

Funding for Pediatric TB Research, 2012

Supplement to the 2013 Report on Tuberculosis Research Funding Trends, 2005–2012

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Introduction

Research is urgently needed for better vaccines, diagnostics, and treatment options to protect children from and cure them of tuberculosis (TB). Funding for TB research and development (R&D) overall is dangerously inadequate—in 2012, TB R&D suffered a \$1.4 billion shortfall, according to Treatment Action Group's (TAG's) *2013 Report on Tuberculosis Research Funding Trends, 2005–2012*. In partnership with the World Health Organization, UNICEF, and others, TAG recently published the *Roadmap for Childhood Tuberculosis*, which outlines key actions and investments needed to address pediatric TB. The report estimates that R&D projects to provide new tools to prevent, diagnose, and treat TB among children specifically will require \$200 million in investments between 2011 and 2015. The portion of TB R&D funding going to pediatrics, and whether this funding is adequate to address knowledge and product gaps, has been unknown. This supplementary report is the first to identify funding amounts for pediatric TB research.

Methodology

TAG tracks investments in TB R&D against funding targets laid out by the Stop TB Partnership's *Global Plan to Stop TB 2011–2015*. For this pediatric supplement, TAG conducted a keyword search in descriptions of funded projects documented in its larger report. Search terms were “pediatric,” “child,” “adolescent,” and “infant.” Using results from this search, cross-checked against a qualitative survey of TB R&D donors, TAG identified funders of pediatric TB R&D in 2010, 2011, and 2012.¹ TAG converted funding reported in non-U.S. currency to U.S. dollars using the July 1 currency exchange rate for each reporting year using the OANDA Corporation's currency conversion tool at <http://www.oanda.com/currency/coverter>.

Limitations

While the keyword search yielded 14 donors in 2012, and 12 donors in both 2010 and 2011, this methodology likely resulted in an underestimate of pediatric TB R&D funding. This methodology misses preclinical and clinical studies that do not explicitly include children, even though they may inform the development of pediatric products. Despite known investments in pediatric TB research, organizations such as the U.S. Centers for Disease Control and Prevention and private-sector drug developers like Otsuka report only aggregate R&D funding data; this renders their investments in pediatric TB research invisible. Another limitation due to aggregation is that some donors—such as companies V and X, and the Canadian Institutes for Health Research (CIHR)—varied by year whether they report TB R&D investments in detail or in aggregate. TAG captured more specific pediatric funding data from these donors in 2012, which likely masked even steeper declines in pediatric R&D funding from 2011 and 2010, when their pediatric investments did not contribute to funding totals.

1. The qualitative survey included the questions, “Did your institution target funds to address pediatric TB research needs in [year]? If yes, in which area and how much?”

Results

In 2012, reported pediatric TB R&D funding amounted to \$10.3 million, with just 14 donors disclosing their funding (see table 1). Pediatric TB R&D received just two percent of the \$627.4 million that 85 funders invested in overall TB R&D in 2012, according to TAG's *2013 Report on Tuberculosis Research Funding Trends, 2005–2012*. However, from 2011 to 2012, pediatric TB R&D investments declined by 11.5%—an even steeper drop than the 4.6% decline in overall TB R&D funding. In 2011, pediatric TB R&D funding from 12 reporting donors totaled \$11.6 million out of a total \$657.8 million for TB R&D from 81 reporting institutions. In 2010, 12 funders contributed just \$6.9 million to pediatric TB R&D, out of a total of \$630.4 million from 74 reporting funders.

In 2012, 14 donors reported investing in pediatric TB R&D. The public sector made the largest contribution: \$7.2 million, or 67 percent of the pediatric funding total. The top two donors to pediatric TB R&D were both from the public sector—one from the United Kingdom, the other from the United

TABLE 1

2012 Pediatric TB R&D Funders by Rank and Compared with Prior Years

2012 Rank	Funding Organization	Funder Type	2012 Pediatric TB R&D Funding	2011 Pediatric TB R&D Funding	2010 Pediatric TB R&D Funding	2012 Total TB R&D Funding	Percentage of 2012 Total R&D Funding Allocated to Pediatrics
1	U.K. Medical Research Council (MRC)	P	\$2,644,610	\$3,111,533	\$408,718	\$14,790,087	17.9
2	Other National Institutes of Health Institutes and Centers (Other NIH ICs)*	P	\$2,624,745	\$1,917,849	\$1,772,537	\$36,646,883	7.2
3	Company X	C	\$1,718,595	N/A	N/A	\$22,844,099	7.5
4	U.S. National Institute of Allergy and Infectious Diseases (NIAID)*	P	\$954,061	\$532,394	\$554,003	\$169,092,971	0.6
5	Wellcome Trust	F	\$551,017	\$2,606,924	\$322,682	\$13,418,817	4.1
6	Company V	C	\$481,080	N/A	N/A	\$4,297,934	11.2
7	U.S. President's Emergency Plan for AIDS Relief (PEPFAR)	P	\$450,000	\$0	\$0	\$6,606,609	6.8
8	Canadian Institutes of Health Research (CIHR)	P	\$326,268	\$661,616	N/A	\$6,017,561	5.4
9	Australian National Health and Medical Research Council (Australia NHMRC)	P	\$166,738	\$295,363	\$153,590	\$4,060,791	4.1
10	Danish International Development Agency (DANIDA)	P-D	\$154,993	N/A	N/A	\$323,250	47.9
11	World Health Organization (WHO)	M	\$85,260	\$0	\$0	\$1,707,923	5.0
12	U.S. Agency for International Development (USAID)	P-D	\$50,000	N/A	N/A	\$12,174,064	0.4
13	Norwegian Knowledge Centre for the Health Services (NOKC)	P	\$48,460	N/A	N/A	\$48,460	100.0
14	Indian Council of Medical Research (ICMR)	P	\$23,047	N/A	N/A	\$7,131,390	0.3
Grand Total			\$10,278,875				

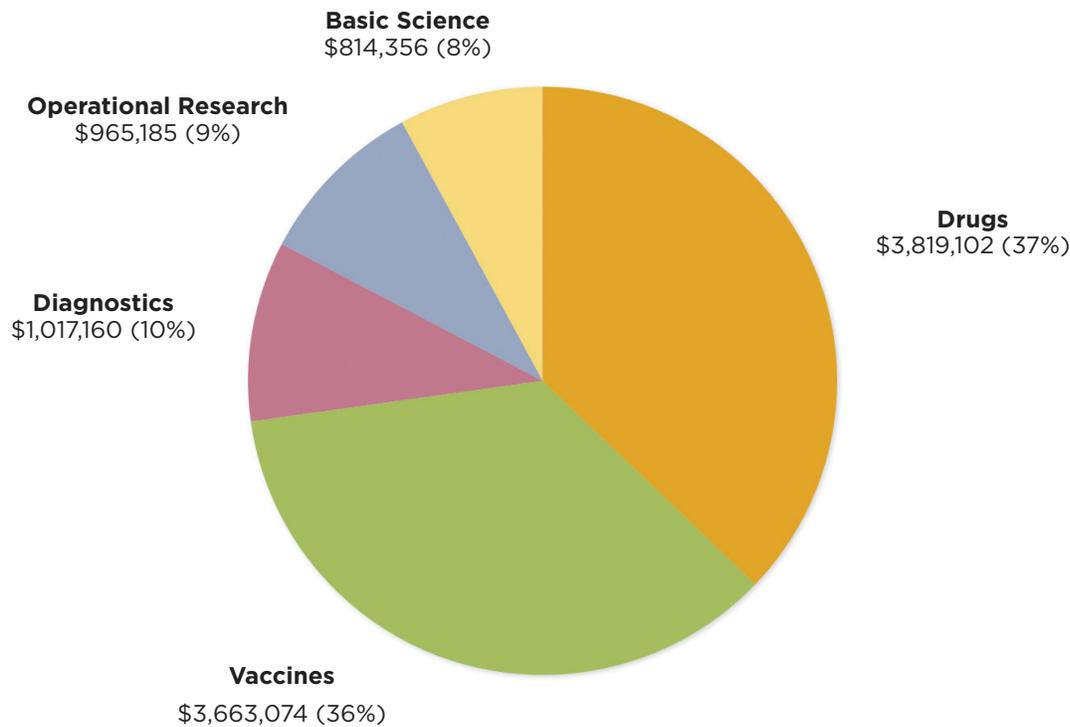
P= public-sector R&D agency; C= Corporation/private sector; M= Multilateral; F=Foundation/philanthropy; P-D= Public-sector development agency

*TAG reports National Institutes of Health (NIH) investments in three categories: 1) National Institute of Allergy and Infectious Diseases (NIAID)—the largest investor in TB R&D overall; 2) the National Health, Lung and Blood Institute (NHLBI)—which did not document investments in pediatric TB R&D; and 3) other NIH institutes and centers (other NIH ICs).

Note: This table records contributions made only by funders investing in pediatric TB R&D in 2012.

FIGURE 1

Pediatric TB R&D Investments by Research Category: 2012
Total: \$10,278,875



States. The second largest contribution by sector came from corporations, with \$2.2 million, or 21% of the funding total. Foundations and multilateral agencies were poorly represented, with only one donor per category contributing to pediatric TB R&D.

Drug and vaccine development received the largest proportion of reported pediatric TB funding (see figure 1), yet even these investments were minimal, further delaying access to the development of new child-friendly TB treatments and prevention products. In 2012, out of \$237.8 million in total TB drug R&D funding, only \$3.8 million was invested in pediatric drug development. Given the limitations of existing drugs in terms of safety and appropriate formulations for children, and the few studies of new TB drugs in children, investments in pediatric TB drug R&D must be rapidly increased.

The scant investment in diagnostics R&D for children is particularly troubling, given that the current sputum-based tests do not work well in children. The relatively higher R&D funding for pediatric TB vaccines, however, has produced some important advances: groups such as the South African Tuberculosis Vaccines Initiative (SATVI) have demonstrated that pediatric testing of TB vaccines based on the BCG platform can be done ethically. The TB vaccine research community should pay more attention to developing candidates that can be given to young children—not just to adolescents—and, as long as safety allows, develop these vaccines with children as a priority, rather than an afterthought, as is usually the case with drugs.

Recommendations

- ▶ **Funders need to invest more in pediatric TB R&D** to ensure that children benefit from much-needed innovations in TB. Current preventive tools are inadequate; available diagnostics do not work well in children; there is little investment in new child-friendly tests; and pediatric formulations and safety and dosing data are lacking for many TB treatment options—even for those that have been on the market for decades.
- ▶ **Pediatric TB R&D funding sources must be diversified** beyond the public sector: development agencies, multilateral agencies, and philanthropic institutions should scale up their investments. This is also an ideal investment area for donors who may not otherwise engage in TB or R&D funding, but who seek to increase child survival.
- ▶ **The Global Plan to Stop TB should include evidence-based funding targets for pediatric research** to determine what resources are necessary to support a coordinated and effective pediatric research agenda.
- ▶ **Product developers must address pediatric needs in R&D earlier**, especially in drug and diagnostics development. Vaccine developers should direct more attention to preventing TB in young children, not just in adolescents.
- ▶ **Researchers need to determine priority areas and plan for pediatric research.** Some research and policy groups have made notable progress on advancing pediatric TB research and calling for future investments. These groups include the Sentinel Project for Pediatric Drug-Resistant TB, the Stop TB Partnership’s Childhood TB Subgroup, the Tuberculosis Trial Consortium’s Pediatric Interest Group, the NIH’s International Maternal Pediatric Adolescent AIDS Clinical Trials Group, and a new NIH-convened multi-stakeholder panel that is promoting timely pediatric safety and dosing evidence for TB drugs and regimens. Drug sponsors Otsuka, the TB Alliance, and companies X and V are also advancing work in this field. Yet overall, pediatric research agendas have advanced slowly and without sufficient coordination.
- ▶ **Regulators can accelerate the development of pediatric drugs and combinations** by mandating the development of pediatric medications. The European Medicines Agency already has this requirement in place; changing U.S. law to allow the U.S. Food and Drug Administration to require sponsors seeking approval for new agents to develop and submit a pediatric investigational plan could help close the regulatory approval gap between adult and pediatric medications.
- ▶ **Donors should strive to better track funds and identify pediatric awards.** Comprehensive and transparent reporting is needed to fully understand pediatric TB R&D funding trends, and to enable proper credit to be given to companies such as Otsuka that are leading the way in investing in pediatric TB R&D.

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