

Deadly gaps persist in new drug development for neglected diseases

October 24 2013

In a study published today in the open-access journal *The Lancet Global Health*, the Drugs for Neglected Diseases initiative (DNDi) and other researchers report a persistent deficiency in truly new therapeutics for neglected diseases, despite nominal progress and an acceleration in research and development (R&D) efforts. This continued 'fatal imbalance' in medical R&D points to the urgent need to develop and deliver groundbreaking new treatments for the world's poorest and most neglected patients.

Researchers from DNDi, Médecins Sans Frontières/Doctors Without Borders (MSF), the Special Programme for Research and Training in Tropical Diseases (WHO-TDR), and three universities (University Hospital of Grenoble, France; Joseph Fourier University, France; University of Oxford, UK) found that of the 850 new drugs and vaccines approved for all diseases, 4% (37) were for [neglected diseases](#), defined broadly as those prevalent primarily in poor countries: malaria, tuberculosis, 17 [neglected tropical diseases](#) (NTDs) as defined by the World Health Organization (WHO), 11 diarrheal diseases, and 19 other diseases of poverty, excluding HIV/AIDS. Globally these neglected diseases represent an 11% health burden, based on a recent assessment of 2010 disability-adjusted life-years (DALYs).

Most newly developed therapeutic products were repurposed versions of existing drugs. Of the 336 brand-new drugs (new chemical entities, or NCEs) approved for all diseases in 2000-2011, only four, or 1%, were for neglected diseases; three were for malaria, and one for diarrheal

disease. None were for any of the 17 WHO-listed NTDs.

'While [drug](#) and vaccine development shows signs of acceleration for neglected diseases, we must keep pushing to keep these diseases on the international policy agenda and move quickly to deliver truly transformative, life-saving treatments', said Dr Bernard Pécoul, Executive Director of DNDi.

Study highlights:

New drugs for neglected diseases have a measurable medical benefit: Using inclusion on the WHO Essential Medicines List (EML) as a proxy measure for medical benefit, 48% of all new therapeutic products (excluding vaccines/biological products) approved 2000-2011 for neglected diseases were on the EML, compared with 4% for all other diseases.

Clinical trials are lacking for neglected diseases: Of the nearly 150,000 registered clinical trials for new therapeutic products in development as of December 2011, only 1% were for neglected diseases.

Most new candidates in development are vaccines: 123 new products are currently in development for neglected diseases, with over half (55%; 68) being vaccines or biological products, including 21 for malaria. A little over a quarter (28%; 34) are for the 17 NTDs, with only 3 NCEs (for onchocerciasis, Chagas disease, sleeping sickness).

Drug repurposing and NCEs are further along in development than vaccines: 56% (38/68) of vaccine/biological product candidates are in Phase I clinical trials, whereas 85% (29/34) of repurposed-drug products and 63% (10/16) of NCEs are in Phases II-III.

Nearly 80% of neglected diseases have R&D gaps: Of the 49 neglected

diseases included in the study, 11 (22%) had no R&D gaps; 25 (51%) had R&D gaps and some ongoing R&D; and 13 (27%) had R&D gaps and no ongoing R&D.

Public sponsorship leads R&D: Clinical trial sponsors were 54% public (governments, academia, public research institutes), 23% private industry (pharma/biotech), and 15% private non-for-profit (product development partnerships, charities, foundations). Remaining 8% were mixed.

Forecasting sees numerous vaccines but few brand-new drugs: Applying attrition rates, the authors forecast 28 new registered products for neglected diseases over the next six years, but only five being NCEs. Fifteen new vaccines or biological products are forecasted to be registered in the next 10 years.

Neglected-disease R&D has accelerated somewhat over the past 35 years: Previous studies reported 0.6-1.3 new products/year for neglected diseases for 1975-1999. This study reports a slight increase of 2.4 new products/year for 2000-2011 and predicts 4.7 new [products](#)/year through 2018.

'Although strides have been made in the last decade, we still see deadly gaps in new medicines for some of the world's least visible patients', said Dr Nathalie Strub-Wourgaft, Medical Director of DNDi. 'We need to get more treatment candidates, NCEs or existing ones for repurposing, into and through the R&D pipeline to fundamentally change the way we manage these diseases.'

'Our patients are still waiting for true medical breakthroughs', said Dr Jean-Hervé Bradol of MSF, a co-author of the study. 'People are still suffering and dying from these diseases, and healthcare providers must be able to offer all patients - irrespective of their ability to pay - the best

treatment possible. Only then will we say that we have made progress.'

More information: Pedrique B et al. The drug and vaccine landscape for neglected diseases (2000-11): a systematic assessment. *Lancet Global Health*, Early Online Publication, 24 Oct 2013.

[www.thelancet.com/journals/lan ... \(13\)70078-0/fulltext](http://www.thelancet.com/journals/lan ... (13)70078-0/fulltext)

Provided by Drugs for Neglected Diseases Initiative

Citation: Deadly gaps persist in new drug development for neglected diseases (2013, October 24) retrieved 3 May 2024 from

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