

Research impact: making a difference

Reigniting research and development on antibiotics

LSE Health influenced global initiatives to spur renewed research and development of new antibiotics for neglected diseases

What was the problem?

General practitioners frequently prescribe antibiotics for diseases which do not respond to them or which will resolve without treatment. This overprescription has led to millions of cases of resistance to bacterial infection, with hospital deaths in the European Union alone reaching 25,000 each year.

In her 2011 annual report, the UK's Chief Medical Officer called for more attention to be given to a resistance strategy and for politicians to prioritise antibiotic resistance as a major area of concern, including placing it on the national risk register and pushing for national and international action.

Due to a combination of low profits and lack of appropriate economic incentives, the pharmaceutical industry has largely stopped investing in new antibiotic development. Antibiotics have a particularly poor return on investment for pharmaceutical companies because they are taken for a short period of time and cure their target disease, in contrast to drugs which treat chronic illness such as high blood pressure, which are taken daily for the rest of a patient's life.

What did we do?

Since 1996 LSE Health, a centre headed by Professor of Health Policy Elias Mossialos and funded by many UK and international organisations, has researched ways to stimulate the development of new vaccines and drugs for neglected diseases.

This research led the Swedish Government to make antibiotic development a priority during its Presidency of the European Union (2009). Subsequent to LSE Health's research focusing specifically on unmet medical need, the Swedish Ministry of Health asked the centre to identify the best ways to promote the development of new antibiotics.

In Policies and Incentives for Promoting Innovations in Antibiotic Research (2010), Mossialos and colleagues at LSE and the Mayo Clinic explored the reasons why the market was failing to produce new antibiotics. They analysed 20 different incentive frameworks, looking at the impact of 'push' mechanisms (reducing the costs of research and development for smaller research groups) and 'pull' mechanisms (promising rewards to larger companies if goals are achieved). They then quantified the financial and political feasibility of possible combinations of these incentives. They recommended:

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1. The need for new approaches to risk-sharing between governments and private producers. Rewards should motivate 'pull' strategies, while 'push' incentives should seek to reduce the costs of clinical trials.
2. The importance of regulatory reform that would legally protect intellectual property over an extended period. This is particularly important in the field of antibiotics where long-term efficacy is vital.

The research was published in key journals, including the British Medical Journal, and was expanded in 2011 to provide a comparative analysis of the merits of different incentives, bearing in mind the different weight given to each of the criteria from the perspectives of different stakeholders. The 2011 research proposed a new type of incentive that combined elements from existing regulatory incentives with new incentives to limit over-marketing and over-consumption of any new drug in the medium to long term.

What happened?

The Policies and Incentives report was presented at the 'Stockholm Conference' during the Swedish Presidency of the EU. Its importance was publicly acknowledged and led the EU Council to request that the European Commission develop a comprehensive action plan on new antibiotics within 24 months.

Policies and Incentives was also used as a pre-Conference document for review by leading US academics, non-governmental organisations and industry representatives (including AstraZeneca and the European Federation of Pharmaceutical Industries and Associations). In 2010 the World Health Organisation published it as a book.

After the Stockholm Conference, Swedish Prime Minister Reinfeldt proposed to US President Obama the formation of a Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) between the European Union and the United States to encourage global research and address resistance. It was explicitly intended to build on the Policies and Incentives report, which was cited extensively in TATFAR's later findings.

Professor Otto Cars, Director of the Swedish Strategic Programme Against Antibiotic Resistance, described the centre's work as a 'marked influence on future development in the field'. Time and CNN covered its findings, and Nature published an article stressing the need to reignite antibiotic

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research, concluding that the LSE 'push and pull' recommendations were a 'clear front-runner' for future courses of action.

Between 2009 and 2011, LSE Health research was presented on over ten occasions to key stakeholders in Sweden, London, Washington DC and Brussels. In early 2012, the public-private partnership between the European Commission and the European Federation of Pharmaceutical Industries and Associations (the Innovative Medical Initiative) announced a shared commitment of €220 million for the development of new antibiotics.

LSE Health's recommendation for greater market protection of intellectual property rights via regulatory reform was cited in expert testimony to the United States Congress in 2010 and 2012 and was crucial to the passing of cross-party legislation (the 'GAIN Act') in 2012. This was expected to enable vital new antibiotics to reach the market.

The Policies and Incentives report was presented to an expert panel at the US Institute of Medicine's workshop on medical countermeasures to terrorism, which is generally accepted as having enabled the US Biomedical Advanced Research and Development Authority to award a series of contracts for antibiotic research. In addition, the report was discussed by industry executives who had not been part of the original Stockholm group, demonstrating general industry acceptance of its findings.

LSE Health is now undertaking new research funded by the Pew Charitable Trust (2012), which is intended to resolve the issues that currently prevent diagnostic tests for bacterial infections from appearing on the market.

Elias Mossialos is Brian Abel-Smith Professor of Health Policy at the Department of Social Policy at the London School of Economics and Political Science, and Director of LSE Health. He is internationally recognised for his comparative work on health care financing and his research on EU law and governance. He is currently examining approaches to stimulating research for neglected diseases based on the concept of a financial call option. In 2010 he was awarded the Andrija Stampar medal by the Association of Schools of Public Health in Europe (ASPHER) and the European Public Health Association (EUPHA), for contributions to European public health. He received the 2002 and 2007 Baxter Award from the European Health Management Association for the best publication in health policy and management in Europe. In 2009, under his directorship, LSE Health and Social Care was honoured with the biennial Queen's Anniversary Prize for Higher and Further Education.

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