Designing a delinked incentive for critical antibiotics – lessons from Norway
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Introduction
The antibiotic market is broken with all antibiotics on the market today discovered in the 1980s or before. Several initiatives have proposed new economic incentives to stimulate antibiotic innovation, including so-called “pull” incentives which fully or partially delink revenues from unit sales. At the same time, older antibiotics that are included in the World Health Organization’s Essential Medicine List as “access” are increasingly more difficult to procure, with fragile supply chains relying on just one or two providers of active pharmaceutical ingredients. DRIVE-AB has worked with the Norwegian government and health authorities to design a potential delinked model to secure access to critical antibiotics.

Methods
The Norwegian pilot was designed by a multi-disciplinary project group consisting of representatives from the Norwegian Directorate of Health, Norwegian Medicines Agency, the South-Eastern Norway Regional Health Authority, Norwegian Advisory Unit for Antibiotic Use in Hospitals, National Center for Medicine Shortages and Preparedness, the Hospital Procurement Agency, and the Norwegian Institute of Public Health. The project lasted one year and included: an assessment of critically important antibiotics for Norway, incentives for stable supply, exploring the possibility of expanding the health technology process to include the unique societal values of antibiotics, and designing a delinked model that could be implemented in Norway with buy-in of all stakeholders.

Results
Determining critically important antibiotics
• Norway does not (as of 2017) collect data regarding which specific bacteria were targeted with the administered antibiotics. Without these data we could not score antibiotics based upon their activity, placement in the guidelines, use of health care resources, ecological profile, and accessibility.
• Our expert group recommended a more pragmatic approach to the missing resistance data, by solely focusing on antibiotics effective against ESBL and carbapenem-resistant infections, two areas of concern for the national hospitals. This resulted in identifying two, patented combination antibiotics: ceftazidime-avibactam and ceftolozane-tazobactam.

Enhancing Health Technology Assessments (HTA) to include the societal value of the antibiotic
• Additional HTA criteria that could estimate the societal value of new antibiotics are: (1) the value of reducing and controlling a specific drug-resistant threat, (2) the value of stable supply, and (3) the value of preparedness.
• From modest and incomplete first look at the societal values, it appears that there is a wide gap between Norway’s societal value for novel antibiotics and an amount that Norway would need to contribute to “a global pot” to stimulate greater antibiotic innovation. This is due to current low levels of multi-drug resistant bacteria and little sign of this changing in the near future.

Designing a delinked model
Implementing a fully delinked model within the current system was problematic for the following reasons:
• Having a unit price of zero can be a perverse incentive to overuse the antibiotic.
• Norway utilizes reference pricing for pharmaceuticals, and a fully delinked price would disrupt the system.
• The benefit did not exceed the cost of implementing a complicated accounting system where unit sales (charged at the maximum price) were rebated back to the correct hospital.
• In Norway there are stringent controls regarding physician contact with the pharmaceutical industry, and correspondingly there is no evidence to suggest that hospital physicians are overusing novel antibiotics.

A partially delinked model, i.e., one where manufacturers continue to receive revenues from unit sales and then additionally receive an insurance top-up payment, was preferred by all stakeholders. The hospital purchase organization is assessing specific tenders for antibiotics to ensure stable supply and incentivize manufacturers.

Conclusions
The Norwegian pilot design has clearly demonstrated several practical challenges of implementing a delinkage model. A fully delinked model was rejected as impractical and unnecessary. A partially delinked model was determined simpler to adapt to existing systems with little concern for abuse. Since Norway has low rates of antibiotic resistance, the societal value of novel antibiotics is likely to be low, lower than a level needed to stimulate innovation. Norway will need to determine if it will contribute to stimulating antibacterial innovation, and the best way of doing so.