



# FILLING THE GLOBAL HEALTH GAPS – WHERE COULD EU R&I FUNDING CONTRIBUTE?

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## Poverty-related and neglected disease (PRNDs) R&I will be anchored in Horizon Europe:

“Infectious diseases, including poverty-related and neglected diseases” are one of the health cluster’s intervention areas, and “specific challenges in low- and middle-income countries (LMICs), such as AIDS, tuberculosis and tropical diseases, including malaria” one line of activity therein<sup>1</sup>. The co-designed orientations document towards the first strategic plan includes “the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases are contained” as one of the targeted impacts<sup>2</sup>.

**Horizon Europe work programmes should therefore contribute to filling PRND research gaps**



## PREVENTIVE TOOLS NEEDED TO REDUCE THE BURDEN OF DISEASES

In the absence of a fully effective vaccine or cure, for many Neglected Tropical Diseases (NTDs) and malaria which are transmitted through mosquitoes, flies, snails, or bugs, **vector control**<sup>9</sup> is a critical way to protect at risk populations from transmission. Some interventions that have helped massively to reduce the disease burden, such as insecticide treated bed-nets and indoor residual spraying in malaria control, risk losing their effectiveness with increasing insecticide resistance of the vectors. As highlighted in the World Malaria Report<sup>10</sup>, young children at risk from malaria greatly benefit from **seasonal malaria chemoprevention (SMC)**. Similarly, pregnant women in endemic regions benefit from **intermittent preventive treatment for malaria in pregnancy (IPTp)**.

The following tools would be key to improving prevention and vector control:

### SMC and IPTp need to be constantly improved.

**Improved antimalarials** are also needed to prevent relapse in *Plasmodium vivax* malaria

### New tools to address the growing threat of

**outdoor biting**, such as Attractive Targeted Sugar Baits (ATSBs)

### Dual insecticide-treated bed nets with novel

**active ingredients** and new modes of action, to address the growing threat of insecticide resistance

### Extra long-lasting next-generation Indoor

**Residual Spray** (up to 12 months) which could be sprayed at any time of the year and proactively rotated sub-nationally

<sup>1</sup> Cf. Council of the EU: Partial General Approach on the Decision on establishing the specific programme implementing Horizon Europe (April 2019), available at: <http://data.consilium.europa.eu/doc/document/ST-8550-2019-INIT/en/pdf>

<sup>2</sup> Cf. European Commission: Orientations towards the first Strategic Plan for Horizon Europe (Dec 2019), available at: [https://ec.europa.eu/info/sites/info/files/research\\_and\\_innovation/strategy\\_on\\_research\\_and\\_innovation/documents/ec\\_rtd\\_orientations-he-strategic-plan\\_122019.pdf](https://ec.europa.eu/info/sites/info/files/research_and_innovation/strategy_on_research_and_innovation/documents/ec_rtd_orientations-he-strategic-plan_122019.pdf)

<sup>3</sup> For more information please refer to the WHO website on NTDs, available at [https://www.who.int/neglected\\_diseases/diseases/en/](https://www.who.int/neglected_diseases/diseases/en/)

<sup>4</sup> Controversies around Dengvaxia, the only licensed Dengue virus vaccine persist, and FDA approval was granted only for individuals with a laboratory-documented prior infection.

<sup>5</sup> Cf. e.g. Ibrahim A Khalil, MD et al: Morbidity, mortality, and long-term consequences associated with diarrhoea from Cryptosporidium infection in children younger than 5 years: a meta-analyses study The Lancet (July 2018), available at: [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(18\)30283-3/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30283-3/fulltext)

<sup>6</sup> Cf. Ole Olesen, Fareed Abdullah, Rene Coppens et al.: New hope for tuberculosis vaccines, The Lancet (July 2019), available at: [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(19\)30280-4/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(19)30280-4/fulltext)

<sup>7</sup> Cf. the Mosaic clinical trial, available at: <https://www.iavi.org/newsroom/the-right-approach-iavi-clinical-network-helps-janssen-assess-promising-mosaic-hiv-vaccine;> and the ALVAC and AIDSVAX trials in Thailandia, available at: <https://www.nejm.org/doi/full/10.1056/NEJMoa0908492>

<sup>8</sup> Cf. WHO: Q&A on the malaria vaccine implementation programme (Nov 2019), available at: <https://www.who.int/malaria/media/malaria-vaccine-implementation-qa/en/>

<sup>9</sup> For more information please refer to the WHO website on vector control, available at: <https://www.who.int/vector-control/en/>

<sup>10</sup> WHO: World Malaria report (2019), available at: <https://www.who.int/publications-detail/world-malaria-report-2019>



## NO LICENSED VACCINE AVAILABLE FOR THE MAJORITY OF PRND<sub>s</sub>

Vaccines are the most powerful public health tool in the fight against communicable diseases. Vaccines prevent disease, are more cost-effective and more sustainable than treatment, help avoid future drug resistance and contribute to improved educational and economic outcomes.

### Highest burden NTDs have no licensed vaccine

Among the 20 (groups of) NTDs<sup>3</sup>, vaccines are only available for rabies and dengue virus<sup>4</sup>. **Safe, effective and low-cost vaccines** against the most common neglected diseases need to be developed and should be **heat-stable and easy-to-administer** to allow use by frontline health workers in low resource health systems. **Co-formulated products** could prevent multiple diseases in a single dosing and facilitate higher immunisation coverage. There is also a need to look into other infectious diseases that are clearly poverty-related and that disproportionately affect marginalised populations in LMICs, such as **diarrheal diseases including cryptosporidiosis**<sup>5</sup>, against which there is no approved vaccine yet.

### Broad tuberculosis (TB) vaccine R&I strategy needed

The TB vaccine field has recently seen exciting scientific breakthroughs, with candidates generating positive results in clinical trials<sup>6</sup>. There is now a rich pre-clinical and clinical portfolio of candidates in the pipeline. It is however necessary to invest in **further research to take candidates forward to the next stage, as well as supporting the discovery of further novel candidates**. Only by doing so can we eventually get new vaccines to market by 2025 - 2030.

### HIV vaccines need further support

Experts agree that an HIV vaccine could help save millions of lives and end the pandemic, as well as save billions in healthcare costs. Scientists have recently made positive progress<sup>7</sup>, but **further investment is needed to accelerate the testing of vaccine candidates and to identify more antibodies** to fight HIV infection.

### Malaria vaccines have potential but need further development

The world's first malaria vaccine (RTS,S) has been shown to reduce cases of malaria in young children by 39%<sup>8</sup>. The vaccine is currently being implemented through immunisation programmes in three African countries and is being evaluated for wider-scale use as a complementary malaria control tool. While this is a historic scientific breakthrough, **a vaccine that prevents infection and/ or parasite transmission is needed for malaria elimination**. Promising vaccine candidates are in development, but additional investment is needed to help them progress along the pipeline.





# ESSENTIAL DIAGNOSTICS ARE MISSING

Access to appropriate diagnostic tools is critical to identify causes of disease, interrupt transmission, prevent the development of disabilities, and protect against the potential development of drug resistance. Diagnostics are essential for the management of PRNDs initiatives in LMICs, including vaccination campaigns, mass drug administration efforts and elimination programmes, as well as for epidemic surveillance and outbreak response in Europe and worldwide.

Due to the resource – poor, climatically challenging and often remote rural environments in which PRNDs mostly occur, **point-of-care, easy-to-use, reliable and low-cost diagnostic tools** are needed, including:

## Tests that detect multiple infections

(e.g. a combination test for both malaria and sleeping sickness) and target multiple pathogens in the same specimen (e.g. soil-transmitted helminthiases and *Schistosoma mansoni* in stool specimen)

## Tests to guide antibiotic prescription

(e.g. to differentiate bacterial vs. non-bacterial infections)

## Tests for non-specific symptoms that require a 'syndromic approach'

(e.g. for fever or diarrhoea)

## Tests that can be used outside of the clinic

(e.g. self-tests for hepatitis C)

### Significant gaps remain for TB tests

TB is the world's biggest infectious disease killer<sup>11</sup> but appropriate diagnostic tools for both latent and active TB infection are missing. To prevent TB reactivation in people at increased risk, **a diagnostic test that reliably predicts the occurrence of TB disease within the next 1-2 years** needs to be developed. Despite the recent progress made by the implementation of molecular technologies for the diagnosis of active TB, there is still a gap and a need for **rapid, easy-to-perform, non-sputum based diagnostic test for active TB**.

### Better diagnostics for childhood pneumonia

Pneumonia, which is largely preventable and treatable, is the biggest infectious killer of children under 5 worldwide. Research to identify and evaluate new **diagnostic tools for improved classification and diagnosis of pneumonia at the community level** (i.e., automated respiration counter, child's jacket with digital monitors, automated integrated device to monitor vital signs, possibility of pulse oximetry etc.) and to understand the contribution of *Haemophilus influenzae* type b (Hib), non-typable *H. influenzae* (NTHi) and *Mycobacterium tuberculosis* to the burden of pneumonia would be invaluable.



<sup>11</sup> TB claimed 1.5 million lives in 2018 according to the WHO 2019 World Tb report available at: <https://apps.who.int/iris/bitstream/handle/10665/329368/9789241565714-eng.pdf?ua=1>

<sup>12</sup> For more information on NTDs and product gaps, please see the WHO website available at [https://www.who.int/neglected\\_diseases/diseases/en/](https://www.who.int/neglected_diseases/diseases/en/) and the Drugs for Neglected Diseases Initiative's (DNDi) website at <https://www.dndi.org/diseases-projects/>

<sup>13</sup> Cf. Pedrique et al.: The drug and vaccine landscape for neglected diseases 2000-2011: a systematic assessment, *The Lancet* (2013); 1(6) e371–e379



## APPROPRIATE TREATMENT OPTIONS ARE LACKING

Many drugs to treat PRNDs have suboptimal efficacy, toxicity and protocol complexity, and are prohibitively expensive, difficult to administer, or require hospitalisation. This harms patients, hinders treatment adherence, may introduce resistant strains in endemic populations, and hampers moving from control to elimination programmes. Although NTDs<sup>12</sup> account for 11% of the global disease burden only 4% of new therapeutic products approved between 2000 and 2011 were indicated for neglected diseases<sup>13</sup>. Additionally, in some cases, like HIV/AIDS, advancing research towards a cure would accelerate progress towards ending the pandemic by helping overcome challenges posed by treatment drop-out, stigma and discrimination, and uncertainties related to the financial sustainability of programmes.

**New, improved treatment options or combinations of existing drugs need to be developed and tested in clinical trials, including for:**

**Malaria:** novel combination therapies that are active against resistant strains are needed, and improved, easy-to-take, single-dose cures to support compliance, particularly in children, that ideally would have the ability to block transmission of the parasite and provide post-treatment prophylaxis

**Mycetoma:** research to understand the exact route of infection, and more effective and affordable treatment options for the fungal form of the disease;

**Pneumonia:** Develop and test ways to power oxygen concentrators to improve access to oxygen at secondary health facilities and in hard to reach areas, develop innovative device(s) and ways to improve pneumonia treatment

**Snakebite:** there is a dire need for innovation at every point in the continuum of care, from the improvement of antivenom manufacturing to post-treatment wound management.

**Tuberculosis:** a novel, short (2-4 months) treatment for all patients needs to be developed, that is successful irrespective of resistance against current drugs, with once daily fixed dosing

**Visceral leishmaniasis:** an oral, safe, effective, low cost treatment of short course

**Chagas:** an affordable, age-adapted, safe paediatric formula, and a new drug for chronic disease that works in both stages of the disease

**Cryptosporidiosis:** a drug that is safe and effective in populations most severely affected, including immunocompromised individuals, such as HIV patients, and malnourished children

**Cutaneous leishmaniasis:** a safe, topical or oral well tolerated, self-administered and affordable treatment which could cure the lesions without leaving deep scars

**HIV & AIDS:** a safe, effective, scalable, and globally available and accessible cure that responds to the needs of people living with HIV. Ideally, it would also protect against reinfection

**Leprosy:** new post-exposure chemoprophylaxis (PEP) regimens are needed to improve effectiveness and reduce the risk of antimicrobial resistance. Implementation research is also needed to identify optimal strategies for implementation of the single dose rifampicine regimen in different settings and endemicity levels

**Lymphatic filariasis** (elephantiasis), and **onchocerciasis** (river blindness): a drug that can kill the adult worms



## NEED FOR IMPLEMENTATION RESEARCH

The EU should allocate resources to support operational and implementation research into effective models for scaling up access to existing interventions, as the coverage of many life-saving and innovative tools remains low in most affected countries.



## NEED FOR MORE RESEARCH TARGETING WOMEN

Diseases such as HIV, TB, and malaria are closely linked to direct causes of maternal mortality such as postpartum haemorrhage and sepsis, and there is a lack of tools that can be safely used during pregnancy. Despite advances in prevention and treatment, women remain at an alarming risk of HIV infection, in particular, young women aged 15 – 24 years, who are twice as likely to be living with HIV than men<sup>14</sup>.

In HIV prevention, there is an urgent need for **new women-centered tools**, which come in discrete forms, and allow women to reduce their infection risk on their own terms, without partner negotiation, such as **long-acting microbicide vaginal rings**. **Multipurpose products** like vaginal rings that prevent both HIV and unintended pregnancy could give women a new way to address dual threats to their sexual and reproductive health.

In malaria treatment and prevention, **new medicines are needed to treat and protect pregnant women**, particularly in the first trimester of pregnancy. Pregnant women should also be considered for inclusion in clinical studies so that they can benefit from new drugs earlier in the process.

There is also an urgent need for basic and clinical **research to better understand the inter-connection between causes of maternal mortality and HIV, TB and malaria infection**, and to develop and test the efficacy of new treatments to reduce maternal mortality.



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## LMICs WILL BEAR THE GREATEST BURDEN

According to the latest World Bank report on antimicrobial resistance (AMR), LMICs will bear the greatest burden of AMR's rising social and economic impacts, which makes AMR an important development challenge far beyond public health that threatens several gains made in the 20th century<sup>15</sup>. Already today, about 29% of AMR-related deaths globally are due to drug-resistant TB, and multidrug-resistant TB (MDR-TB). Existing treatment for tuberculosis, especially drug resistant TB is long (6 – 24 months) and ineffective, with low treatment success rates (only 56% in patients with resistant TB). There is also rising concern about resistance to antiviral drugs against HIV & AIDS, and first-line treatment for malaria (artemisinin-based combination therapies). Without novel therapies, malaria could become untreatable in some parts of the world.

<sup>14</sup> UNAIDS Global HIV & AIDS statistics factsheet 2019, available at: <https://www.unaids.org/en/resources/fact-sheet>

<sup>15</sup> Cf. World Bank (2019): pp. Vi –ix, available at: <https://openknowledge.worldbank.org/bitstream/handle/10986/32552/>

[Pulling-Together-to-Beat-Superbugs-Knowledge-and-Implementation-Gaps-in-Addressing-Antimicrobial-Resistance.pdf?sequence=1&isAllowed=y](https://openknowledge.worldbank.org/bitstream/handle/10986/32552/Pulling-Together-to-Beat-Superbugs-Knowledge-and-Implementation-Gaps-in-Addressing-Antimicrobial-Resistance.pdf?sequence=1&isAllowed=y)

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