Validation of elimination of schistosomiasis as a public health problem

and

verification of interruption of schistosomiasis transmission

Criteria and procedures

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Abbreviations

DOI: Digital Online Identifier

NEC: National expert committee

EPIRF: Epidemiological Data Reporting Form

EPHP: Elimination as a Public Health Problem

JAP: Joint Application Package

JMP: Joint Monitoring Programme

JRSM: Joint Requested for Selected Medicines

NGO: Non-Governmental Organization

NSCP: National Schistosomiasis Control Programme

NTD: Neglected Tropical Disease

PMM: Programme Managers Meetings

RPAG: Regional Programme Advisory Group

SAC: School-aged Children

SCH: schistosomes / schistosomiasis

SPR: Schistosomiasis Programme Review

STH: Soil Transmitted Helminths

Th2: T helper type-2

WASH: Water, Sanitation and Hygiene

WHA: World Health Assembly

WHO: World Health Organization

Glossary

The terms defined below relate to their use in this manual and may not be valid in other contexts.

baseline assessment

An assessment of the prevalence and intensity of schistosome infections before any large-scale control interventions.

coverage

eligible population

Group of individuals qualified or entitled to receive anthelminthic treatment in preventive chemotherapy interventions. Eligible populations may vary from high-risk groups in targeted treatment interventions to the entire population living in endemic areas in mass drug administration (MDA) interventions

target eligible population

population in an implementation unit that is targeted for treatment. In the context of schistosomiasis, the target population for mass drug administration is the same as the population eligible to receive the medicines (>=2 years)

effective coverage

A measure, when relating to soil-transmitted helminthiases and schistosomiasis control programmes, defined by the World Health Organization (WHO) as treating ≥ 75% of the target population.

geographical coverage

The proportion of endemic administrative units that are implementing preventive chemotherapy of all administrative units that require the intervention.

national coverage

The proportion of individuals in an endemic country requiring preventive chemotherapy who have ingested the medicines from all those requiring the intervention at national level.

programme coverage

The proportion of individuals in the target population ingesting the preventive chemotherapy medicines in the designated endemic area targeted for treatment.

treatment coverage

The proportion of individuals in a defined population who took the treatment. The defined population can be (i) a target group for treatment, for instance, school-aged children; (ii) the entire population of a geographical region, administrative area or community where the diseases are endemic; or (iii) the entire population of a country.

deworming round

The distribution of an anthelminthic medicine to a population during a defined period according to WHO guidance on control and elimination of schistosomiasis. The number of rounds can vary from one round to several rounds of treatment in a year to less frequent rounds such as one round every 2 or 3 years.

disability-adjusted life year (DALYs)

A measure of overall disease burden, expressed as the number of years lost due to ill health, disability or early death; DALYs for a disease or health condition are calculated as the sum of the years of life lost due to premature mortality in the population and the years lost due to disability resulting from the health condition or its consequences.

disease burden

The cumulative mortality, disability and morbidity attributable to a disease.

ecological zone

A geographical area that is homogeneous in terms of humidity, rainfall, vegetation, use of same water bodies, population density, and sanitation level.

eggs per gram (epg) and eggs per 10 mL

The number of parasite eggs per gram of faeces or eggs per ten (10) milliliters of urine. When using the Kato–Katz method, the number of eggs counted per slide should be multiplied by 24 to calculate the number of eggs per gram (when using the standard 41.7 mg template). These measures provide an indirect measure of the intensity of helminth infection. See also **intensity of infection**.

elimination as a public health problem (EPHP)

A term related to both infection and disease, defined by achievement of measurable public health targets set by WHO in relation to a specific disease. When reached, continued actions are required to maintain the targets and/or to advance to the interruption of transmission. The process of documenting achievement of this goal is called **validation**.

WHO has identified the following indicator indicative of reaching EPHP schistosomiasis: < 1% prevalence of heavy intensity infections.

endemic area

A geographical area where infection is transmitted. Specifically, in the context of schistosomiasis, the term “endemic” is more commonly used to refer to areas where ongoing transmission occurs, and substantial morbidity is seen.

female genital schistosomiasis and male genital schistosomiasis

A granulomatous reaction to eggs of *Schistosoma haematobium* causing genital signs and symptoms similar to those of sexually transmitted infections. Female genital schistosomiasis commonly includes vaginal bleeding, inflammation of the cervix, tubal obstruction, pain during sexual intercourse, nodules in the vulva and infertility. Male genital schistosomiasis causes haemospermia and pain when ejaculating.

granuloma

A focal lesion resulting from an inflammatory reaction caused, in the case of schistosomiasis, by schistosome eggs. The initial lesion can evolve into fibrosis of the liver and urinary tract following the production of reactive fibrous tissue.

haematuria

A condition frequently present in individuals infected by *S. haematobium* characterized by red blood cells in the urine. Visible haematuria refers to blood present in sufficient quantity to be detectable by visual inspection of the urine. Micro hematuria refers to blood that is invisible to the naked eye, but that is detectable using a reagent strip or microscopy.

hotspot (for schistosomiasis)

persistent hotspot

Communities with baseline prevalence of *Schistosoma* spp. infection ≥ 10% who demonstrate lack of an appropriate response to at least 2 consecutive years of preventive chemotherapy, despite effective treatment coverage (≥ 75%). The lack of an appropriate response should be (provisionally) defined as a reduction in prevalence of less than one third between the baseline prevalence survey and a repeat prevalence survey completed after two annual rounds of preventive chemotherapy.

potential hotspot

Communities with baseline prevalence of *Schistosoma* spp. infection ≥ 10% who, because of frequent water contact behaviour, low coverage WASH, ecological or environmental situation, including the presence of irrigation schemes or dams, are considered at risk of being an area of high transmission and where potentially the normal control measures may be not sufficient to control morbidity.

implementation unit (IU)

An administratively defined area in which the same control intervention is applied. This is normally a district, a subdistrict or communities in the case of schistosomiasis depending on local endemic situation (because schistosomiasis is focal and is intensely acquired near freshwater bodies where the intermediate snail host is present).

intensity of infection

The number of adult helminths infecting an individual (also known as worm burden). It is usually measured indirectly by counting helminth eggs excreted in faeces (expressed as eggs per gram) or urine (schistosome eggs per 10 mL). Indirect methods are less intrusive, more convenient and more commonly used as proxy markers. The intensity of infection is often categorized as light, moderate or heavy. Infections. Intensity is largely responsible for the morbidity.

mass drug administration

In the case of helminths, the administration of anthelminthic medicines at regular intervals to the entire eligible population of an area (e.g. state, region, province, district, subdistrict, village/community), irrespective of the individual infection status. Mass drug administration is one form of preventive chemotherapy.

morbidity

The clinical consequences of infections and diseases that adversely affect an individual's health. In the case of schistosome infection, evident morbidity can be overt (e.g. haematuria, diarrhoea or ascites) or subtle (e.g. malabsorption, stunted growth or infertility). Subtle morbidity is that attributable to either schistosomiasis or other infection that is not normally identified in the clinical case definition for that infection, such as anaemia, growth impairment, decreased cognitive and work performance, and synergy with other infections.

neglected tropical disease (NTD)

A group of diseases linked to poverty and mainly transmitted in tropical and sub-tropical countries that are considered to have received insufficient attention from the donor community and public health planners. The World Health Organization lists 21 NTDs,[1] including schistosomiasis and soil-transmitted helminthiases.

One Health

A collaborative, multisectoral and transdisciplinary approach – working at local, regional, national and global levels – with the goal of achieving optimal health outcomes for people, animals and ecosystems/environment. This approach acknowledges the interconnectedness of humans, animals, plants and their shared environment to effectively address health challenges.

preschool-aged children (pre-SAC)

Children aged <5 years, but in case of eligibility for mass treatment of schistosomiasis pre-SAC refer to children aged between 24 and 59 months (2–4 years).

prevalence of infection

The proportion of infected individuals in a population. It is calculated as the number of infected individuals divided by the total number of individuals tested.

preventive chemotherapy

Large-scale use of medicines, either alone or in combination, in public health interventions. There are several forms of preventive chemotherapy: (i) mass drug administration (when the entire population is treated); (ii) targeted drug administration (when specific population groups such as school-aged children and women of childbearing age are treated); (iii) selective chemotherapy (when treatment is provided after screening); and (iv) event-based treatment (e.g. when treatment is distributed to preschool-aged children at a particular immunization visit, to school-aged children at school enrolment and graduation, and to women of reproductive age at antenatal care).

recrudescence (rebound)

The tendency, after reduction of the frequency of preventive chemotherapy, of infection prevalence and intensity to rise to levels requiring intervention. To promptly identify potential recrudescence, it is crucial to maintain surveillance after reducing the frequency of preventive chemotherapy. If recrudescence is identified, restarting previous levels of preventive chemotherapy is essential before new morbidity emerges.

schistosomes (SCH) and their life cycle

Schistosome infections in humans are caused by six species of trematodes: *Schistosoma mansoni*, *S. haematobium, S. japonicum*, *S. mekongi*, *S. intercalatum* and *S. guineensis.* The species that predominate globally are *S. haematobium* and *S. mansoni*. Adult schistosomes live in the blood system and produce eggs of which some are expelled in the faeces or urine of the host. Free-swimming larvae (miracidia) hatch from eggs when they come into contact with fresh water within 12 hours and infect specific snails (intermediate host) where they develop into mother sporocysts and undergo asexual multiplication over a period of approximately 4-6 weeks (depending on species) giving rise to daughter sporocysts. After the 4–6-week period numerous free-swimming fork-tailed larvae (cercariae) emerge from the snails and should within 48 hours find a definitive host (human or any other mammal). Through an enzymatic process individual cercariae penetrate the skin of the definitive host, shed the tail and transform into schistosomula and migrate to the liver where male and female worms mate and stay in

[1] Buruli ulcer; Chagas disease; dengue and chikungunya; dracunculiasis; echinococcosis; foodborne trematodiases; human African trypanosomiasis; leishmaniasis; leprosy; lymphatic filariasis; mycetoma, chromoblastomycosis and other deep mycoses; noma; onchocerciasis; rabies; scabies and other ectoparasitoses; schistosomiasis; soil-transmitted helminthiases; snakebite envenoming; taeniasis/cysticercosis; trachoma; yaws.

copular. The paired worms then migrate to the blooder (for urinary schistosomiasis) or intestinal tract (for intestinal schistosomiasis) where they will reside and produce eggs leading to continuation of the life cycle.

school-aged children (SAC)

School-aged children (SAC) are children aged between 5 and 14 years, regardless of their school enrolment status. The exact ages of school enrolment can vary between different countries. In some countries, a primary school's enrolment may include individuals aged older than 14 years.

transmission assessment survey

A standardized survey designed to measure whether evaluation units have lowered the prevalence of infection to a level where recrudescence is unlikely to occur, even in the absence of mass drug administration interventions.

water, sanitation and hygiene (WASH) interventions

Safe, clean water, basic sanitation and good hygiene practices are essential for the survival and development of children and are human rights for all individuals. WASH interventions incorporate activities aimed at improving the infrastructure (sanitation and access to water) and promoting behavioural changes (use and maintenance of latrines, handwashing and reduction of contact with contaminated water). These activities that complement the distribution of medicines for the control of schistosomiasis and soil-transmitted helminthiases play a key role in reducing environmental contamination with human faeces and urine thereby reducing the force of transmission of the parasite.

women of reproductive age

Usually defined as women aged between 15 and 49 years.

Introduction

In 2015, the World Health Organization (WHO) Strategic and Technical Advisory Group for Neglected Tropical Diseases endorsed standardized processes for acknowledging and validating success for all NTDs targeted for eradication, elimination of transmission, or elimination as a public health problem [1]. Following this, in 2020, the seventy-third World Health Assembly (WHA) endorsed the WHO Roadmap for Neglected Tropical Diseases 2021-2030 [2]. The roadmap includes the elimination of schistosomiasis as a public health problem in all endemic countries as a key target, outlining core strategic interventions to be used and critical actions needed to do so, and the interruption of transmission in selected ones. Two years later, in 2022, the WHO introduced new guidance that provides evidence-based recommendations to countries in their efforts to achieve control and elimination of schistosomiasis as a public health problem and move towards interruption of transmission in endemic areas [3]. This is completed by the publication in 2024 of the frameworks for monitoring and evaluation of schistosomiasis and soil transmitted helminthiasis control programmes (4).

The present document outlines a standardized process for schistosomiasis endemic countries wishing to request validation of national elimination of schistosomiasis as a public health problem and verification of interruption of schistosomiasis transmission.

The validation process will require the measurement and documentation of completed programmatic targets as well as further implementation considerations for eliminating schistosomiasis. It will rely principally on high-quality national control and elimination programmes and a comprehensive system for surveillance, allowing the production of documents that clearly outline how programmatic impact targets have been achieved and how they will be maintained.

The verification process in line with the NTD roadmap and the schistosomiasis guideline for control and elimination of schistosomiasis as a public health problem will require the demonstration of:

First

- The absence of infection in human,

and then

- Absence of schistosomiasis infection in snails and the environment
- Absence of schistosomiasis infection in non-human animals

Official acknowledgement is granted by WHO after a rigorous review of epidemiological data, and programmatic evidence demonstrating sustained absence of transmission.

The intention of this document is to provide schistosomiasis endemic countries with guidance on the process for validation of elimination of schistosomiasis as a public health problem, and subsequently verification of elimination of transmission. It gives definitions, guidance on the tools, activities, and dynamic strategies required to achieve elimination as public health problem and interruption of transmission and to prevent re-establishment of schistosomiasis. It describes the process for obtaining WHO official acknowledgement of schistosomiasis elimination.

Section 1. describes the key interventions to achieve schistosomiasis morbidity control and *elimination as public health problem*. **Section 2**. describes the criteria and the process for validation of elimination of schistosomiasis as public health problem. **Section 3.** describes the criteria and the process for verification of elimination of schistosomiasis transmission. The annexes provide guidance and tools for the constitution of the country dossier, and survey for verification for the transmission interruption of schistosomiasis

Schistosomiasis elimination is granted by WHO to a country, further to a request from its government respectively, after it has been proven beyond reasonable doubt that human schistosomiasis:

1. Burden has been reduced to below the critical threshold (i.e. < 1% prevalence of heavy intensity infection) (EPHP); or

2. Transmission has been interrupted, resulting in zero indigenous schistosomiasis cases for at least 5 consecutive years, and a programme for the prevention of re-establishment of transmission is in place. WHO was given the mandate to certify countries schistosomiasis-free by the World Health Assembly.

Validation schistosomiasis elimination as public health problem or verification of elimination of transmission is voluntary and is initiated at a country's request. The process provides an expert, objective and independent review and evaluation of a country's declaration of schistosomiasis elimination and its programme to prevent recrudescence and re-establishment of morbidity or transmission respectively.

Objectives of the document

The purpose of this document is to extend guidance to countries that are nearing schistosomiasis elimination on preparing for WHO official recognition. It provides an overview of the procedures and details of activities required in national preparation for application. It includes tools that countries can use to organize the documentation required, to prepare a national elimination report and to assess their readiness for dossier submission.

Target audience

The target readership of this manual is officials in ministries of health and other relevant departments (agriculture and livestock, education, water and sanitation etc.), national schistosomiasis programme managers and staff, national elimination advisory committees and partners who support countries in eliminating schistosomiasis and preventing re-establishment.

This manual provides guidance to Member State who wishes to submit a dossier to request to the WHO to validate a claim of having achieved the elimination of schistosomiasis as a public health problem or interruption of schistosomiasis transmission in their country.

Approach to development

The WHO Technical Advisory Group on schistosomiasis and soil-transmitted helminthiases control and elimination (TAGSS) was created in November 2021. At its first meeting, priority areas for guidance were identified, including the preparation of manuals for the validation of elimination as a public health problem, and verification of transmission interruption of schistosomiasis. The meeting decided to develop one manual for the guidance on schistosomiasis elimination as public health problem and Schistosomiasis transmission interruption. The manual was developed following the WHO procedures on technical product development (5). The manual was drafted by volunteers of the technical advisory schistosomiasis and submitted to the whole TAGSS, WHO regional advisors, programme managers and for comments. The successive drafts went through an iterative revision process. The comments received have been addressed by the drafting group. It went also through expert peer review. The final version of the manual was endorsed during the meeting of the TAGSS on ……. June 2025.

Management of conflicts of interest

The management of conflicts of interest was a key priority throughout the development process of this manual. Before the first meeting of the group, all experts submitted written disclosures of competing interests and disclosed academic or scientific activities that were relevant for consideration before their confirmation as members of the meeting. The declaration of interest is updated every year before each meeting of the advisory group. (see Annex .1).

Section 1. Overview on schistosomiasis and elimination acknowledgement

1.1 Epidemiology and burden of schistosomiasis

Schistosomiasis is a neglected tropical disease (NTD) caused by infection with parasitic trematodes of the genus *Schistosoma* that can lead to debilitating morbidity and mortality. Whilst it is estimated that over 260 million people are currently infected globally, approximately 91% of all cases occur within sub-Saharan Africa. Of these, around two-thirds are deemed urogenital schistosomiasis, caused by infection with *Schistosoma haematobium*. The remaining third of schistosomiasis cases in sub-Saharan Africa are deemed intestinal schistosomiasis, caused predominantly by infection with *Schistosoma mansoni* but also less commonly by infection with *Schistosoma intercalatum* and *Schistosoma guineensis* in some restricted areas of central Africa. Outside of sub-Saharan Africa, *S. mansoni* is also endemic in restricted areas of the Americas (primarily in Brazil and the Caribbean) and the Middle East, whereas *Schistosoma japonicum* and *Schistosoma mekongi*, which also cause intestinal schistosomiasis, are localised to restricted areas of Asia (primarily in the Philippines and China).

Pathologies and morbidity induced by infection with schistosomes occur primarily because of the copious number of eggs produced by female adult worms which inhabit either the venus plexus of the bladder (*S. haematobium*), or the mesenteric veins of the intestines (*S. mansoni, S. japonicum, S. intercalatum, S. guineensis* and *S. mekongi*). To perpetuate the parasite's life cycle, eggs will penetrate blood vessel walls and migrate through surrounding tissues in aim of reaching the bladder lumen (*S. haematobium*) or intestinal lumen (*S. mansoni*, etc.) for excretion and onward transmission. A large proportion of eggs, however, are not excreted and instead become sequestered throughout the bladder and urogenital system (*S. haematobium*), or the intestines and liver (*S. mansoni*, etc.). This can evoke a T helper type-2 (Th2) cell-driven granulomatous response that often leads to chronic inflammation, causing the disease manifestations of schistosomiasis [6].

Eggs that are successfully excreted will hatch into the first schistosome larval stage (miracidia) upon freshwater contact. Hatched miracidia will then actively seek and penetrate the soft tissues of obligate freshwater snail intermediate hosts which are needed for schistosome development and onward transmission. Each schistosome species has a specific range of suitable freshwater snail host species. For example, *S. haematobium* and *S. mansoni* require certain species *Bulinus* spp. and *Biomphalaria* spp. freshwater snails, respectively, whereas *S. japonicum* requires certain species of *Oncomelania* spp. freshwater snails. The epidemiology and distribution of schistosomiasis is therefore defined by each schistosome species' specific freshwater snail host's habitat range

[6]. After a developmental period of approximately 4-6 weeks, during which asexual reproduction will occur, the second schistosome larval stage (cercariae) are shed from infected freshwater snail intermediate hosts. Shed cercariae will then actively seek and penetrate the skin of humans making contact with contaminated freshwater. As hundreds of cercariae can be shed daily from a single freshwater snail previously infected with just one miracidium, a rapid resurgence of schistosomiasis infections can occur in a community following just one infected human, harbouring even a low-intensity schistosomiasis infection, contaminating a body of freshwater.

Schistosomiasis infection in humans is divided into three phases: migratory, acute and chronic. In the migratory phase, cercariae present in freshwater penetrate and migrate through the skin upon contact. This phase is usually asymptomatic, but sensitized individuals may experience some minor and transient dermatitis. During the acute phase, hypersensitivity responses such as headaches, cough, gastrointestinal discomfort and pain, myalgia, diarrhoea with blood and/or mucus present in faeces, may occur. These symptoms are collectively known as Katayama syndrome. The most prevalent form of schistosomiasis is chronic disease, which occurs in response to the cumulative deposition of schistosome eggs after repeated exposure to freshwater contaminated with infectious schistosome cercariae. In endemic regions, initial infection typically occurs before a child is two years of age, with the burden of infection increasing during the following 10-14 years as new infections are established. Therefore, the highest prevalence and intensities of schistosomiasis infection usually occur in school-aged children (SAC) and young adults.

1.2 Control programmes and interventions

The current WHO recommendations for schistosomiasis control programmes focus primarily on the reduction and elimination of schistosomiasis-associated morbidity through the periodic large-scale distribution of the oral anthelmintic praziquantel, as well as through the provision of adequate water, sanitation, and hygiene (WASH) infrastructure, community education, environmental interventions and snail control (3).

1.2.1 Large-scale preventive chemotherapy

The large-scale distribution of the oral anthelmintic praziquantel should be implemented in schistosomiasis-endemic communities to reduce the intensity of schistosomiasis infections. In doing so, not only should disease-associated morbidity be reduced, but disease transmission should also be reduced, reducing the incidence of infections. This should be performed based on the prevalence of infection within a given community. In endemic communities where schistosomiasis is ≥ 10% prevalent (diagnosis based on parasitological microscopy), annual preventive chemotherapy with a single dose of praziquantel (40 mg/kg) should be provided at ≥75% treatment coverage in all age groups above two years old, including adults, pregnant women after the

first trimester and lactating women. Children below two years of age may be treated on an individual clinical basis. Where prevalence is < 10%, one of two approaches should be taken: (1) where there has already been a programme of regular preventative chemotherapy, continue the intervention at the same or reduced frequency; or (2) where there has not previously been a programme of regular preventative chemotherapy, use a clinical test-and-treat approach to provide praziquantel on a case-by-case basis. In endemic communities where schistosomiasis is ≥ 10% prevalent that do not demonstrate an appropriate response to annual preventative chemotherapy, or in areas of schistosomiasis prevalence ≥50%, biannual (twice-yearly) preventive chemotherapy should be implemented. It should be noted that public health awareness campaigns are necessary to ensure high coverage in preventive chemotherapy programmes and to address concerns about any adverse events caused by medication.

Preventive chemotherapy can be implemented as long as needed (7) according to local transmission conditions. The WHO framework on monitoring and evaluation of schistosomiasis and soil transmitted programmes (4) recommend to conducted evaluation survey very 5 years in general to assess the situation and to change the PC frequency to adapt to the updated epidemiology (4).

1.2.2 Provision of adequate and functioning water, sanitation and hygiene (WASH) infrastructure, community education, snail control and environmental interventions.

The provision of adequate and functioning WASH infrastructure to limit human contact with infectious freshwater, thereby reducing disease transmission and the incidence of infections, is also recommended. This can include the provision of potable drinking water, the safe management of excreta (e.g., through provision of functional and properly maintained toilets), and improved water supply to reduce the use of surface freshwater for domestic activities [3, 8]. Likewise, environmental interventions can include cleaning of irrigation canals, large-scale water engineering projects and focal freshwater snail control using molluscicides [3, 9], whereas community education aims to raise community awareness of schistosomiasis and encourage behaviors that would limit exposure to, and transmission of, disease (e.g., avoiding freshwater contact when possible and the safe management of excreta).

1.3 Control and elimination strategies

It should be noted that there is no “one-size-fits-all” approach that can guarantee transmission interruption as schistosomiasis is epidemiologically distinct throughout its geographical distribution. In addition, the integration of activities to control or eliminate schistosomiasis into other NTD control programmes, such as those targeting

soil transmitted helminths (STHs) or filarial nematodes, or malaria, should also be considered, where available for efficient use of the resources.

Schistosomiasis transmission can be controlled, reduced, and interrupted through an integrated approach combining large-scale preventive chemotherapy, the provision of adequate and functioning WASH infrastructure, environmental interventions, and community education [3]. An intensified schistosomiasis control programme can be divided into the following phases:

1. *Morbidity control and management by reducing the intensity of schistosomiasis infections.*
2. *Elimination of schistosomiasis as a public health problem.*
3. *Interruption of schistosomiasis transmission (disease elimination).*
4. *Post-transmission interruption monitoring and surveillance.*
5. *Verification of elimination.*

Activities to control schistosomiasis should be fully integrated into the health system, including monitoring, evaluation and surveillance that allows assessment of impact as well as identification of remaining foci of high transmission. Surveys should be initiated and carried out by the peripheral health centres closest to the transmission foci.

Improving the lifestyle of endemic communities, in particular provision of improved water supply and sanitation, and changing human behavior, strengthen the hygiene, ought to be sustained.

In communities approaching the interruption of transmission (defined as having no autochthonous human cases reported for 5 consecutive years), WHO suggests a two-step diagnostic process for the verification of absence of *Schistosoma* infection in human, snails and the environment and in non-human mammalian hosts (3).

Post elimination surveillance

Post validation surveillance

It is important to note that although the overall prevalence is <10%, “hot spot” areas, where the prevalence rate (and probably the intensity of infection) remain higher, exist. There is a need to carry out remapping exercises to identify hot spots of transmission for intensified intervention. Mapping of schistosomiasis in low-transmission areas would require more sensitive diagnostic tools in addition to the standard parasitological techniques (urine filtration method and Kato-Katz stool examination) currently used, to move towards transmission interruption.

It is important furthermore to have case reporting fully integrated in the country health information system health with case reporting from all health facilities as described in the schistosomiasis health facility tool kit (10) with the aim to detect any rebound of transmission.

Post transmission interruption surveillance

Surveillance should be strengthened in all previously endemic areas with the aim of detecting and responding to resurgence of transmission and to prevent reintroduction from regions or countries where the disease is still endemic.

Before countries declare elimination of schistosomiasis, they need to implement an effective surveillance system for documenting that no autochthonous cases have been observed over a specified period of time. The observation period necessary to validate a claim that transmission has been interrupted depends greatly on the risk of re-emergence or reintroduction in the particular situation, but should not be less than 5 years.

Several steps should be taken to serve as an early warning system during the observation period:

Schistosomiasis should be added to the national list of notifiable diseases so that the infection/disease would be reported when they are diagnosed by health workers or laboratories. A monthly report from different health institutions should be sent to the Health Director at the District level.

In depth epidemiological investigation to know the origin of infection should be carried out for each case diagnosed as schistosomiasis (Annex 5)

Active surveillance of schistosomiasis should be carried out to test high-risk groups (e.g. schoolchildren, farmers and fishermen) and untreated pre-school age children (<5 years) in selected sentinel sites. Even in low-transmission areas, older primary-schoolchildren and exposed occupation groups (farmers and fishermen) remain the best populations among which to conduct surveillance survey.

Passive surveillance of schistosomiasis should be implemented through existing, permanent channels and procedures, such as screening of migrants, random testing among blood donors, during medical examinations for military recruitments, physical examination carried by school health and university pre-participation health examination.

As a programme moves towards the low-prevalence end, more accurate and precise diagnostic tools are required.

1.4. Imported cases

An imported case is a case acquired outside the country where transmission of schistosomiasis has been interrupted. Every effort must be made in the surveillance programme to detect such cases among migrants and tourists, in order to diagnose them and treat them effectively so as to avoid reintroduction.

Regarding cases reported to the WHO, only cases from other countries should be considered as ‘imported’. The major concern with imported cases is local spread.

1.5. Cases of recrudescence

This is the occurrence of an increased number of cases of schistosomiasis in an administrative unit where the disease has been eliminated as a public health problem. An alert is given on the basis of an increase in cases in health facilities or by school teachers when they observe an unusual frequency of children urinating blood in the school, or detected during sentinel site surveillance survey.

An investigation must be carried out and mass treatment reintroduced if necessary.

1.6. Community involvement

To achieve sustainable elimination of schistosomiasis, it is important to involve communities and the school system, as well as professional associations such as groups of market gardeners, rice growers, car washers and fishermen in the interventions, and in particular in surveillance. Good monitoring at community level can be achieved if these different groups cooperate fully.

The objectives of community participation should include: -

- encourage people to seek care when necessary.

- strengthen community access to, and participation in, screening, treatment and the notification system, for example through community health workers or teachers.

- Promote acceptance of vector control tools (such as molluscicides) and their appropriate use.

- empowering communities to strengthen self-monitoring and decision-making regarding schistosomiasis, for example by resuming mass treatments.

1.7. National Expert Committee

The purpose of an independent national schistosomiasis elimination expert committee is to provide an external view of progress and gaps to the national programme, assist in adapting WHO guidance to the national context, review schistosomiasis trends and progress towards elimination and support the national programme in the preparation of the national schistosomiasis elimination dossier (Annex 2).

The National expert committee will play a major role in validating the national strategy, support in maintaining high political commitment and engaged in advocacy for ensuring and sustaining required resources (human and financial) to achieve the objectives of the programme.

The committee should be independent from the national schistosomiasis programme to provide a frank and open review of the programme's activities, strengths and weaknesses. Several countries who have established such or similar committees have benefitted from retired academic or government schistosomiasis experts as committee chairpersons.

Terms of reference for an independent national schistosomiasis elimination expert committee

• Advise the programme on implementation of the national strategic plan for schistosomiasis elimination.

• Monitor progress towards elimination and review strategy

• Provide assistance in adapting WHO guidelines and policies.

• Identify bottlenecks towards schistosomiasis elimination, develop potential responses to address these issues, and evaluate bottleneck resolution.

• Support the national programme in the preparation of the national elimination dossier to be submitted to the WHO

- Evaluate programme data and validate that the criteria for having interrupted schistosomiasis transmission have been met

• Advise the national programme on the plan to prevent rebound or re-establishment of schistosomiasis transmission.

• Advise on Subnational elimination of schistosomiasis in large countries. The independent national schistosomiasis elimination expert committee should monitor and verify the work of the national programme in subnational elimination and help document verification of elimination (where relevant).

Composition of the committee

The committee should be independent from the national schistosomiasis programme and could comprise the following types of members:

- retired academic or government schistosomiasis and public health experts;
- Public health specialists.
- animal health experts
- WASH experts
- experts in environmental management
- experts from vector borne diseases;
- representative/s from academia;
- representative/s from research institutions;
- representative/s from Education sector;
- Representative of agriculture sector;
- Representative of local administration;
- experts from information, health education or communication for behaviour change

WHO could be included as a technical partner, while other technical partners, donors and international/other nongovernmental organizations could serve as observers.

The committee should meet on a regular basis, as determined by country needs and resources. The secretariat (i.e. the national programme) should develop and circulate the agenda of the meeting in advance. Additional relevant partners will be invited depending on the agenda of the meeting.

The secretariat should produce concrete recommendations and action items, all to be made publicly available on the website of the ministry of health.

1.8. Follow-up to WHO acknowledgment

WHO Acknowledgment of elimination confirms to the international community that a country as a whole has reduced the prevalence and intensity of schistosomiasis infection (EPHP validation) or eliminated schistosomiasis transmission in humans according to defined criteria. It also demonstrates that the country has taken all necessary steps to maintain the status of elimination as a public health problem and progress towards the ultimate goal of eliminating transmission.

In order to assess the risk of international travelers being exposed to schistosomiasis and the epidemiological risk of importing schistosomiasis parasite vectors into free areas that are receptive to transmission, it is necessary to have reliable information on the distribution of schistosomiasis worldwide. Each year, validated/verified countries must therefore continue to report data to the WHO to maintain their status.

In the event of the occurrence of indigenous cases of schistosomiasis or an upsurge in the prevalence and intensity of infection status of EPHP or elimination of transmission respectively may be revoked, following a serious investigation by the WHO to confirm the new epidemiological situation.

Section 2. Criteria and process for validation of elimination of schistosomiasis as a public health problem

2.1 Technical indicators of elimination of schistosomiasis as a public health problem

Elimination as a public health problem is the achievement of specific and measurable targets for infections and diseases outlined by the WHO (1). When elimination as a public health problem is achieved, continued action is required to maintain this status. Ongoing surveillance will be required to ensure infection remains below target thresholds and to verify interruption of transmission.

Schistosomiasis is considered as "eliminated as a public health problem" when the morbidities attributed to schistosomiasis are no longer a general threat to public health. As it is recognized that schistosomiasis morbidity is generally caused by infections of heavy intensity [3, 4], elimination as a public health problem is determined by:

- Prevalence of heavy intensity of any schistosomiasis species is < 1% of all persons tested. Heavy intensity infections are currently defined as ≥ 50 eggs/10 mL urine (using urine-egg microscopy) or visible hematuria (upon urine examination) for urogenital schistosomiasis and ≥ 400 eggs per gram of faeces (epg) for intestinal schistosomiasis (using faecal-egg microscopy) (3).

And

- The prevalence of any schistosomiasis species in SAC is < 10% in ALL implementation units/COMMUNITIES.

The two criteria have to be observed for at least 3 consecutive years.

Table 1: Criteria to initiate process of validation of elimination of schistosomiasis as public health problem

Criteria	**Steps Towards Validation**
The prevalence of schistosomiasis in SAC is < 10% in ALL implementation units/COMMUNITIES. AND The prevalence of heavy intensity infections (or visible heamaturia) is <1% in ALL implementation units/communities for at least the past 3 consecutive years (36 months)	**<u>The validation process can be initiated by MoH.</u>** Until validation is confirmed by WHO, programme activities, including PC drug distribution, should be maintained per WHO M&E framework*
Notes: The survey sample should include children 10 – 14 years old. **See "Assessing schistosomiasis and soil-transmitted helminthiases control programmes: monitoring and evaluation framework. Geneva: World Health Organization; 2024. (4)*	

Validation is the process of documenting having achieved the elimination of schistosomiasis as a public health problem through a completed validation dossier and receiving approval for the achievement from the WHO. Validation is not a permanent state and does not represent an end to control programme activities. In most cases, especially if water, sanitation, and hygiene (WASH) infrastructure remains insufficient, continued preventative chemotherapy will be needed. In addition, control programmes should continue to undertake post-validation surveillance and ensure that treatment (oral anthelmintic praziquantel) remains available within the health care system.

A completed validation dossier will contain all the evidence needed to support the claim of having achieved elimination criteria. It enables the WHO to:

1. *Validate a country's claim of having achieved elimination of schistosomiasis as a public health problem*.
2. *Provide feedback about necessary action needed to receive WHO acknowledgement*.

The validation process can be initiated only when all implementation areas of the country that are classified as needing preventive chemotherapy for schistosomiasis meet the criteria for elimination as a public health problem.

Validation of schistosomiasis elimination as a public health problem is granted by WHO to a country, further to a request from its government, after it has been proven beyond reasonable doubt that the prevalence of heavy

intensity infection of human schistosomiasis has been reduced to less than 1% in the country, for at least the past 3 consecutive years, and a programme for the prevention of rebound of transmission is in place.

While survey methodology may vary (4), validation of having eliminated schistosomiasis as a public health problem requires an appropriate sample frame and survey methodology to allow for an accurate evaluation of the current epidemiologic status of schistosomiasis within a country. The WHO generally recommends assessing programme impact through a national cross-sectional survey of schistosomiasis intensity and prevalence in SAC. In resource-limited settings, where school enrollment is > 75%, impact assessment can be conducted using school-based surveys to estimate infection in SAC. Preferably, SAC aged between 10 and 14 years are surveyed for a more thorough insight into preventive chemotherapy impact due to their more frequent exposure to infection, and so typically more heavy infections, when compared to younger SAC. The prevalence of infection in SAC may be used as a rough proxy to estimate the prevalence of schistosomiasis infections amongst the entire community (11). The impact survey should be conducted at least six months after the last round of praziquantel distribution and just before an upcoming round of praziquantel distribution, to ensure that survey results are representative of the true epidemiological status of the treated population and so are not skewed by temporary reductions caused by recent treatment.

2.2. Other Requirements for validation of elimination of schistosomiasis as a public health problem.

In addition to the epidemiological criteria, the country must demonstrate:

- Schistosomiasis control programme capacity: A very well structured and decentralized control programme led by the ministry of health should exist in the country with office space, dedicated personnel and adequate domestic funding.

- The schistosomiasis Control programme integration into health system, with availability of diagnostic and treatment all health facilities and reporting though the national health information system. The programme needs to be integrated as appropriate with school health, one health and relevant health programmes.

- Good data collection and repository with time, allowing to follow the history and trends of schistosomiasis transmission and elimination in the country.

- Morbidity management programme with good availability of Praziquantel at all levels, and treatment for severe morbidity such as portal hypertension, urinary and genital complications.

- Laboratory and snail control capacity for diagnostic (parasitology, serology, molecular) and breading and basic testing of snails.

- Decentralized Surveillance systems to detect any rebound of infection or introduction of schistosomiasis in an ear free of the infection.

- Improvement of Water sanitation and hygiene (WASH) and water contact behavior to sustain the achievements of the disease prevalence reduction and prevent from reinfection

- Community engagement to support the programme activities through participation to treatment, survey and vector control activities.

2.3: Steps involved in validation of EPHP

The steps involved in validating having achieved elimination of schistosomiasis as a public health problem are summarized in Figure 1.

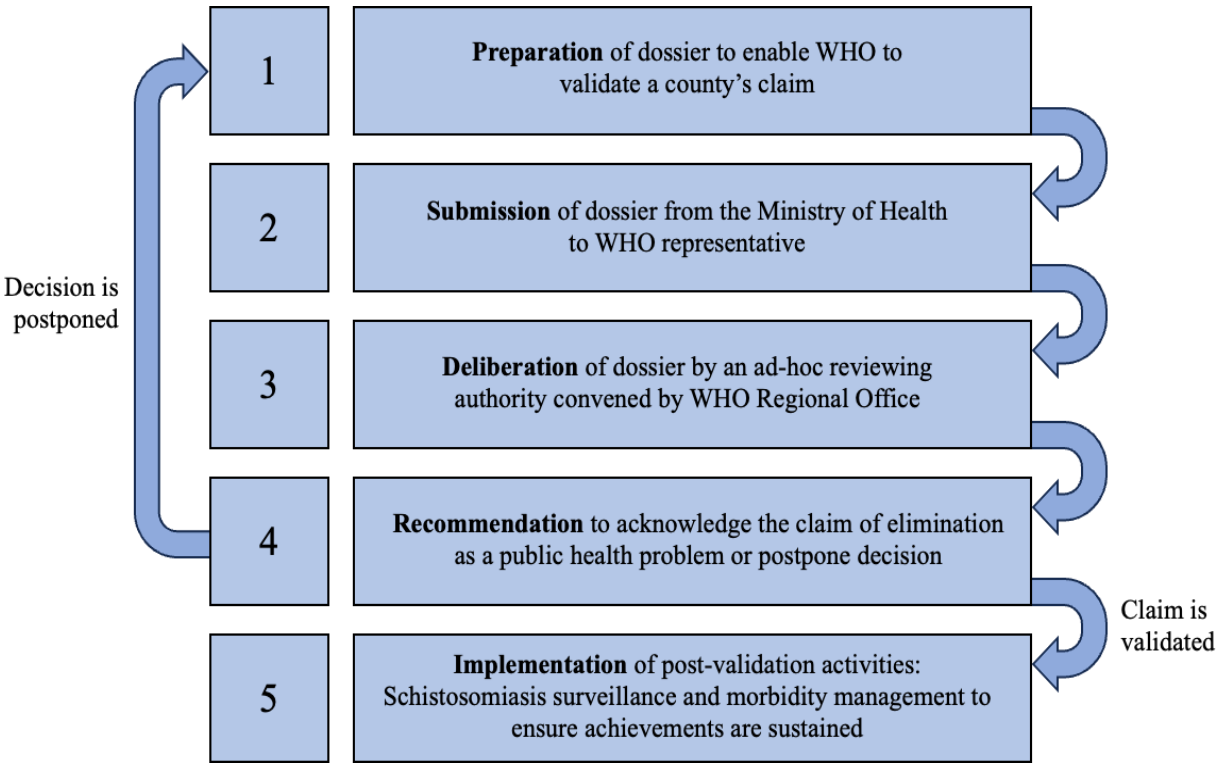

Figure 1. Summary of the steps involved in validating having achieved elimination of schistosomiasis as a public health problem.

2. 3.1 Preparation and submission of dossier

Member States seeking official acknowledgement from the WHO as having met the criteria for the elimination of schistosomiasis as a public health problem should submit a completed dossier to the WHO detailing the measures taken to achieve, and all available evidence supporting, this claim. Member States should reference the WHO dossier template (Annex 2) for guidance and ensure that the information provided meets the minimum necessary criteria to support the claim. If desired, Member States may request feedback on any draft country dossier from the Secretariat, through the WHO regional office prior to official submission.

Control programmes must gather appropriate data to prepare the dossier. Each section of the template dossier should be addressed and completed using control programme data. A national schistosomiasis control programme should archive information throughout the entirety of the programme. If archived data is not available, the following information sources may contain data required for completion of the dossier:

- Ministry of Health/Department of Health reports.
- Control programme data captured within an integrated NTD database or any similar national data management system.
- Previous reports submitted to the WHO:
    - Schistosomiasis reports submitted to the WHO.
    - Presentations given at Regional Programme Advisory Group (RPAG) meetings and Programme Managers Meetings (PMM).
    - WHO Joint Application Package (JAP) forms
    - Joint Requested for Selected Medicines (JRSMs)
    - Epidemiological Data Reporting Form (EPIRF)
- The WHO preventative chemotherapy databank.
- Publications in peer reviewed journals from research projects or surveys
- Publications from the WHO Regional Office, including official meeting reports of RPAG and PMM
- Activity reports from collaborating institutions, nongovernmental organizations, or bilateral organizations
- Reports from control programme evaluations, situational analyses, or consultants

The Member State should submit the completed dossier (one hard copy and one electronic copy) to the WHO Country Office for the attention of the WHO representative. The Country Office should then acknowledge receipt of the dossier to the submitting Member State and forward it to the RD, copying the focal point for NTD in the WHO Regional Office. The WHO Regional Office should then notify the Department of Control of Neglected Tropical Diseases at WHO headquarters (Geneva, Switzerland).

Annex 3 contains some frequently asked questions to assist Member States in preparing dossiers to document and validate the elimination of schistosomiasis as a public health problem in their country.

2.3.2. Review of dossier

The submitted dossier will be reviewed by an ad hoc independent regional reviewing group (herein referred to as the Review Group). The purpose of the Review Group is to determine whether the information

provided in the dossier supports the claim of having achieved elimination of schistosomiasis as a public health problem according to the criteria outlined by the WHO.

The WHO Regional Office will be the secretariat and responsible for determining the membership of the Review Group following consultation with, and agreement from, the Department of Control of Neglected Tropical Diseases at the WHO headquarters (Geneva, Switzerland). The Review Group should be comprised of at least three members who meet the following criteria:

1. The Review Group should include at least 3 members with expertise in public health, schistosome biology, schistosomiasis epidemiology, and schistosomiasis control and elimination strategies (e.g., the implementation of large-scale distribution of preventative chemotherapy). In particular, the Review Group must include members with expertise in schistosomiasis survey. Membership should also include broad geographic and gender representation.

2. Members should not have supported the development of the dossier under review, should be considered independent, and there must be no conflicts of interest with regards to any statements made within the dossier.

3. Members will be invited to participate as individuals, not as representatives of an organisation, institution, or government. Nomination of proxies will therefore not be permitted.

2.3.3 Review procedures

Members of the Review Group will elect a Chair. The Chair will be responsible for chairing Review Group meetings; coordinating and completing (with other Review Group members) a report on the country visit (if a visit is deemed necessary) to the Member State; and signing off the summary report to WHO Regional Office and headquarters (Geneva, Switzerland).

The scope of the work of the Review Group is as follows:

1. Members will examine dossiers on a voluntary basis, independently maintaining the highest ethical standards and declaring any conflict of interest prior to participation in collective discussions.

2. A visit to the submitting country may be undertaken by the Review Group for the purposes of the validation process, only if there is a consensus amongst the Review Group that such a visit is required.

3. Members will provide written comments on the dossier and will clarify comments during collective discussions during the development of a summary report.

4. The Review Group will obtain consensus and recommend that the WHO either:

    i. Validates the claim of elimination of schistosomiasis as a public health problem

    ii. Clearly determines that the claims of elimination of schistosomiasis as a public health problem are not supported by the documents and information submitted

    iii. Postpones the decision until more evidence is provided within the dossier to demonstrate that the elimination criteria have been appropriately met

    Regardless of the recommendation, written justification of the decision made will be provided.

5. The Review Group will also provide a summary report of deliberations with clear recommendation, including:

    i. Conclusions, in which the Review Group discusses the compliance of the data with the elimination criteria set by the WHO and express its opinion on whether to validate the submitted claim.

    ii. Recommendations to the country: in the case of validation, recommendations should focus on post-validation surveillance activities and post validation strategies and activities towards interrupting transmission ; in case of denial or postponement, recommendations should focus on what steps are needed to achieve elimination targets in the future, including a clear description of any reasons for postponement outlining the additional evidence needed in the dossier to be returned to the submitting country.

Secretariat functions will be assured by the WHO throughout the process. It will:

1. Provide the dossier and other information needed to each Review Group member.
2. Organize discussions of the Review Group via teleconference, videoconference, or in-person meetings,
3. Specify the responsibilities and decision-making process of the Review Group.
4. Liaise with the Member State authorities to obtain any additional information requested by the Review Group.
5. Collate the independent reviews of Review Group members and ensure the preparation of a summary report.
6. Obtain sign-off of the summary reports by members.

7. Process and permanently archive the summary report.

Each Review Group member will:

1. Keep the contents of the dossier, and all other information to which Review Group members are given access, strictly confidential. This includes the deliberations and recommendations of the Review group, discussing them only with relevant WHO staff members and other Review Group members. Information should not be discussed directly with the Ministry of Health of the Member State, or with any organization or person.

2. Review the dossier independently, within the specific timeframe and following all directions given.

3. Discuss the dossier collectively, via videoconference, teleconference, or in-person meetings.

4. Participate in country visits (if deemed necessary).

5. Review any draft summary reports within specific timeframes.

2.3.4. Processing of recommendations

The following actions are taken after the Review Group has signed off the summary report:

1. If the Review Group recommends denial of validation, or postponement, the summary report will be forward by the WHO Regional Office to the Member State with clarification of what additional evidence is required prior to achieving validation of elimination as a public health problem.

2. If the Review Group recommends validation of the claim, the summary report will be forwarded by the WHO Regional Office with the request for acknowledgement of the achievement to the WHO headquarters.

3. At the discretion of the WHO Director-General, the official acknowledgement to the country will be provided through a letter of notification presented to the Member State by the WHO Regional Office.

4. Validation of having achieved elimination of schistosomiasis as a public health problem will be acknowledged in the following additional ways:

    i. Reported in the disease-specific global progress update published annually in the Weekly Epidemiological Record by WHO headquarters (Geneva, Switzerland).

    ii. Noted by updating the status of endemicity of schistosomiasis in the Global Health Observatory by WHO headquarters (Geneva, Switzerland).

2.3.5. Post-validation

Validation of having achieved elimination of schistosomiasis as a public health problem implies a potentially reversible state. It is critical that all stakeholders remain aware of this at all stages of the validation process, including post-validation, to ensure that resurgence of schistosomiasis infections above the elimination threshold does not occur following validation. Countries should outline a thorough and clear plan to ensure that programmatic activities can be resumed if post-validation surveillance suggests recrudescence of schistosomiasis as a public health problem. Even once schistosomiasis has been eliminated as a public health problem, preventive chemotherapy, as well as other control interventions, may still need to be administered periodically to control any ongoing transmission and associated morbidity. Validation of having achieved elimination of schistosomiasis as a public health problem does not imply that preventive chemotherapy should be stopped.

Once validation of having eliminated schistosomiasis as a public health problem is achieved, countries should continue to conduct post-validation surveillance and a country's commitment to continue surveillance should be stated within the submitted dossier.

Surveillance data and large-scale preventive chemotherapy administration data should continue to be reported to the WHO. Where these data indicate that infection has recrudesced above elimination as a public health problem thresholds, the in-country Ministry of Health should notify the WHO country office. Following this, the WHO country office will inform the WHO regional and head office for an appropriate response. Recrudescence about original elimination target thresholds will be noted by a change in status in the Global Health Observatory and in the Weekly Epidemiological Record.

With the agreement of the Member State and once the WHO Director General has acknowledged the elimination of schistosomiasis as a public health problem, the submitted dossier may be made available online as a reference document for other countries hoping to also complete and submit the dossier.

2.3.5 Sustaining gains towards interruption of schistosomiasis transmission

Achieving the elimination of schistosomiasis as a public health problem is a state, not a destination. As such, achieving EPHP unequivocally does not signify the cessation of programmes. Given the reproductive biology of schistosomes, the resurgence of schistosomiasis above the elimination threshold can rapidly occur in a country recently validated as having eliminated schistosomiasis as a public health problem if control and elimination strategies are not continued after the validation. It is therefore imperative for national programmes to continuously monitor the prevalence and incidence of schistosomiasis (in both human and non-human hosts) and continue the implementation of interventions to progress towards interruption of transmission of schistosomiasis.

Section 3. Criteria and process for verification of the interruption of schistosomiasis transmission

3. 1. Criteria for triggering the verification process

The procedure used by the WHO to recognize and verify that the applicant country has interrupted schistosomiasis transmission should not be different from those of other NTDs. The Ministry of Health of the applicant country would initiate the verification process by sending a letter to the WHO Regional Office. Figure 2 outlines propose steps for the applicant country and WHO to follow until the final decision to issue verification that schistosomiasis transmission has been interrupted has been reached.

Once the control programme has conducted periodic assessments to ascertain that schistosomiasis transmission has remained interrupted over a minimum period of five years, the process of applying to verify a claim of having interrupted schistosomiasis transmission can begin.

A country programme must have completed a surveillance period of at least five years during which the following must be demonstrated:

4. *No locally acquired case of human schistosomiasis is detected*
5. *No locally acquired schistosome infection transmissible to humans is detected in non-human animals*
6. *No freshwater snail intermediate hosts are found to be infected following thorough malacological surveillance and cercarial shedding analyses at previously identified schistosomiasis transmission sites*

For the purposes of verification, *interruption of transmission* (or *elimination*) can be defined as reduction of transmission (either from intermediate snail hosts to definitive hosts, or *vice versa*) of schistosomes to a level where continued transmission or recrudescence is not expected (i.e., no new locally contracted, human or non-human definitive host, cases). In addition, *elimination* is defined as a reduction to zero of the incidence of schistosomiasis in a defined geographic area as a result of deliberate efforts. This definition includes all schistosome species that infect humans and non-human definitive hosts in a given geographical area. The minimum geographical area for verification of having interrupted transmission would be a country (nation, WHO member state).

The following critical interventions needed to achieve interruption of schistosomiasis transmission:

1. High-quality surveillance systems should be implemented with full coverage of populations in previously identified endemic areas. Surveillance should be based on sensitive and specific diagnostic test that have been performed correctly, and a high-throughput screening method for the rapid identification of any new cases. An effective surveillance system should be maintained for at least five years from achieving interruption of schistosomiasis transmission
2. High-quality laboratories, for molecular detection of schistosome infection within freshwater snail intermediate hosts, should be maintained and used
3. Well defined protocols for epidemiological investigation of suspected cases to provide evidence for the absence of autochthonous cases
4. Continuous and clear communications between the national programme at the central level and local health services
5. The maintenance of supportive operational research activities

Once the country programme reports collected surveillance data to the National expert committee (NEC), an internal, but independent, assessment should be initiated to document all evidence confirming that the interruption of schistosomiasis transmission has been achieved.

The key indicator of elimination of transmission is based on case reporting in countries known to be endemic. Many previously endemic countries have not reported cases of schistosomiasis for a long time. This is the case in many islands of the Americas, Japan, Turkey, Lebanon, etc. Provided that the surveillance system is dense and efficient, countries that have not had an autochthonous case for more than 5 years could apply for an accelerated procedure to verify the elimination of schistosomiasis transmission.

3.2. Steps in the verification of schistosomiasis transmission interruption

The NEC should assist and support the national schistosomiasis control programme (NSCP) to prepare a country report/dossier to document that the country has achieved interruption of schistosomiasis transmission. The report should include all documentation inherent to the NSCP with regards to achieving required objectives, interventions carried out, how the epidemiology of schistosomiasis was altered following any control interventions, investigative reports and their impact on the epidemiology of schistosomiasis transmission, and any published or in-progress studies on schistosomiasis within country.

The secretariat is responsible for providing the national review group with essential documentation and for liaising with national authorities to organize and arrange for necessary field visits.

Figure 2: Proposed steps for the applicant country and WHO to follow until the final decision to issue verification that schistosomiasis transmission has been interrupted has been reached.

3.2.1. Preparation and submission of dossier

All control programmes should carry out an ongoing system for the systematic collection, analysis, and interpretation of data. Control programme surveillance data are particularly important as they provide a direct measure of the epidemiological situation of schistosomiasis in the population. The preparation of the national report provides an opportunity to review, in depth, the progress of the control programme and the results

obtained since its launch (see Table 1). The preparation of the national report involves three phases: the collection of programme data, a schistosomiasis control programme review, and drafting a national report on having interrupted schistosomiasis transmission.

3.2. 1.1. Phase one: Collection of programme data and needed documentation

This is the most delicate phase as it requires diligent efforts to identify and collate all available sources of information/data and to ensure the availability of all information/data. All collected materials will be made accessible to the National Expert Committee.

The dossier template is detailed in Annex 3. In addition, the NEC has to make sure that the following information are included:

1. An outline of the organizational structure of the schistosomiasis control programme and any schistosomiasis-related activities that take place in general health services, with detailed information regarding associated budgets and staff.
2. An outline of any guidelines and manuals dedicated to schistosomiasis control
3. All schistosomiasis surveillance reports produced at least over the past ten years
4. All available information concerning active schistosomiasis transmission sites five years prior to the diagnosis of the last indigenous case, with supporting maps
5. A national schistosomiasis case register with case investigation forms for all cases diagnosed over the past five years prior to the diagnosis of the last indigenous case
6. Reports outlining quality-assurance activities carried out with regards to any schistosomiasis diagnostic approaches used
7. A detailed report outlining all in-country malacological surveillance activities carried out in the past 5 years
8. A detailed report outlining all freshwater snail intermediate host control activities carried out in the past 5 years
9. Any recently published (and unpublished where possible) research reports detailing schistosomiasis epidemiology and the epidemiology/distribution of Schistosoma spp. and freshwater snail intermediate hosts
10. Information/data describing any changes in the living conditions of people in active schistosomiasis transmission areas. (e.g., quality of housing, access to safe drinking water and adequate water sanitation infrastructure, access to electricity, owning electronic appliances such as a radio and television, level of education and literacy, etc.)
11. Plans for social mobilization and community participation

12. Plans for the training and retraining of personnel dedicated to the control and elimination of schistosomiasis
13. Legislation and regulations or guidelines related to schistosomiasis control and the control of freshwater snail intermediate hosts
14. Detailed reports of any intersectoral collaborations
15. Detailed reports of boarder coordination activities, if relevant
16. A detailed plan outlining actions to be taken to prevent the reintroduction of schistosomiasis

3.2. 1.2 Phase two: Schistosomiasis programme review

Collected data and information should be collated and analyzed to describe any changes in the epidemiology of schistosomiasis since implementation of the first intervention(s) took place, until the interruption of transmission (elimination) has been achieved and verified.

3.2.1.3 Phase three: Drafting a national report on the elimination of schistosomiasis

As part of the verification process, each country should prepare a comprehensive written report (see Annex 3). The length and detail of reports will vary from a brief document (for countries where the geographical distribution of schistosomiasis was limited), to highly detailed documentation with supporting data (needed from countries with many transmission foci and large at-risk populations). National teams are strongly encouraged to publish data relevant to elimination in peer-reviewed journals. Such publications can be included in written reports and will strengthen the case for elimination considerably. In addition, the methodology and results of any schistosomiasis epidemiological surveys, as well as any malacological surveys, should be outlined.

The country report will include programme information (data records, reports, survey data, published literature, articles, etc.) available on schistosomiasis epidemiology/control to validate evidence of the interruption of schistosomiasis transmission. Such data should cover a minimum period of 10 years before the country reached the goal of interruption of transmission and post-elimination surveillance data. This information should cover all areas related to the organization of the health system, the epidemiology of schistosomiasis over this period, interventions put in place and resources used, etc. as detailed in Table 1.

3.2.1.4 Validation of the national report

The NEC team should review, edit, and endorse the country report. In addition to documenting the epidemiological aspects of the control/elimination intervention measures described within the country report, other activities including social mobilization, community participation, health education, strengthening of epidemiological surveillance, and improvements to living conditions and basic sanitation should be emphasized in

the report. Ideally, the report will include a concluding statement, supported by relevant and robust data, indicating that there is no more risk of re-introduction or resurgence of schistosomiasis following elimination.

3.2.2. Review of the dossier

The submitted dossier will be reviewed by an ad hoc independent regional reviewing group (herein referred to as the Review Group), see chapter 2.3.2-4. The purpose of the Review Group is to determine whether the information provided in the dossier supports the claim of having achieved elimination of schistosomiasis as a public health problem according to the criteria outlined by the WHO.

The WHO Regional Office will be the secretariat and responsible for determining the membership of the Review Group following consultation with, and agreement from, the Department of Control of Neglected Tropical Diseases at the WHO headquarters (Geneva, Switzerland). The Review Group should be comprised of at least three members who meet the following criteria:

- The Review Group should include at least 3 members with expertise in public health, schistosome biology, schistosomiasis epidemiology, and schistosomiasis control and elimination strategies (e.g., the implementation of large-scale distribution of preventative chemotherapy). In particular, the Review Group must include members with expertise in schistosomiasis survey. Membership should also include broad geographic and gender representation.
- Members should not have supported the development of the dossier under review, should be considered independent, and there must be no conflicts of interest with regards to any statements made within the dossier.
- Members will be invited to participate as individuals, not as representatives of an organisation, institution, or government. Nomination of proxies will therefore not be permitted.

3.2.2.1. Review procedures

The scope of the work of the Review Group, its members and the secretariat are described above in chapter 2.3.3. In addition to the desk review, a country visit by the review group and the secretariat (HQ and regional level) will be organize if the desk review is in favor of recognition to verify the claim.

3.2.2.2 Review Group mission to the applicant country for verification of the interruption of schistosomiasis transmission

The national report should be discussed and evaluated by the Review Group. Based on the review decision, the Review Group expert mission to the applicant country will be organized by the WHO Regional Office as a first step to initiate the process of verification of elimination. The experts mandated by mission terms of references will work with national health authorities to review available data/documents describing the implementation of the control programme and any changes in the epidemiology and transmission of schistosomiasis, to conduct field visits (particularly to previously identified sites of active schistosomiasis transmission), and to ensure that interruption of schistosomiasis transmission has taken place, and that all measures to prevent reintroduction of schistosomiasis are sufficient and operational.

The methodology of work to be followed during the expert mission should include:

1. Critical assessment of the national report dossier and any other relevant documents related to the programme
2. Interviews of and round table discussions with programme personnel and other technical staff involved in schistosomiasis control/elimination activities at the central and peripheral level, and community members living in one or more areas of previously identified schistosomiasis transmission

By the end of the assignment, the expert team should compile all findings within a mission report. This report should recommend any necessary post-intervention surveillance surveys.

Meetings and round table discussions

As part of the mission, the group of experts should conduct a series of meetings and round table discussions with authorities at the Ministry of Health central and peripheral levels, as well as with those of other ministries and public health institutes involved in the control/elimination of schistosomiasis. Such meetings will help in facilitating finalization of the activities of the mission and the necessary logistic arrangements. The national programme manager should identify key members of the programme to plan field visits and provide records/documentation for examination. The list of documents to be consulted by the mission should also be agreed upon. It is necessary for the mission members to hold discussions with former key programme officials on historical information of the schistosomiasis control programme.

Table 1. Data, information, and documentation on the implementation of control interventions and any changes in schistosomiasis epidemiology and transmission across time and space.

Domain	Information required
Organization of the schistosomiasis control programme	• Ministry of Health organizational chart • Schistosomiasis control programme organization at: Central level Province level District level • Other partners (ministries, NGOs, etc.) involved in schistosomiasis control/elimination
Chronology of schistosomiasis adopted control strategies	• Is schistosomiasis control part of national public health priorities? Is there a specific budget for it? • Is there a strategy described in an official document of the Ministry of Health? • Is the strategy integrated with other programmes, or stand alone? • When was this strategy implemented? • Has this strategy been subjected to some modifications? If so, what modifications and when were these implemented? • Has the strategy been formulated in an annual plan of action?
The initial epidemiological situation of schistosomiasis prior to the implementation of control interventions	• Date and circumstances of the discovery of the existence of schistosomiasis transmission foci • Location of the primary foci of transmission before the implementation of control interventions • Primary results of any schistosomiasis epidemiological studies and malacological surveillance studies • Epidemiological characteristics of primary transmission foci (temporary, permanent, irrigation etc.)

Achievements of the programme interventions (e.g., diagnosis, treatment, and management of cases, freshwater snail intermediate host control interventions, health education interventions, One health, etc.)	**Diagnosis** • Number of stool and urine samples examined and the proportion of samples positive for schistosomiasis infection (by provenance, district, and village) • Data by year and age group (total population/school-aged children) preferable **Treatment and management of cases** • Type of anthelmintic drugs used by the programme for the treatment of detected schistosomiasis cases indicating source of drugs (donated or bought by programme) • Treatment protocols used (individual test-and-treat, mass preventative chemotherapy, etc.) • Parasitological follow-up after treatment of diagnosed/treated patients • Epidemiological investigation of each case detected **Freshwater snail intermediate snail host control** • Physical interventions (environmental modification, etc.) • Molluscicide interventions • Intersectoral collaboration **Health education** • Social mobilization • Audiovisual media products produced and/or used (films, pamphlets, booklets, presentations, etc.) • Do the staff have a specific manual used to describe schistosomiasis control interventions, how they and why they are implemented, etc.? **Water and sanitation hygiene (WASH) and environmental modification** • Sanitation • Provision of safe water and safe irrigation practices • Livestock management • Management of small temporal waterbodies, etc. • Dams and large irrigation fields **One Health (12)** • Zoonotic species or hybrids • Use of animals / machine in agriculture • Schistosomes worm monitoring in abattoirs • Surveys in animals • Treatment of animals with praziquantel

Resources dedicated to the schistosomiasis control programme	**Human resources** • Human resources/personnel dedicated to the schistosomiasis control programme (e.g., epidemiologists, malacologists, physicians, nurses, laboratory technicians, etc.) at central, provincial, and district levels **Material resources** • Infrastructure dedicated to the schistosomiasis control programme, including laboratories used and deployed • Material resources dedicated to schistosomiasis control and elimination **Financial resources** • Any changes (increase/decrease) in budgets allocated to the schistosomiasis control programme during the length of the programme • Primary sources of funding (state grants, etc.) • Proportion of the budget dedicated to the schistosomiasis control programme in the global budget dedicated to the control of communicable diseases • Budget allocation by interventions, e.g., diagnosis, treatment, and control of freshwater snail intermediate hosts

Epidemiological situation of schistosomiasis (change in epidemiology/transmission over time and space, incidence, prevalence, primary transmission foci, distribution of cases by age group, etc.)	• Detailed mapping of schistosomiasis transmission foci • Any changes in the number of stool and urine samples examined for the diagnosis of schistosomiasis over time and space • Any changes in the proportion of positive stool and urine samples over time and space • Data describing the intensity of schistosomiasis infections (quantified during stool and urine microscopy) • The distribution of cases by age groups, including pre-school aged children, school-aged children, and adults • Any changes in the proportion of freshwater snail hosts found to be infected with/actively transmitting schistosomes • Any changes in the proportion of livestock found to be infected with schistosomes • Reporting of any studies describing human contact with contaminated/infectious bodies of freshwater • Reporting of any studies describing immunological methods (e.g., circulating cathodic antigen rapid diagnostic tests (CCA-RDTs) used for the diagnosis of disease • Reporting of any studies describing molecular methods (e.g., polymerase chain reaction (PCR)) used for the diagnosis of disease • Reporting of any studies describing the risk of infection in irrigated areas • For transmission foci close to country boarders, describe human migration/movements over these boarders and potential impact on schistosomiasis transmission • When schistosomiasis was added to the notifiable disease list

Visits to endemic areas

Visits to previously identified sites of schistosomiasis transmission should be undertaken with the following aims:

1. To hold consultations and discussions with local health authorities and operational staff to assess the steps taken as part of post-intervention surveillance to ensure interruption of schistosomiasis transmission
2. To have a direct view of the landscape in previously identified areas of schistosomiasis transmission and to inquire about any investments in infrastructure for improving water and sanitation conditions, e.g., improved water supplies, and sanitation facilities, e.g., lavatories and pit latrines, in previously endemic areas

During visits, the evaluation team should:

1. Consult archived data on any interventions implemented at the peripheral level
2. Examine any records describing any schistosomiasis cases diagnosed during the last five years before the interruption of transmission, their classification according to the origin of infection, and any epidemiological investigations regarding these cases
3. Discuss with personnel in charge the different interventions implemented for the control/elimination of schistosomiasis
4. Inquire about the different transmission monitoring approaches and protocols used throughout the schistosomiasis control/elimination programme and the current surveillance systems established for the early detection of cases, as well as early detection of a possible reintroduction or resurgence of the infection
5. Visit any diagnostic laboratories to inquire about current personnel, training provided, and quality assurance regarding all schistosomiasis diagnostic techniques used
6. Inquire about any malacological surveillance/monitoring that has been carried out during the control programme, or that is ongoing
7. Observe how field health workers and laboratory technicians are integrated/involved in current schistosomiasis transmission surveillance systems
8. Inquire about the existence of any local intersectoral collaborations

A summary of activities during field visits by the expert team are described in Table 2.

Table 2. Information to be evaluated during field visits by the expert team.

Domain	Information required

Understand environmental and epidemiological aspects that contributed to the interruption of transmission, and determine where sampling in humans and freshwater snail intermediate hosts could be done for transmission monitoring and surveillance purposes	• Summary of results from all epidemiological studies on the primary sites of schistosomiasis transmission • Ranking of transmission foci based on the initial prevalence of infection • The general trend(s) in prevalence towards zero for each transmission foci • Selection of foci where serological diagnosis in humans is needed • Selection of foci where molecular diagnosis in humans and freshwater snail intermediate hosts is needed
Assess the infrastructure and personnel that were deployed for the schistosomiasis control programme, and that can be used to determine whether transmission interruption was achieved	**For each site visited:** • Observe and analyze the organizational structure of the schistosomiases control programme • Determine available resources (human and materials) as well as opportunities for capacity building • Analyze the capability of the surveillance system in place to maintain the interruption of transmission and to quickly detect early resurgence of reintroduction of schistosomiasis transmission
Assess the surveillance system currently in place	• Assess the quality of the surveillance system in terms of usefulness, simplicity, flexibility, and data quality (completeness and validity) • Sensitivity and specificities of the diagnostic methods used • Assessment of the laboratory quality assurance system for serological and molecular assays

Other programmatic issues	• Proportion of fully investigated foci relative to the overall number of previously identified transmission foci • Local intersectoral collaborations in maintaining and monitoring schistosomiasis transmission interruption • Level of involvement of the community and civil society in post-intervention surveillance • For transmission foci located on the border with other schistosomiasis endemic countries or regions, define the implemented measure to prevent cross-border transmission

At the end of the mission, the expert team should have debriefing meetings with the same officials to discuss observations and findings. At this stage, the need to carry out further investigations to confirm the absence of schistosomiasis transmission should be discussed and planned in case of need.

.3.2.3. Processing of recommendations

Interruption of schistosomiasis transmission (elimination) should be considered as achieved in an applicant country when adequate surveillance systems in all endemic areas in that country have appropriately demonstrated an absence of infection in humans, non-human definitive hosts (e.g., cattle), and freshwater snail intermediate hosts. This includes no evidence of exposure or infection in school-aged children and other highly exposed groups.

The independent Review Group should be asked to reach one of the following possible conclusions:

1. Data suggest that the interruption of schistosomiasis transmission (elimination) has been achieved
2. Data suggest that the interruption of schistosomiasis transmission (elimination) has not yet been achieved
3. Data show that the interruption of schistosomiasis transmission (elimination) has not yet been achieved
4. Insufficient data to infer a decision; additional data are required in order to reach a conclusion on whether the interruption of schistosomiasis transmission (elimination) has been achieved

The report produced by the independent Review Group must provide details on the reasons for reaching one of the above conclusions and provide guidance and recommendations in case conclusions 2, 3, or 4 are reached.

If the Review Group recommends validation of the claim, the summary report will be forwarded by the WHO Regional Office with the request for acknowledgement of the achievement to the WHO headquarters. At the discretion of the WHO Director-General, the official acknowledgement to the country will be provided through a letter of notification presented to the Member State by the WHO Regional Office.

The achievement of elimination of schistosomiasis transmission will be acknowledged in the following additional ways:

i. Reported in the disease-specific global progress update published annually in the Weekly Epidemiological Record by WHO headquarters (Geneva, Switzerland).

ii. Noted by updating the status of endemicity of schistosomiasis in the Global Health Observatory by WHO headquarters (Geneva, Switzerland).

iii. Removal of the country from the list of schistosomiasis endemic countries from the WHO international travel and health guide

3.3. Post verification of having interrupted schistosomiasis transmission

Verification of having interrupted schistosomiasis transmission is based on an assessment of the current situation and the likelihood that elimination can be maintained. Applicant countries are required to continue reporting on an annual basis to the WHO data describing the maintenance of their schistosomiasis-free status. Detection of new schistosomiasis infections in a non-endemic or recently verified schistosomiasis-free country should be reported to the WHO immediately, so that the WHO can provide assistance where needed and alert international travelers visiting affected areas that they should take suitable preventive measures.

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Annexes

Annex 1. Summary of declarations of interests and their management

Schistosomiasis		Country	Declared interest	Management
1.	Louis-Albert Tchuem Tchuente	Cameroon	None declared	
2.	Uwem Friday Ekpo	Nigeria	Developed health educational board games "Schisto and ladders" and "Worms and ladders" to be used in schools to create awareness about schistosomiasis and soil-helminthiases control, sold at production cost	The assessment concluded that no financial interests could directly affect, or could appear affect, the professional judgement of the expe were identified.
3.	Jean Bosco Mbonigaba	Rwanda	None declared	
4.	Doudou Sow	Senagal	None declared	
5.	Moses John Chimbari	Zimbabwe	None declared	
6.	Narcis Bujune Kabatereine	Uganda	None declared	
7.	Song Liang	USA		
8.	William Evan Secor	USA	None declared	
9.	Otávio Sarmento Pieri	Brazil	None declared	
10.	Souad Bouhout	Morocco	None declared	
11.	Bonnie L. Webster	UK	None declared	
12.	Joanne P. Webster	UK	Awarded UKRI research funding (£ 80 000–250 000) for non-commercial purposes/no conflict of interest	The assessment concluded that no financial interests that could directly affect, or could appear to affect, the professional judgement o the expert were identified.
13.	John Russell Stothard	UK	None declared	
14.	Hala Elmorshedy	Egypt	None declared	
15.	Lydia R. Leonardo	Philippines	None declared	

Soil-transmitted helminthiases		Country	Declared interest	Management
1.	Jean Tena Coulibaly	Côte d Ivoire	None declared	
2.	Hadley Matendechero Sultani	Kenya	None declared	
3.	Clara Fabienne Rasoamanamihaja	Madagascar	Received a US$ 2500 travel grant from SCIF to attend the programme managers' meeting in Addis Ababa in 2019	The assessment concluded that no financi interests (resulting from funding sources) that could directly affect, or could appear affect, the professional judgement of the expert were identified.
4.	Moussa Sacko	Mali	None declared	
5.	Theresa Gyorkos	Canada	Awarded research grants from BMGF (ended in 2017) and a travel grant from CWW (US$ 1000)	The assessment concluded that no financi interests (resulting from funding sources) and employment that could directly affect or could appear to affect, the professional judgement of the expert were identified.
6.	Judd Walson	USA	Awarded research grants for research into the feasibility of interruption of soil-transmitted helminthiases transmission from BMGF and CIFF (amount not specified)	The assessment concluded that no financi interests (resulting from funding sources) and employment that could directly affect or could appear to affect, the professional judgement of the expert were identified.
7.	Waleed Rabbani	Pakistan	None declared	
8.	Jennifer Keiser	Switzerland	None declared	
9.	Francisca Mutapi	UK	None declared	
10.	Yael Velleman	UK	Awarded research grants from Bayer (€ 30 000) and Merck (€ 30 000)	The assessment concluded that no financi interests (resulting from funding sources) and employment that could directly affect or could appear to affect, the professional judgement of the expert were identified.
11.	Chandra Aggarwal	India	None declared	
12.	Nilanthi de Silva	Sri Lanka	Received a research grant (US$ 34 000) to carry out a national survey of intestinal nematode infections in Sri Lanka in 2017 from CWW (work completed)	The assessment concluded that no financi interests (resulting from funding sources) that could directly affect, or could appear affect, the professional judgement of the expert were identified.
13.	Susana Vaz Nery	Australia	None declared	
14.	Virak Khieu	Cambodia	None declared	

15.	Somphou Sayasone	Lao PDR	None declared	

BMGF: Bill & Melinda Gates Foundation; CIFF: Children's Investment Fund Foundation; CWW: Children Without Worms; UK: United Kingdom of Great Britain and Northern Ireland; UKRI: UK Research and Innovation; USA: United States of America.

Annex 2: Template for programme managers to document having achieved elimination of schistosomiasis as a public health problem

This template document is designed to support NTD programme managers prepare a dossier, with supporting evidence, for presentation to the WHO when requesting validation for having achieved elimination of schistosomiasis as a public health problem or verification of transmission interruption. The information provided in this document will provide the context necessary to help reviewers understand control programme achievements and all submitted supporting epidemiological evidence. However, the minimum information necessary to support the claim of elimination of schistosomiasis as a public health problem includes the following elements:

1. *Thorough descriptions of, and data supporting, how endemic and non-endemic areas were classified as such*.
2. *Thorough descriptions of all interventions implemented to combat schistosomiasis and relevant data on these interventions (e.g., targeted populations, frequency and duration of large-scale preventative chemotherapy, annual coverage, etc).*
3. *Thorough descriptions of data collected relevant to schistosomiasis epidemiology: baseline prevalence, impact surveys (conducted at national level or more focally and including any surveys conducted in sentinel and spot-check sites).*
4. *A clear commitment to ongoing post-validation surveillance.*

1. Introduction

*1.1. Demographic and development context [**optional**]*

In narrative form, summarize (approximately 1-2 pages) the overall demographic and economic attributes of the country, referencing the most recent population census data, Demographic and Health survey data, and any other relevant documents or data. Where possible, provide indicators and/or map data on poverty, development and household access to adequate water and sanitation infrastructure in both rural and urban areas. Define and quantify all implementation units within the country and outline related health structures (total number of states and/or districts, etc.; District Health Offices, etc.).

*1.2. Health systems [**optional**]*

In narrative form, provide a brief (approximately one page) overview of the country's health system, including the following:

1. *Health system structure, including the delivery of primary healthcare services.*
2. *Any major infectious diseases, neglected tropical diseases (NTDs), and any chronic diseases prevalent in the country relevant to the schistosomiasis elimination control programme.*

*1.3. Schistosomiasis control programme overview [**required**]*

1.3.1. Background epidemiological information

In narrative form, describe the schistosomiasis control programme (approximately X page(s), including the following (any published studies should be fully cited):

1. *Any historical documentation of schistosomiasis in country.*
2. *Chronology of the development and implementation of the programme*
3. *Historical evidence of clinical cases, including geographical distribution and confirmed diagnoses.*
4. *Historical evidence and detail of any co-endemicity of two or more schistosome species.*
5. *Historical evidence and detail of any co-endemicity with soil transmitted helminths infections.*
6. *Thorough detail of any interventions against schistosomiasis prior to the launch of the current national control programme.*
7. *Historical evidence of the presence and distribution of any genera of freshwater snail intermediate hosts.*
8. *Thorough detail of any interventions against freshwater snail intermediate hosts prior to the launch of the current national control programme (required for transmission interruption) .*

1.3.2. Schistosomiasis control programme structure

In narrative form, describe the schistosomiasis control programme structure (approximately X page(s)), including the following:

1. *National NTD control programme goals and objectives, outlining date of programme establishment.*
2. *Organizational responsibilities of the national NTD programme for:*
    i. *Planning and implementation of school-based large-scale preventive chemotherapy.*

ii. *Planning and implementation of large-scale preventive chemotherapy distributed to other at-risk groups (adults including women of reproductive age, preschool-aged children.*

iii. *Supervision of the control programme, and response to any serious adverse events*

3. *How the schistosomiasis control programme is integrated and coordinated with other NTD programmes*.

4. *How the schistosomiasis control programme is integrated and coordinated with other national health programmes (e.g., immunization or child health programmes)*.

5. *Information regarding any intersectoral collaboration*

6. *How community-based MDA is organized*

7. *How distribution of praziquantel to adolescent girls and women of reproductive age is organized*.

8. *How distribution of praziquantel to preschool-aged children is organized.*

9. *The data collection and management system used by the control programme, including how large-scale preventive chemotherapy coverage data are reported and translated from community to national level*.

2. Background on control programme implementation [required]

2.1. Data used to classify implementation units as endemic or non-endemic

Produce and provide maps of baseline endemicity, highlighting any areas that were determined to have had over 10% schistosomiasis prevalence (in need of large-scale preventive chemotherapy once per year), and over 50% prevalence (in need of large-scale preventive chemotherapy once every six months).

In narrative form (approximately X page(s)), describe:

1. *The implementation unit used in the country and, if different, the geographical unit used for mapping endemicity data, include the following information:*

    i. *The total number of implementation units (endemic and non-endemic) at the start of the control programme.*

    ii. *The current number of implementation units and a description of any change in the total number since the start of the programme (e.g., due to redistricting).*

    iii. *The methods used to determine endemicity or non-endemicity, including all survey sampling methods and diagnostic protocols followed.*

iv. *If the endemicity status of any implementation units was reassessed during the control programme, please describe why and how this was done.*

Please also list the endemicity status of all implementation units in the country.

3. Interventions used to achieve elimination of schistosomiasis as a public health problem [required]

3.1. Large-scale preventive chemotherapy

3.1.1. Large-scale preventive chemotherapy implementation.

In narrative form (approximately X page(s)), summarize all large-scale preventive chemotherapy activities, including a description of the following:

1. *Anthelmintic used (if any anthelmintic other than praziquantel (40 mg/kg dose) was used at any point, please specific)*
2. *Distribution strategies:*
    i. *When and how anthelmintics were delivered, and who delivered them.*
    ii. *If the correct dose was provided and if the ingestion of treatment was observed.*
    iii. *Supervision structures during anthelmintic delivery.*
3. *Age group(s) targeted.*
4. *Training cascade (who was trained to deliver anthelmintics, and who provided training)*
5. *Who was responsible for recording of and reporting all data, and how these data were recorded and reported.*
6. *Anthelmintic acquisition, quality control, repacking (if any).*
7. *Any serious adverse events that took place because of anthelmintic distribution, and details on response and outcome.*

3.1.2. Large-scale preventive chemotherapy coverage.

In narrative form (approximately X page(s)), provide the following information concerning large-scale preventive chemotherapy coverage:

1. *Sources used for the denominator in reporting coverage for each age group targeted (e.g., population projections collated from national census data, school registration data, district and local population data).*

2. *Any problems with reported coverage, such as estimation of at-risk populations owing to population immigration/emigration.*

3. *Activities used to monitor coverage.*

4. *If any data quality assessments or coverage surveys were carried out, describe all protocols used and summarize the results (any published studies should be fully cited).*

5. *Response of the national control programme to any evidence of systematic non-compliance.*

   Summarize national large-scale preventive chemotherapy data using Table 2.

Table 2. National large-scale preventive chemotherapy data by year.

Year	Total number of IUs* in country	Total number of IUs* targeted	Total number of IUs* covered	Total number of SAC* requiring PC*	Total number of SAC* treated	SAC* treatment coverage (%)

**Where*:
IU: Implementation units / communities/ subdistricts
SAC: School-aged children
PC: Large-scale preventative chemotherapy

3.1.3. Expansion of large-scale preventive chemotherapy to other at-risk groups

In narrative form (approximately X page(s)), demonstrate how the control programme has expanded its coverage to reach and target other at-risk groups including:

1. *Sources used for the denominator in reporting coverage for other at-risk groups (e.g., population projections from national census data or district/local government population data).*
2. *Any problems with reported coverage, such as estimation of at-risk populations owing to population immigration/emigration.*
3. *Activities used to monitor coverage.*
4. *If any data quality assessments or coverage surveys were carried out, describe all protocols used and summarize the results (any published studies should be fully cited).*
5. *Response of the national control programme to any evidence of systematic non-compliance.*

Summarize national large-scale preventive chemotherapy data relevant to other at-risk groups in the format used by Table 2.

3.1.4. Routine data at health facility and communities

In narrative form (approximately X page(s)), demonstrate how the control programme has expanded its coverage to collect routine data (diagnostic and treatments) at health facility (see ref. 10) and communities including:

1. *Sources used for the denominator in reporting (e.g., population projections from national census data or district/local government population data).*
2. *Any problems with data reporting, such as Health information system, registers, estimation of at-risk populations owing to population immigration/emigration.*
3. *Reporting of patient consultation in different healthcare facilities including hospitals and rural health units*
4. *Response of the national control programme to any evidence of increase of cases*
5. *Annual reports on schistosomiasis including autochthonous **and imported cases** of schistosomiasis*

Summarize national case report and treatment by risk group in the format used by Table 2.

3.2. Supplementary interventions

In narrative form (approximately X page(s)), summarize any supplemental interventions that could have affected (reduced or increased) the transmission of schistosomiasis, some examples are provided below:

1. *Water and sanitation hygiene **(WASH)** interventions*

    i. *Proportion (%) of population using basic drinking water from an improved source, provided collection time is not more than a 30-minute roundtrip, including queuing.*

    ii. *Proportion (%) of population using improved WASH facilities that are not shared with another household.*

    iii. *Proportion (%) of population practicing open urination and/or defecation.*

    iv. *Proportion (%) of population using handwashing facilities with soap and water at home.*

    Note: The WHO/UNICEF Joint Monitoring Programme (JMP) for WASH produces and provides estimates of national progress on WASH activities (https://washdata.org/monitoring).

2. ***Community education interventions** to encourage behaviors that would limit exposure to, and transmission of schistosomiasis.*

    i. *Proportion (%) of population targeted using community education*

    ii. *Targeted age groups*

    iii. *Whether community education is expected to continue, how and for how long*

    iv. *Integration of schistosomiasis prevention in school health programmes*

    v. *Any reports of community participation in schistosomiasis control programmes*

3. *Point detailing **interventions targeting freshwater snail intermediate hosts**: protocol used and reports including the snail species and snail infection rates, molluscicide*

4. *Point detailing **environmental interventions** for control or representing a risk for transmission such as new dam construction or irrigation fields.*
5. ***One Health interventions**: description of zoonotic species and hybrids, surveys in animals, abattoir reports, treatment of animals, use of animals in transmission sites etc. (see ref.12)*

4. Epidemiological monitoring [required]

4.1. Ongoing periodical surveillance

In narrative form (approximately X page(s)), summarize any epidemiological surveys conducted to assess the impact of interventions (any published studies should be fully cited), and any epidemiological investigations on previously identified sites of schistosomiasis transmission including a detailed description of:

1. *Changes in surveillance system(s) over time and space*
2. *All methods used.*
3. *Protocols followed for the surveys (selection of communities, schools, and participants; Sample size, including calculations and sources used to calculate sample size)*
4. *Quality control used.*
5. *Supervision carried out, and by whom.*
6. *Data reporting on the prevalence and intensity of infection*
7. *Any issues encountered during survey implementation that may have affected survey methods, results, or outcomes*.

5.Laboratory capacity

Country capacity on diagnosis of schistosomiasis to support surveillance at all levels, including community screening, case detection and confirmation, and malacology.

Capacities in the following diagnostic techniques (in alphabetical order) according to the health structure level must be described.:

- *Dipstick Dye Immunoassay (DDIA) kit for S. japonicum and S. mansoni*
- *Dot immunogold filtration assay (DIGFA)*
- *Enzyme-Linked Immunosorbent Assay (ELISA)*
- *Hatching test*
- *Indirect Haemagglutination Assay (IHA)*
- *Loop Mediated Isothermal Amplification (LAMP)*
- *Polymerase Chain Reaction*
- *Urine circulating cathodic antigen (Urine-CCA) cassette test*
- *Urine dipstick*

6. Post-validation surveillance activities [required]

6.1. Post-validation preventive chemotherapy

List, by implementation unit, all preventive chemotherapy to be conducted after validation of elimination of schistosomiasis as a public health problem has been achieved, including a description of the following:

When (at what frequency), where (schistosomiasis-endemic and non-endemic implementation units), geographical distribution, teams/technicians carrying out large-scale preventive chemotherapy, and target populations.

6.2. Ongoing periodical surveillance and integration

Describe national control programme commitments to sustain schistosomiasis surveillance activities post-validation. Include descriptions of existing plans and potential platforms for post-validation surveillance.

Summarize any ongoing surveillance activities, including descriptions of the following:

i. Approach (sentinel site selection and activities, any integration with other NTD surveys, etc), how (protocols used for sample collection and diagnosis), when (at what frequency), where (schistosomiasis-endemic and non-endemic implementation units), geographical distribution, district capacity to conduct surveys, teams/technicians carrying out large-scale preventive chemotherapy, and target populations.

ii. Describe and outline plans to restart intensified frequency of large-scale preventive chemotherapy in case of recrudescence in schistosomiasis prevalence above elimination thresholds post-validation.

iii. Describe any ongoing activity to monitor transmission via freshwater snail hosts.

iv. Describe all activities integrated into the routine health services (diagnostic, health facility treatment, community-test and treat, data reporting

7. Extenuating circumstances [optional]

In narrative form (approximately X page(s)), provide the following:

- Thorough descriptions of any extenuating circumstances that may have affected the implementation, monitoring, and evaluation of the control programme. This could include, but is not limited to, any national stability or security issues.
- Thorough descriptions of any effort to investigate infections and/or intervention coverage in difficult-to-reach populations (e.g., nomadic populations or seasonal workers).

8. Resources and partnerships [optional]

In narrative form (approximately X page(s)), briefly describe the human resources involved in implementing the control programme and estimate the financial resources used. In addition, complete Table 3 to describe any partnerships of the national control programme.

Table 3. National control programme partners.

Year	Partner name	Activities supported	Geographical area or IUs* of support

**Where*:

IU: Implementation units

9. Bibliography [required]

Include a bibliography citing all sources of data used to develop the dossier, including:

- Ministry of Health records
- Published studies
- Academic theses and dissertations
- Any other data sources

In all instances, cite the authors, the title, and digital online identifier (DOI), if available, of all articles and reports. All reports should be kept on file in the national control programme offices.

10. Abbreviations [optional]

Provide a list of all abbreviations used with accompanying definitions.

Annex 3: Frequently asked questions

Validation is a process endorsed by the global Strategic and Technical Advisory Group for Neglected Tropical Diseases that allows the WHO to officially acknowledge elimination of schistosomiasis as a public health problem. Several relevant and important questions have been raised by countries, partners, doners, Regional Programme Advisory Groups (RPAGs), and reviewers of the regional reviewing authorities concerning the dossier and its process. These questions are outlined here to facilitate understanding, improve transparency, and assist programme managers of schistosomiasis control programmes.

1. Preparation and submission of dossier

1.1. When should control programme managers prepare the dossier?

Data collection, processing, and archiving should start as soon as possible during control programme implementation and continue throughput the programme (including during post-validation activities). Implementation Unit-level data should be updated at least annually as reports are submitted to the WHO. Control programme managers should consider preparing all data and narrative sections of the dossier as soon as schistosomiasis-endemic Implementation Units show no infections of heavy intensity during disease surveillance.

1.2. When should control programme managers submit the dossier?

Countries are encouraged to submit the validation dossier once all required sections listed in the template (Annex 2) have been completed. The dossier should not be submitted before the prevalence of schistosomiasis infections of heavy intensity is measured < 1% in all targeted areas. See Table 1 for more details.

1.3. How long does it take to prepare the dossier?

The amount of time required to prepare the dossier depends mostly on the availability of supporting data and the availability of personnel responsible for completing and submitting the dossier. As an example, it has previously taken some countries approximately one year from initial draft to official submission to the WHO. Consider how much time will be required to gather, compile, and thoroughly check the necessary information needed to prepare the dossier. Many different people and organizations, including former control programme staff, any supporting non-governmental organizations (NGOs), and the WHO will likely need to be consulted. Given turnover of staff and possible loss of data, national control

programmes are encouraged to begin preparing a draft dossier whilst large-scale preventive chemotherapy is still ongoing; completing sections on schistosomiasis endemicity mapping, preventive chemotherapy coverage, etc., as soon as information and data become available.

1.4. In what languages can the dossier be submitted?

The dossier should be submitted in one of the six official working languages of the United Nations (UN). These are: Arabic, Chines, English, French, Russian and Spanish. Countries can and should request support from the WHO if translation is required.

1.5. How can technical support be requested during preparation of the dossier?

National control programme managers can request the WHO to provide technical support when preparing the dossier. The WHO will coordinate technical support for requesting countries. Preparation of the dossier takes time and may require resources for data collation, analysis and writing. Some control programmes have hired consultants to review, consolidate, and/or organize data to support in writing the first draft of narrative sections. All control programme stakeholders should be engaged in preparing the dossier.

1.6. How can countries request an informal review of any draft dossiers prior to official submission?

National control programme managers can submit a draft dossier to the WHO requesting informal feedback. The WHO will coordinate and carry out an informal review and provide feedback to strengthen and enhance the dossier.

1.7. What if some supporting data are missing?

The control programme should seek assistance from the WHO if supporting data are missing. The WHO has a large archive of reports previously submitted by many countries and other files that may be of use such as presentations, meeting reports, and mission reports, etc. If missing data cannot be found using all available resources, there may be key informants who can provide knowledge of the setting and situation surrounding activities for which data are missing. This should be clearly outlined and described in the narrative of the dossier, allowing consideration from the WHO.

2. Processing of the submitted dossier and acknowledgement of having achieved elimination of schistosomiasis as a public health problem

2.1. How long does the validation process take after submission of the dossier?

The WHO aims to coordinate the review of the dossier and provide communication (either acknowledgement or detailed reasons for postponing acknowledgement) between six months and one year from the date of official submission.

2.2. How Is the ad-hoc Regional Reviewing Group selected?

The regional offices of the WHO are responsible for the selection of experts to review dossiers as part of a Regional Dossier Review Group that serves as the reviewing authority.

2.3. What happens after the dossier has been approved by the WHO?

The WHO acknowledges the achievement of having eliminated schistosomiasis as a public health problem in a letter from the WHO Director-General and the Regional Director to the Minister of Health. In addition, the achievement is noted in the Weekly Epidemiological Record.

2.4. If acknowledgement of having achieved elimination of schistosomiasis as a public health problem is postponed, what are the next steps needed?

Based on the report provided by the Dossier Review Group, the WHO will provide feedback to the national control programme to identify specific concerns and provide guidance for the steps needed to sufficiently address each concern. The national programme should then develop an activity plan to gather any additional evidence, revise the dossier, and resubmit the dossier for validation. Additional activities may range from amending the dossier with data not provided in the initial draft t collecting more data through additional surveys.

2.5. What are some reasons the WHO will recommend postponing validation of having achieved elimination of schistosomiasis as a public health problem?

Validation may be postponed if any of the required components of the dossier are not sufficiently addressed. Ensure that all control programme data concerning schistosomiasis endemicity, requirement of large-scale preventive chemotherapy, preventive chemotherapy coverage, sentinel site monitoring, survey implementation, and commitment to post-validation intervention activities are well documented.

3. Classification of schistosomiasis endemicity and requirement of large-scale preventative chemotherapy

3.1. What evidence is needed to determine whether an implementation unit requires preventive chemotherapy?

In principle, countries should document the results of initial mapping surveys showing the proportion of persons tested that were infected.

3.2. Should implementation units considered non-endemic for schistosomiasis during baseline surveillance need to be re-mapped?

Where the evaluation of endemicity can be clearly documented, no re-mapping of non-endemic areas is required. If any new reports, findings, or changes are noted that may indicate that schistosomiasis prevalence has risen > 10%, then implementation units initially classified as non-endemic should be re-mapped using a more robust sampling methodology.

4. Surveys to measure elimination targets

4.1. What surveys should be carried out to demonstrate that schistosomiasis has been eliminated as a public health problem?

A survey with power to reliably detect a level of schistosomiasis infections of heavy intensity < 1% (with an upper bound 95% confidence interval limit no more than 2%) is acceptable if the methodology used was robust and the results support that infection remains below target threshold levels. See Table 1 for more details.

5. Post-validation intervention activities

5.1. What post-validation intervention activities and surveillance should be carried out?

Even after validation of having achieved elimination of schistosomiasis as a public health problem has been acknowledged, preventive chemotherapy may still be needed at a reduced frequency in areas where the prevalence of schistosomiasis is > 1%.

For more information, please refer to *Annex C1: Decision tree for frequency of large-scale preventive chemotherapy distribution for schistosomiasis* in the WHO guidance manual on *Monitoring and Evaluation Framework for soil-transmitted helminthiasis and schistosomiasis control programmes* [7].

Continuous effort should also be made to improve access to adequate WASH infrastructure and provide community education to encourage behaviors that would limit exposure to, and transmission of, schistosomiasis (e.g., avoiding freshwater contact when possible and the safe management of excreta).

The types of surveillance that should be implemented, but are not limited to, include:

1. *Periodic cross-sectional surveys in representative sentinel sites*
2. *Periodic large cross-sectional remapping surveys*
3. *Routine surveillance of target population groups*
4. *Collection of health facility routine data*
5. *Periodic malacological surveillance at previously identified transmission sites to measure transmission via freshwater snail intermediate hosts.*

Post-validation surveillance activities are carried out to identify any possible recrudescence in schistosomiasis prevalence. If any recrudescence is detected, control programmes are required to respond accordingly. This response may include restarting and intensifying the frequency of large-scale mass chemotherapy. For more information, please refer to the WHO guideline for control and elimination of schistosomiasis (3) and the monitoring and evaluation framework (4).

5.2. How should post-validation surveillance results be sent to the WHO?

Surveillance data can be submitted annually using the Epidemiological Data Reporting Form (EPIRF). All activities and results of activities should also be shared during Regional Programme Manager and Regional Program Review Group meetings, to allow for consideration of and discussion about the results, identification of any challenges, and to inform best practices during post-validation activities.

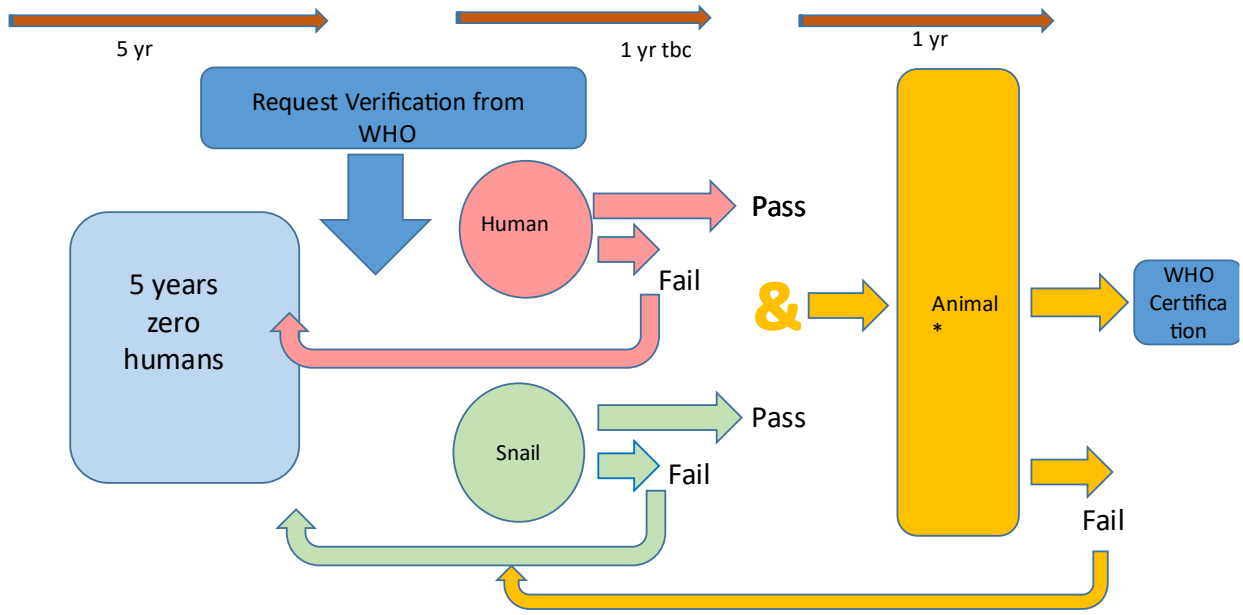
Table 5. Minimum technical requirements needed to achieve validation for having eliminated schistosomiasis as a public health problem.

Dossier section	Data required	Recommended criteria
Control programme overview and baseline data	IUs throughout country	If IUs have changed in the past five years, justifications as to why should be provided
	Geographical distribution of schistosomiasis infections	Urogenital and intestinal schistosomiasis infections should be differentiated, where possible
	Data used to classify IUs as endemic or non-endemic for schistosomiasis	Thorough descriptions should be given as to how to endemicity status of each IU was determined at baseline by providing: 1. All survey sampling methods 2. All survey diagnostic protocols 3. Results for each IU
Large-scale preventive chemotherapy	Data used to report large-scale preventative chemotherapy coverage during previous five years	Annual coverage should be reported per IU for the previous five consecutive years (see Annex 2: Table 2) Large-scale preventive chemotherapy should be carried out according to dossier section *1.2.1: Large-scale preventive chemotherapy.* Both the numerator and the denominator used for reported coverage should include non-enrolled school-aged children. Ideally, reported coverage should be validated using a coverage validation survey. When reporting coverage using population projections from the national census, a coverage validation survey should be conducted for the year prior to the impact survey. There should be no significant difference between the reported and surveyed coverage.

		Demonstrate that the control programme has expanded large-scale preventive chemotherapy to include and target adults at risk including women of reproductive age, preschool-aged children by reporting coverage of these over the previous five years. The report should indicate a policy for treating these demographic groups, how treatment is integrated into routine care, presenting data highlighting progress in increasing the proportion of those treated over the past five years, and establishing a national plan for ongoing treatment.
Epidemiological surveys implemented to assess the impact of implemented interventions: Condition to initiate a validation process	The prevalence of schistosomiasis infections of heavy intensity is < 1%. Heavy-intensity infections are defined in Annex 1: Table 1.	The control programme should clearly outline a five-year post-validation epidemiological surveillance plan, which should include: 1. Annual collection of epidemiological data in selected sentinel sites • Sentinel surveillance sites should be selected and defined in all transmission foci. 2. A plan to conduct large-scale mass chemotherapy according to *Annex C1: Decision tree for frequency of large-scale preventative chemotherapy distribution for schistosomiasis* in the WHO guidance dossier *Monitoring and Evaluation Framework for soil-transmitted helminthiasis and schistosomiasis control programmes* [4].

*<u>*Where*</u>:
IU: Implementation Units (comnunities or subdistricts)

Annex 4. General steps in assessing absence of schistosomniasis infection in human, snail and environment and in non human animal (verification)



Annex 5: Form for epidemiological investigation around a newly identified schistosomiasis case

Patient identification
Name:
Age:
Address:
Occupation:
Diagnosis made by:

History of infection
Date of onset of schistosomiasis symptoms:
Date of urine and/or stool sample provision:
Date of urine and/or stool sample examination:
Results of examination (diagnostic outcome, egg count(s)):

Movement of the patient in the last six months (inside and outside of country): (
The patient has had any contact with the water when traveling (work, leisure, etc.)
Characteristics of the physical/ecological environment near to the patient (are there bodies of freshwater, what form do these take? etc.)

Laboratory method(s) used for diagnostic examination
Urogenital schistosomiasis
Urine-egg microscopy, serology, urine dipstick RDT, molecular method (e.g., PCR), etc

Intestinal schistosomiasis
Kato-Katz faecal-egg microscopy, POC-CCA RDT, serology, molecular method (e.g., PCR), etc

Malacological surveillance
Presence/absence of freshwater snail intermediate hosts
Infection identified in collected freshwater snail hosts

Entourage surveillance
Diagnostic examination of stool/urine sample of close family member
Results of examination (diagnostic outcome, egg count(s)):

Case classification
Autochthonous
Imported
Residual