Effective TB, HIV, malaria vaccines missing from pipeline

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Many of the vaccines critically needed to fight some of the world's most prevalent infectious diseases are not likely to be developed, a new analysis of current candidates in the research and development pipeline has found.

The study, led by Duke University's Center for Policy Impact in Global Health, analyzed 538 candidate products for 35 neglected diseases to estimate the costs and likelihood that each would progress to a product launch. Using a new financial modeling tool known as Portfolio-to-Impact (P2I), the researchers found that under current conditions and funding, about 128 of those candidates would make it through the pipeline, including new diagnostics and repurposed and novel medicines.

But the model suggests the current pipeline is unlikely to yield highly effective vaccines for tuberculosis (TB), HIV or malaria—advances that global health experts have said could be game-changers in the effort to control the worldwide spread of infectious diseases.

"What this tells us is that the current development pipeline is not likely to give us all the pieces to fight these diseases," said Gavin Yamey, professor of global health and public policy and director of the Center for Policy Impact in Global Health. "It underscores the need to substantially scale up resources and innovative development approaches to fill those gaps."

The P2I model was developed by TDR, the Special Programme for Research and Training in Tropical Diseases, and collaborators. The work was funded by the Swiss Agency for Development and Cooperation and the Bill & Melinda Gates Foundation. The findings and the model appear in *Gates Open Research*.

Yamey's team used the tool to analyze candidate medicines, vaccines, diagnostics and other technologies at various stages of development—from preclinical research to advanced clinical trials. To calculate the costs of developing these products, the team painstakingly classified each candidate into one of several development pathways. The model does not attempt to gauge the clinical value or utility of the launched innovations, only the costs incurred and the likelihood that a

candidate will make it to the launch phase.

In all, the researchers estimate it would cost about $16.3 billion to move the current candidates through the pipeline, with three-quarters of those costs coming in the first five years. Of the 128 expected launches, nearly six in 10 are for new diagnostic tests. Repurposed drugs accounted for another 13 percent of the predicted successes.

While highly effective vaccines for TB, HIV or malaria are unlikely to be launched, the P2I model did estimate some 85 other types of products for these three diseases would reach launch, reflecting the predominant share of R&D funding those diseases receive. By contrast, the model estimates there would be no launches for several tropical diseases like leprosy and trachoma. Each of those diseases currently receives less than one-half of 1 percent of all funding for neglected disease R&D, Yamey notes.

Researchers also identified 18 high-priority "missing" products, where the pipeline is not likely to yield advances of particular need. Bringing those additional products to market would require an investment of between $13.6 billion and $21.8 billion over the next 10 to 12 years, according to the study.

The authors note their estimate likely understates the total costs. Given that the current annual global spending on product development is about $3 billion, this suggests that an additional $1.5 billion to $2.8 billion—at least—is needed annually to close the R&D funding gap.

"The model shows us where the current pipeline is most robust and where it is lacking," said Yamey. "For global health advocates, this is a broad picture of what pieces we are likely to still be missing, and where we can direct priorities in funding and product development."

TDR Director John Reeder said the study shows how tools such as P2I can point to unexpected gaps in the R&D pipeline.

"From TDR's perspective, this is especially true for the many missing products highlighted for neglected tropical diseases," Reeder said. "As we work with countries to combat poverty-related infectious diseases, this capture of the gap in tools is essential to improve the health of the most vulnerable."

  More information: Ruth Young et al, Developing new health technologies for neglected diseases: a pipeline portfolio review and cost model, *Gates Open Research* (2018). DOI: 10.12688/gatesopenres.12817.2

Robert F Terry et al. Funding global health product R&D: the Portfolio-To-Impact Model (P2I), a new tool for modelling the impact of different research portfolios, *Gates Open Research* (2018). DOI: 10.12688/gatesopenres.12816.2

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