Diagnostic Target Product Profile for scabies to Start and Stop Mass Drug Administration

Scabies is a ectoparasitic disease that is found worldwide. There are approximately 400 million cases a year.

Epidemiology

Scabies is caused by infestation with the human ectoparasite *Sarcoptes scabei* var *hominis*. Worldwide the highest burden of disease is in low-and-middle income settings[1,2]. Scabies is particularly common amongst young children. Infestation is associated with skin lesions and severe itch which profoundly impacts quality of life. Individuals with scabies are at an increased risk of secondary bacterial skin infection (impetigo) and this may result in more severe complications (such as necrotizing soft tissue infections and bacteraemia) and also to immunologically mediated phenomenona including glomerulonephritis and rheumatic feve ; these complications are not theoretical or rare – rather, they are frequent sequelae of scabies, particularly in highly-endemic populations.

Public Health Response

In 2019 WHO held a first Informal Consultation on a Framework for the Public HealthControl of Scabies[3]. In areas where the prevalence of scabies is particularly high, the best available evidence supports the use of ivermectin-based mass drug administration (MDA) to control scabies. This strategy consists of 2 doses of oral ivermectin delivered 7-14 days apart (with 5% topical permethrin offered to individuals in whom ivermectin is contraindicated)[4].

On the basis of current best evidence the informal recommendation is to commence MDA in settings where the community prevalence of scabies is ≥ 10%. The current informal recommendation is to conduct 3-5 rounds of MDA before re-assessing the burden of disease. If the prevalence of scabies is below 2% then MDA can be halted.

In 2021, supported by the World Scabies Programme, the first national programmes will be initiated in Fiji and the Solomon Islands supported by the World Scabies Programme. The 2021-2030 NTD roadmap has set a target for 25 countries to have rolled out MDA for scabies control by 2030.

Available Diagnostic Tools

Currently, clinical examination is the mainstay of scabies diagnosis. In high-income settings dermatoscopy and other diagnostic tests are occasionally used to supplement clinical examination. However, these tests are insensitive and not practical for field use within community based programs. Other diagnostic tests such as PCR remain at a developmental stage.

Diagnostic Technical Advisory Group

The WHO Department of Control of Neglected Tropical Diseases (NTD) manages a diverse portfolio of twenty diseases and disease groups, each with its own unique epidemiological and diagnostic challenges. It was decided by the Strategic and Technical Advisory Group (STAG), the principal advisory group to WHO on the control of NTDs, that a single WHO working group would help ensure that a unified approach could be used to identify and prioritize diagnostic needs, and to inform WHO strategies and guidance on the subject of NTD diagnostics[5].

The first meeting of this group, the Diagnostic Technical Advisory Group (DTAG), an advisory group to the Department of Control of Neglected Tropical Diseases, was held in Geneva, Switzerland, on 30 and 31 October 2019.

DTAG members discussed priorities for the year ahead as well as how to manage the complexity of supporting the diagnostics agenda across the entirety of the WHO NTD portfolio. Recommendations were made, based on the understanding that they would be reviewed at the next meeting, as it had been made clear that all NTDs had diagnostic needs which would have to be addressed in due course.

One of the recommendations was that Target Product Profiles (TPPs) for diagnostics were needed to support emerging scabies control programmes and specifically TPPs were needed for both starting and stopping MDA.

These TPPs are therefore focused on diagnosis of 'common scabies' and not crusted scabies.

Purpose of the TPP

Currently there is no formal WHO guideline on scabies MDA. A provisional strategy for the control of scabies was developed at the WHO Informal Consultation in Manilla (2019). The major areas of consensus were on strategies when the prevalence of scabies was high (≥ 10%) and therefore the initial programmatic needs are framed around these areas.

The purpose of this TPP proposed by WHO NTD is to lead to development of new diagnostic tools to measure when there is evidence to support starting and/or stopping ivermectin-based MDA.

For starting MDA, when deployed as part of an appropriately-powered population-based survey, the test must be able to demonstrate that the surveyed prevalence exceeds the defined prevalence threshold of 10% in a designated geographic area with a specified probability

For stopping MDA, when deployed as part of an appropriately-powered population-based survey, the test must be able to demonstrate that the surveyed prevalence is below the defined prevalence threshold of 2% in a designated geographic area with a specified probability

It is recognised that the evidence informing these TPPs is at a more preliminary stage than that of other NTDs and there is likely to be ongoing evolution of programme targets and survey/mapping strategies which will influence the parameters offered in this document.

Bibliography

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