DIAGNOSTIC TARGET PRODUCT PROFILE

for monitoring and evaluation of soil-transmitted helminth control programmes

World Health Organization

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1. Introduction

Soil-transmitted helminths are a group of intestinal worms that include *Ascaris lumbricoides* (giant roundworm), *Trichuris trichiura* (whipworm), and *Ancylostoma* spp. (*A. duodenale, A. ceylanicum*) and *Necator americanus* (hookworms). Despite the clear biological differences among the different species, their transmission is characterized by the same sequence of events: (i) infected individuals excrete worm eggs through their stool in soil; (ii) under optimal conditions of moisture and temperature the excreted eggs develop into infectious stages; and (iii) finally, infection occurs through oral uptake (*Ascaris, Ancylostoma* and *Trichuris*) or skin penetration (*Ancylostoma* and *Necator*) of these infectious stages (embryonated eggs and third stage larvae) that reside in the soil and/or in the environment (referring to their common name).

2. Epidemiology

It is estimated that 800 million people worldwide are infected with at least one species of soil-transmitted helminth, resulting in a global disease burden of more than 3 million disability-adjusted life years. Given the route of transmission, these infections and their associated disease burden predominate in (sub)tropical countries where optimal climate conditions for egg survival and larval development in the environment, poor socioeconomic status and lack of appropriate access to water, sanitation and hygiene facilitate transmission. Attributable morbidity is mainly associated with infections of moderate-to-heavy intensity and mainly affects children and women of reproductive age. Effects include impaired growth and cognitive development, malnutrition, anaemia and school absenteeism in children, and malnutrition and anaemia in women.

3. Public health response

In areas where soil-transmitted helminths are endemic, the World Health Organization (WHO) recommends preventive chemotherapy with a single tablet of an anthelminthic medicine (400 mg albendazole or 500 mg mebendazole), which is periodically administered to both preschool-aged and school-aged children and to other populations at risk. Both medicines are safe for healthy people who do not have infections; it is more cost-effective to treat all populations at risk than to test and treat each individual. The frequency of large-scale deworming is based on the observed prevalence of any of the species, as measured by Kato-Katz thick smear on stool samples, and whether or not this prevalence exceeds a predefined decision threshold. For example, at the start of the preventive chemotherapy programme, it is recommended to distribute medicines twice a year when the prevalence is at least 50% and once a year when the prevalence is at least 20%. During the implementation phase, the prevalence of any soil-transmitted helminth infection is periodically re-evaluated to verify whether objectives are being met, and, if necessary, to adjust the frequency of administration (observed prevalence ≥ 50%: 3 rounds of preventive chemotherapy per year; > 50% observed prevalence ≥ 20%: maintain frequency of preventive chemotherapy; > 20% observed prevalence ≥ 10%: 1 round of preventive chemotherapy per year; > 10% observed prevalence ≥ 2%: 1 round of preventive chemotherapy for 2 years; observed prevalence < 2%: no preventive chemotherapy).

However, this is insufficient to interrupt transmission without additional measures such as increased access to clean water and sanitation and education as well as behavioural change, or by expanding preventive chemotherapy to entire communities. As a result, WHO guidelines for most countries target reducing the prevalence of moderate-to-heavy intensity infections to < 2% (in preschool-aged and school-aged children), which is the target defined for elimination of soil-transmitted helminthiases as a public health problem.

4. Available diagnostic tools

Traditionally, soil-transmitted helminths have been diagnosed by detecting worm-specific eggs in stool samples examined by microscope. Since the 1990s, WHO has recommended Kato-Katz as the diagnostic standard for quantifying eggs in stools. During the past decade, a variety of new diagnostic tests have been introduced to the field, including both microscopy-based (e.g. FECPAK^{G2} and (mini-) FLOTAC), and DNA-based methods (quantitative polymerase chain reaction (qPCR)). Each of these tests has important advantages and disadvantages over Kato-Katz. Important advantages are a clearer microscopic view (FECPAK^{G2} and (mini-)FLOTAC); a higher clinical sensitivity (proportion of infected individuals correctly diagnosed as infected ((mini-)FLOTAC, and qPCR); opportunities for automated egg counting and quality control (e.g. FECPAK^{G2}); and abilities to differentiate hookworm species and to simultaneously detect parasites other than soil-transmitted helminths (qPCR). Chief limitations of these novel tests are the need for well-equipped laboratories with well-trained, skilled technicians (e.g. FLOTAC and qPCR), the higher cost of processing large numbers of samples (FECPAK^{G2}, mini-FLOTAC and qPCR) and the lack of standardized protocols and commercially available kits (qPCR). This is in particular when samples are processed in a laboratory distant from the collection site. Currently, most technologies based on other biomarkers (e.g. antigens, antibodies and metabolites) or other sample matrices (e.g. serum and urine) are either not yet explored, in the research phase or only commercialized for certain worm species.

5. Diagnostic Technical Advisory Group

The WHO Department of Control of Neglected Tropical Diseases manages a diverse portfolio of 20 diseases and disease groups, each with its own unique epidemiological and diagnostic challenges. The Strategic and Technical Advisory Group for Neglected Tropical Diseases, WHO's principal advisory group for the control of these diseases, decided that a single working group would help to ensure a unified approach to identifying and prioritizing diagnostic needs and to informing the Organization's