ENSURING CHILDREN BENEFIT FROM SCIENTIFIC PROGRESS: THE PEDIATRIC TB PIPELINE REPORT

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49th Union World Conference on Lung Health
The Hague, The Netherlands
25 October 2018
A part of legally-binding international human rights law.

**Article 27** of the Universal Declaration of Human Rights (UDHR) and **Article 15** of the International Covenant on Economic, Social and Cultural Rights (ICESCR).

Governments “must recognize the right of everyone:

a) to take part in cultural life;

b) to enjoy the **benefits** of scientific progress and its **applications**

c) to benefit from the moral and material interests that stem from scientific, literary or artistic productions which one authors.”

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BENEFITS AND APPLICATIONS

a) Tangible applications
   • e.g., new technologies such as medicines.

b) Intangible applications
   • Access to knowledge and information (the right to information).
   • Applying knowledge as empirical basis for developing laws, devising policies, designing and monitoring public health programs.

c) Benefits includes the results and outputs of science, as well as the means, materials, and methods of science (the right to participation).

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**WHAT OBLIGATIONS DO STATES HOLD?**

Article 15 specifies that full realization of the right to science requires that governments take steps “necessary for the conservation, development and the diffusion of science and culture.”

<table>
<thead>
<tr>
<th>Development</th>
<th>Invest in research and channel resources to support a “purposive development” of science and technology to meet the needs of marginalized and disadvantaged groups.</th>
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<tbody>
<tr>
<td>Diffusion</td>
<td>Connect people to the benefits of science (tangible and intangible) in a way that ensures non-discrimination and enables participation.</td>
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<tr>
<td>Conservation</td>
<td>Ensure that the benefits gained through science are lasting—not just for people alive today, but also for future generations.</td>
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HOW DOES THE RIGHT TO SCIENCE APPLY TO CHILDREN WITH TB?

Development
- Pediatric pharmacokinetic (PK) & safety studies;
- Pediatric efficacy studies; and
- Formulation development and acceptability work

Diffusion
- Pediatric treatment policies & dosing guidelines; and
- Awareness about & access to pediatric formulations and regimens

Conservation
- Establishing and maintaining a stable market for quality-assured pediatric formulations; and
- Ensuring countries can continue to access this market, even without donor support
Prevention

“TB prevention research is advancing, yet inclusion of children is inconsistent.”

Diagnosis

“…the TB diagnostics research community and funders need to join the drug development community in accepting that children are not just small adults.”

Treatment

“Continued investments in pediatric PK and safety studies, and rapid translations of findings into policy and practice will be necessary for children to benefit from ongoing TB treatment optimization work.”
"Funding in 2017 increased in almost every area of TB research tracked by TAG, from basic science to the development of new diagnostics, drugs, and vaccines to operational research. Within these categories, spending on research related to pediatric TB, a traditionally neglected area, nearly doubled to $54 million."

Fair share concept for TB R&D funding suggests that all countries spend 0.1% of what they spend on all forms of R&D (referred to as a country’s gross domestic expenditure on research and development (GERD)).
“[…] children affected by TB have specific needs that merit a pediatric-focused research agenda.”

1. Epidemiology
2. Basic science & fundamental research
3. Prevention
4. Diagnosis
5. Treatment
6. Operational research
Children represent 10% of the global burden of TB, yet funding for pediatric TB research represents only 3% of total TB research funding available in 2016.

Commensurate with the global burden of TB among children, 10% of the US$ 1.8 billion annual TB research-funding target (i.e. US$ 180 million per year) could serve as an appropriate benchmark against which to measure progress towards increasing investments in pediatric TB research initiatives.

To ensure that pediatric-specific research objectives are met, countries could commit to dedicating 10% of TB R&D funding (0.01% of their overall spending on R&D) to pediatric TB.
Globally in 2017, over 75% (of 1.3 million eligible household contacts under 5 years of age) did not access preventive therapy.

1.6 million TB deaths in 2017

- 233,000 children (0-14) TB deaths in 2017
- 80% in children < 5 years
- 96% of deaths in children who did not access TB treatment
- 39,000 (17%) deaths among children living with HIV

(MDR-TB)

An estimated 25,000 children <15 years fell ill with MDR-TB in 2014

Less than 10% of them were diagnosed and had access to treatment

(Dodd et al., 2016 (19); Jenkins et al., 2014 (20))
OUTCOMES OF THE HIGH-LEVEL MEETING: DEVELOPMENT

26. “[…] global collaboration to ensure accelerated development of accessible and affordable diagnostic tools, and shorter and more effective oral regimens, including those that meet the unique needs of children […]”

42. “Commit to advancing research […] and the development of innovative products and approaches, […] including towards delivering, as soon as possible, new, safe, effective, equitable, affordable, available vaccines, point-of-care and child-friendly diagnostics, drug susceptibility tests and safer and more effective drugs and shorter treatment regimens for adults, adolescents and children for all forms of tuberculosis and infection […]”
OUTCOMES OF THE HIGH-LEVEL MEETING: DIFFUSION

24. “Commit to providing diagnosis and treatment with the aim of successfully treating 40 million people with tuberculosis from 2018 to 2022, including 3.5 million children, and 1.5 million people with drug-resistant tuberculosis, including 115,000 children […]”

25. “[...] at least 30 million people, including 4 million children under 5 years of age, 20 million other household contacts of people affected by tuberculosis, and 6 million people living with HIV, receive preventive treatment by 2022 […]”

28. “Commit to address tuberculosis prevention, diagnosis, treatment and care in the context of child health and survival, as an important cause of preventable childhood illness and death, including among children with HIV and as a co-morbidity of other common childhood illnesses, especially pneumonia, meningitis and malnutrition; to enable child-friendly policies and an integrated, family-based approach to tuberculosis care and services, address the vulnerabilities faced by children affected by tuberculosis, support their caregivers, in particular women and the elderly, and provide related social protection; to promote equitable access to child-friendly formulations of medicines to optimize the prevention and treatment of drug-sensitive and drug-resistant tuberculosis among children, including through addressing national regulatory and policy barriers;”
SO WHAT DO WE NEED TO DO?

- We need to shrink research delays and eliminate research and knowledge gaps between adults and children.
- When research results in a new standard of care that redefines the “highest attainable” standard of health, we need to implement it—for everybody, including children.
- We need to think not just about access, but also about its shadow side: exclusion. Who is left out and why?
- We need to recognize that the way research (development) is conducted determines who is excluded and sets limits on diffusion.
  - Market-driven approaches to R&D are inconsistent with the obligation to support purposive (or needs-driven) development.
  - Maximalist approaches to IP mean some people will be excluded from enjoying the benefits of science.
  - Premature withdrawal of donor support may jeopardize conservation if mechanisms for disseminating scientific benefits are weakened (e.g., the threat Global Fund Sustainability, Transition, and Co-Financing policies pose to sustainable and stable access to quality-assured medicines).
- We need to try different approaches to support the development, diffusion, and conservation of science for people with or at risk of TB.
  - Innovative models for financing R&D (e.g., delinkage), including for children.
  - Approaches to aid that see solidarity as a lasting, evolving relationship, not as a contingent arrangement or eligibility to “graduate” from.

*Adapted from slide borrowed from Mike Frick*
THANK YOU!

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