different drugs is fragmented.
- Demonstrating superiority through clinical trials is difficult.

**Human capital:** Universities are not educating enough students in the sciences related to anti-infective technology discovery and development.
The traditional pharmaceutical commercial model

David J. Payne et al. Phil. Trans. R. Soc. B
2015;370:20140086
Application of commercial model to antibacterials

David J. Payne et al. Phil. Trans. R. Soc. B 2015;370:20140086
Commercial model and potential unmet needs

David J. Payne et al. Phil. Trans. R. Soc. B
2015;370:20140086
Resulting in...

...insufficient antibiotic innovation

Yet there is a bigger problem...
Access to antibiotics

Bacterial diseases are still major killers in developing countries because of lack of access to antibiotics

O’Brien et al, Lancet 2009, 374
Access for the millions of people without antimicrobials

Innovation towards creating new antimicrobials

Conservation of effectiveness of existing drugs

Hoffman et al. (2015)
Access without conservation and innovation will speed resistance.

Conservation constrains access and undermines innovation.

Innovation without access is unjust, and without conservation it’s wasteful.

Hoffman et al. (2015)
Call for action

Convergence of principles

- Need for both “push” and “pull” mechanisms
- Delinkage (i.e., revenues delinked from volumes sold) built in
- Access and responsible use are integral considerations for all mechanisms
- Global collaboration and financing necessary
Focus on antibiotic innovation

To produce analysis of the global problems of antimicrobial resistance (AMR), and to propose concrete actions to tackle these internationally.

To explore novel economic strategies and reward models both to promote the development of new antibiotics and to bolster appropriate consumption of existing antibiotics globally.
New Drugs 4 Bad Bugs (ND4BB)

Cross-project communication & collaboration

**COMBACTE (Topic 1)**
- Enabling clinical collaboration and refining clinical trial design
- Clinical development of GSK1322322 and MEDI4893

**TRANSLATION (Topic 2)**
- Research on penetration and efflux in Gram-negative bacteria
- Data hub and learning from R&D experience

**ENABLE (Topic 3)**
- Discovery and development of new drugs combating Gram-negative infections

**Topic 4**
- Driving re-investment in R&D and the responsible use of antibiotics

**Topic 5**
- Clinical development of antibacterial agents for Gram-negative, antibiotic-resistant pathogens

**Topic 6**
- Systemic molecules against healthcare-associated infections due to clinically challenging Gram-negative pathogens

**Topic 7**
- Inhaled anti-bacterials in cystic fibrosis and non-cystic fibrosis bronchiectasis

ND4BB Information Centre
All data generated is submitted and made accessible to all partners

- Ongoing projects
- Projects under development
DRIVE-AB’s work packages

WP3A Project management

WP1A Metrics for responsible use
WP1B Forecast trends in AMR
WP1C Economic value of antibiotics
WP2 New economic models

WP3B Stakeholders

Amsterdam 2016  London 2017
Testing economic models

Example – AMR Review’s hybrid model

- Coordinated by a single global body
- Giving a lump sum payment (US $1 - 1.3 billion per antibiotic) to a company with a new worthy antibiotic
- Freedom to sell the drugs for profit
Testing a model

1. Will it stimulate action? By whom? Cost/benefit?

2. How to pair with responsible use and availability?

3. How can it be implemented?

4. Validation
1. Will it stimulate action? By whom? Cost/benefit?

Incentive → Simulation → Antibiotic Innovator → Antibiotic Innovator → Antibiotic Innovator → Antibiotic Innovator

Number of new antibiotics over time
How to pair with responsible use and availability?
Member states

CERN is run by 21 member states, and many non-European countries are involved in different ways.
Validation

Stakeholder platform

- Policymakers
- Civil society and global health groups
- Professional societies
- Pharma companies
- Small and medium-sized enterprises
- Venture capital firms
- Regulatory authorities
- Payers
- Health technology assessors
- Patient groups
The O’Neill proposals are still rudimentary but they represent the best starting point so far in developing new weapons to see off the threatened antibiotic apocalypse. Governments, health agencies and the pharmaceuticals industry should now engage seriously in drawing up a detailed, practical plan to put them into effect.”
www.drive-ab.eu

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