YAWS STRATEGY DEVELOPMENT

REPORT OF A MEETING, 27–28 OCTOBER 2014, ATLANTA, GA, USA
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CONTROL OF NEGLECTED TROPICAL DISEASES
WORLD HEALTH ORGANIZATION
AND
THE TASK FORCE FOR GLOBAL HEALTH
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EXECUTIVE SUMMARY

Yaws, a neglected tropical disease that affects millions of poor people worldwide, can be treated with a single dose of azithromycin. The World Health Organization (WHO) has targeted yaws for eradication by 2020. In 2012, WHO developed the Morges strategy for the eradication of yaws. Some progress has been made since 2012 with implementing the Morges strategy, but a significant scale-up is needed to reach the goal of eradication of yaws by 2020.

WHO and the Task Force for Global Health (TFGH) convened a meeting and conducted a needs assessment on how to scale up the Morges strategy. The meeting concluded that: (i) yaws should be classified by WHO as both a ‘preventive chemotherapy’ and an ‘intensified case management’ disease; (ii) mapping of the distribution of yaws at global, country, district and village levels must be completed so that the burden of the disease is known and countries can be selected for treatment; (iii) consensus is needed on definitions of the disease; (iv) diagnostic strategies and algorithms must be developed; (v) treatment strategies must be defined in order to estimate the amount of azithromycin that will be needed to scale up global eradication of yaws; (vi) there is enough knowledge to implement the Morges strategy, and operational research to improve the programme should therefore be conducted during the scale up; (vii) funding must be mobilized for implementation of the Morges strategy and for operational research; (viii) commitment from politicians and partners for yaws eradication must be enhanced; and (ix) collaboration with water, sanitation and hygiene (WASH) programmes, and other neglected tropical disease programmes is essential.

The yaws programme managers and public health and laboratory experts advised WHO and the Member States endemic for yaws to: (i) draft a comprehensive roadmap for the upscaling of the Morges strategy, including a timeline for all required activities, taking into account the priorities, roles and responsibilities of all stakeholders; (ii) establish an International Coalition for Yaws Eradication (ICYE) that can assist WHO with coordination, advocacy and mobilization of resources to scale up the Morges strategy, with focus by ICYE working groups on specific aspects such as epidemiology, diagnostics, treatment, monitoring and evaluation, operational research, implementation, knowledge management, communication and partnerships; and (iii) plan annual follow-up meetings to assess progress.

The participants agreed that eradication of yaws by 2020 is feasible; but scaling up of the Morges strategy should start as soon as possible. Operational research aimed at unanswered questions should be conducted while programme activities are under way.
1. BACKGROUND

Yaws is a preventable and treatable infectious disease that has been eliminated from most of the world. WHO has targeted yaws for eradication by 2020, as outlined in resolution WHA66.12 on neglected tropical diseases (NTDs), adopted by the World Health Assembly in 2013, and the WHO roadmap on NTDs, published by WHO in 2012. The disease is caused by *Treponema pallidum* spp. *pertenue* (TPP). Yaws is transmitted by skin-to-skin contact. Children under 15 years of age are mostly affected. The disease is self-limiting in most cases, but in 10% of untreated cases, permanent disfiguring disability and sometimes painful lesions of the skin and bones may develop (the nose is often affected). Yaws can be cured with a single injectable dose of benzathine penicillin or a single oral dose of azithromycin.

In 2012, WHO developed the Morges Yaws Eradication Strategy to eradicate yaws from the endemic countries. One of its important recommendations is to use mass drug administration (MDA) with a single dose of azithromycin as a treatment strategy. In 2013, WHO organized a meeting to draft guidelines for programme managers and criteria for the certification of countries.

Medicins Sans Frontières carried out the first implementation of the Morges strategy in the Congo in 2012. Ghana, Papua New Guinea and Vanuatu began implementation on a pilot basis. Some 90,000 people were treated with azithromycin in 2012-2013 in the Congo, Ghana, Papua New Guinea and Vanuatu, with marked reductions in the prevalence of clinical yaws. A combined trachoma and yaws survey was carried out in the Solomon Islands. A new rapid dual non-treponemal and treponemal point-of-care syphilis test (DPP®, Chembio) has been evaluated for use against yaws in Ghana, Papua New Guinea and the Solomon Islands and in Vanuatu for yaws eradication efforts. Baseline azithromycin resistance studies have been carried out in Ghana, Papua New Guinea and Vanuatu.

A meeting on Yaws Strategy Development was organized by the World Health Organization (WHO) and the Task Force for Global Health (TFGH) in Atlanta, Georgia, USA on 27–28 October 2014. The agenda is contained in Annex 1 and the list of participants in Annex 2.

GOAL

The goal of the consultative meeting was to develop a global strategic plan for yaws eradication.

GENERAL OBJECTIVES

The purpose of the strategy development meeting was to review the progress made so far and to use the lessons learnt to develop a plan for ‘gradual scale-up’ of implementation of the Morges strategy in selected countries.

SPECIFIC OBJECTIVES

1. To review the current knowledge of yaws, by
   - discussing the epidemiology of the disease
   - reviewing the lessons learnt from the pilot projects implemented in Ghana, Papua New Guinea and Vanuatu

2. To identify unanswered questions and critical gaps in the current knowledge of yaws, by
   - identifying operational research areas related to yaws eradication
   - setting out a timeline to reconcile the gaps
   - planning how to generate new knowledge to refine the Morges strategy
3. To plan demonstration projects and operational research that will answer the questions generated, by
   • defining the roles and responsibilities of different stakeholders in the yaws eradication efforts
   • exploring ways of mobilizing the necessary funds and azithromycin to assist the gradual scale-up in selected countries.

2. OPENING OF THE MEETING

Dr Mark Rosenberg, President and Chief Executive Officer, TFGH, opened the meeting. He requested that all the participants express their expectations from this meeting. Dr Rosenberg emphasized that eradication of yaws from the world is feasible but not easy. Lessons can be learnt from the other disease eradication programmes: smallpox, dracunculiasis and polio. Issues must be synthesized from multiple perspectives: think big and think bold. More than 1.3 million Rotary International club members are largely responsible for moving towards eradication of polio. The support of such global organizations and that of others should be harnessed to eradicate yaws. As the implementation of interventions progresses and disease prevalence decreases, the tools and strategies may also change; however, implementation of the Morges strategy can be expanded without knowing all the answers, and the strategy need not be perfect in the beginning.

Dr Dirk Engels, Director, WHO Department of Control of NTDs, indicated that enhanced collaboration between different NTD elimination programmes and various partners is emerging globally. A simple and effective tool is available for yaws eradication. There is therefore both an opportunity and a need to develop a gradual scale-up plan to achieve the target of yaws eradication by 2020.

Dr Mark Rosenberg was the Chair. Dr Huub Gelderblom and Dr Chandrakant Revankar were the rapporteurs.

3. PRESENTATIONS AND DISCUSSION

Dr Kingsley Asiedu, WHO Department of Control of NTDs, in his presentation on the current situation of yaws at global level, highlighted that 100 countries have been noted to be yaws endemic at some time, of which 13 are currently reporting yaws cases. Two countries (Ecuador and India) have reported interruption of transmission and are awaiting certification. In the 1950s, an estimated 160 million people suffered from yaws. About 50 million people were treated with a single dose of long-acting benzathine penicillin during a campaign carried out between 1952 and 1962 in 48 countries. As a result, yaws prevalence declined from 50 million to 2.5 million (95% reduction). However, yaws treatment campaigns lost priority and so disease and infection remained in many pockets of the world, particularly in Africa and Asia.

Dr Asiedu recalled that since the beginning of yaws eradication efforts, success stories have been reported and many publications have appeared. To date, the World Health Assembly has adopted two resolutions related to endemic treponematoses – WHA2.36 (1949) and WHA31.58 (1978) – and one resolution on NTDs – WHA66.12 (2013).
In June 2014, India completed an internal review of its yaws eradication programme (1996–2013) and reported that no yaws cases were found, confirming the complete interruption of transmission nationwide. There had been 3000 cases in 1996, fewer than 1000 cases in 1997, fewer than 50 cases in 2003 and zero cases since then. The programme will be requesting that WHO undertake an international evaluation for certification.

The WHO roadmap on NTDs (2012) included yaws as a target for eradication by 2020. Pilot projects were implemented in the Congo, Ghana, Papua New Guinea and Vanuatu to enable lessons to be learnt and to facilitate the identification of issues or gaps in the gradual scale-up strategy planned for adoption in selected countries. Further work is needed to mobilize the funds and drugs required to support endemic countries in moving forward.

**Dr Patrick Lammie, TFGH**, gave a brief background on the Coalition for Operational Research on NTDs (COR-NTD), which holds the ‘filling the gaps’ grant from the Bill & Melinda Gates Foundation (BMGF). This is not a traditional type of grant with predefined activities but rather a pragmatic grant to fund operational research relevant to the preventive chemotherapy (PC) group of NTDs (lymphatic filariasis, onchocerciasis, schistosomiasis, soil-transmitted helminthiases and trachoma). The aim is to align the research with programme needs; there is a continuous dialogue with all stakeholders to try to achieve this. The four objectives are: (i) coalition-building, connecting researchers and NTD country programmes, (ii) work with the WHO Regional Office for Africa to complete the mapping of NTDs in Africa for all PC-NTDs, (iii) a modelling consortium, wherein several groups work on the same datasets, so that results can be compared, and (iv) new tools for the end-game, i.e. post-MDA surveillance. If yaws is classified by WHO as a new PC-NTD, then COR-NTD can start a dialogue with BMGF to include yaws in COR-NTD.

**COUNTRY PRESENTATIONS**

Participants from Ghana and Vanuatu shared their experience in the pilot implementation of the Morges strategy.

**GHANA**

Mr Abdul Aziz Abdulai, West Akyem Municipal Directorate, Ghana presented the progress in implementation of the Morges strategy in the pilot area in West Akyem district. Yaws is included in the routine integrated disease surveillance system, but not all cases are reported, possibly because yaws is considered a common and transient childhood condition that will disappear when they grow older. During the past 5 years, the reporting rate of yaws has ranged between 84 and 241 per 100 000 of the general population. In November 2013, a comprehensive pilot study was conducted in West Akyem district in Ghana. The study objectives were to (i) learn operational lessons in implementing the Morges strategy, (ii) determine the effect of oral azithromycin on yaws in Ghana, (iii) evaluate the dual path platform (DPP) test for yaws, (iv) determine the baseline resistance to azithromycin using PCR analysis (v) build capacity in planning and implementation of MDA, record-keeping and performing laboratory tests.

The azithromycin dose used was 30 mg/kg, as recommended by WHO. An age-based dosing scale was used. Coverage was 95%; 14 548 of 15 310 eligible people were treated with azithromycin. Mild gastrointestinal side-effects were observed in some individuals because participants were not instructed to eat before taking the drug. No serious adverse events occurred. Azithromycin was given under supervision of health workers. At the time of MDA, 50 clinical yaws cases were identified and serologically confirmed. After 8 weeks, 32 cases were followed up with photography and DPP testing, of which 30 cases had healed. The team found the Morges strategy to be feasible to implement.

**VANUATU**

Dr Jacob Kool, WHO Country Office, Vanuatu (Ms Fasihah Taleo, the yaws programme manager could not attend), presented the progress of the pilot project and lessons learnt. Yaws is endemic in Vanuatu, an island nation in the South Pacific with a population of 262 000. Previous attempts to eradicate yaws have failed due to low treatment coverage
and/or insufficient funding to continue campaigns. A comprehensive pilot MDA with azithromycin was conducted in Tafea province in 2013, where more than 1000 yaws cases had been reported in 2010. Tafea consists of five islands with a total population of 43 650. The azithromycin dose used was 30 mg/kg. An age-based dosing scale was used. Of the 43 650 people, 41 336 were treated with azithromycin (96% coverage). There were no serious adverse events. There was a marked reduction in the number of yaws cases after the MDA. At the local hospital, there was also a reduction in admissions (−26%) and outpatient visits (−55%), especially for respiratory diseases (−83%), after the MDA.

In both Ghana and Vanuatu, the MDA campaigns were well prepared and executed, with extensive training, community mobilization, availability of public educational materials and involvement of community key leaders.

Dr Ron Ballard, United States Centers for Disease Control and Prevention, Atlanta, presented the results of the evaluation of the Chembio DPP® point-of-care (PoC) test used in yaws eradication pilot projects in Ghana and Vanuatu. He reported that the DPP test is as sensitive and specific as the rapid plasma regain (RPR) test at titres equal to or more than 1:4, but lacks sensitivity at lower titres. The DPP treponemal results are equivalent to those of the TPHA/TPPA (Treponema pallidum haemagglutination assay/Treponema pallidum particle agglutination assay) test.

Dr Ballard also discussed the interesting findings from Ghana and Vanuatu on ulcer cases clinically treated as yaws. It was observed that 33% of yaws ulcer cases were confirmed as a true yaws caused by TPP infection, 33% of lesions were caused by *Haemophilus ducreyi* and 33% of lesions were negative for TPP. *H. ducreyi* and *Mycobacterium ulcerans* (PCR was performed for only those organisms). Some ulcer cases had TPP and *H. ducreyi* dual infections. An important implication of this finding is that ulcers of other etiology, but clinically similar to yaws, may remain in the population after MDA with azithromycin. This information must be communicated to the communities beforehand, and the other ulcers may be managed with other drugs and/or symptomatic topical treatment. *H. ducreyi* is sensitive to azithromycin but reinfection is possible if genital *H. ducreyi* is present.

In addition to the DPP-PoC test results, Dr Ballard also discussed several other assays carried out in Ghana and Vanuatu, including antibody testing on the Luminex platform using dried blood-spots, ‘classical’ RPR and TPPA, PCR for identifying *T. pallidum*, *H. ducreyi* and *M. ulcerans*, and PCR for mutations associated with treponemal macrolide resistance.

Dr Ballard presented two flowcharts with proposed diagnostic algorithms (see Annex-3A and Annex-3B) for assessment of potential yaws-endemic countries and post-MDA assessment of targeted countries.

**DISCUSSION**

After the presentations, the participants discussed in four separate groups (i) epidemiology and mapping, (ii) interventions – diagnostics, treatment and syndromic management, (iii) optimal delivery and preferred practices, and (iv) setting up a global yaws effort – partnerships.

The groups considered the topics in the context of:

- identification of gaps and research questions,
- plans for the way forward to fill the gaps and answer the questions,
- priorities for action to fill the gaps and answer the questions as quickly as possible in order to reach the 2020 target for the eradication of yaws.
The participants agreed that the identified operational research can be conducted while implementation of activities is in progress. They also suggested that many operational research studies (i) can piggyback or be integrated with programme activities, and (ii) multiple studies or study arms can be conducted in parallel. When coordinated properly, this integrated-parallel strategy can help to obtain results faster, and at lower costs, compared to separate operational research studies. This approach also meets the objectives of the COR-NTD project of the TFGH/BMGF grant.

Participants reiterated that implementation of the Morges strategy should move forward without waiting for refinements to the interventions and strategies. While progressing, lessons learnt from other MDA implementations may be considered and a common platform could be built to include yaws under the PC-NTD. Simultaneous operational research would advance knowledge to improve the programme monitoring and evaluation. In addition to bio-medical issues, socioeconomic and geo-political issues closely related to the disease eradication end-game should be taken into account: such considerations have proven extremely important in polio and dracunculiasis eradication programmes.

Strong partnership with donors, the pharmaceutical industry, and diagnostic and professional partners will be essential to achieve the target for the eradication of yaws by 2020.

KEY ISSUES ADDRESSED IN THE MEETING

The following key issues were identified:

1. Completion of mapping at global, country, district and village levels.
2. Selection of countries for the gradual scale-up of the global programme.
3. Clear definitions of ‘suspected endemic’ (a country bordering an endemic country but known as a non-endemic country), ‘known endemic’ and ‘formerly endemic’.
4. Selection of diagnostics, including cost considerations and feasibility for field use.
5. Questions on the treatment strategy and hence the amount of azithromycin that will be needed for the scale-up and global yaws eradication.
6. The end-point and how to decide when to stop mass treatment.
7. How to verify interruption of transmission.
8. What operational research will be needed during the gradual scale-up.
9. Funding for operational costs and drugs for implementation.
10. Building political and partner commitment for yaws eradication.
11. Integrated approaches and incorporating WASH interventions.

Details of group discussion and issues identified are given in Annex-4A and Annex-4B.
4. CONCLUSIONS AND RECOMMENDATIONS

The participants appreciated the efforts made by the yaws-endemic countries and WHO in implementation of the Morges Strategy and identification of operational research needs for scale up, despite a number of constraints. After discussing all the key issues in relation to operational research areas and yaws eradication, the participants made the following recommendations to WHO:

1. Prepare a roadmap for the upscaling of the Morges strategy to achieve yaws eradication by 2020, referring to the trachoma programme and other NTD programmes.
2. Include yaws in the PC group of NTDs (for the mass treatment part) and maintain yaws in the ‘intensified case management’ group of diseases (ICM, individual follow-up, diagnosis and treatment after mass treatment, management of ulcers).
3. Develop demonstration or collaborative projects based on the Morges strategy to provide further evidence on the interruption of transmission in Cameroon, Ghana, Indonesia, Papua New Guinea, the Solomon Islands and Vanuatu.
4. Devise a methodology for more accurate epidemiological mapping for improved planning and implementation and end-point assessment.
5. Estimate the requirements for azithromycin and DPP test kits, based on currently available information from the 13 known endemic countries.
6. Provide evidence for thresholds for stopping MDA with azithromycin.
7. Build a WASH strategy as an integral component of yaws eradication.
8. Determine the best health education messages for social mobilization.
9. Establish an International Coalition for Yaws Eradication (ICYE) with all partners to advocate, mobilize resources and coordinate efforts.
10. Create a website for information-sharing and resource mobilization.

A condensed table with all recommendations, priorities and lead partners is contained in Annex-4B.
5. WAY FORWARD (NEXT STEPS)

The Programme Managers, WHO staff and invited experts advised WHO and the Member States endemic for yaws to take the following steps:

1. Draft a roadmap (Plan of Action) to upscale the Morges strategy to eradicate yaws by 2020:
   a. Outline all activities that must be conducted.
   b. Define roles and responsibilities of all stakeholders, who will do what, and who will lead if it is a group effort.
   c. Set a timeline for all activities to be carried out, taking into account the priorities in the recommendations.
2. Plan annual follow-up meetings to assess progress, and identify failures and successes.
YAWS STRATEGY DEVELOPMENT

ANNEXES

ANNEX 1. AGENDA

FACILITATOR: Dr Mark Rosenberg
RAPPORTEURS: Dr Huub Gelderblom and Dr Chandrakant Revankar

<table>
<thead>
<tr>
<th>Time</th>
<th>Day 1 – Monday 27 October 2014</th>
<th>Presenter(s)</th>
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<tr>
<td>09:00–10:30</td>
<td>Introduction</td>
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<td></td>
<td>Self-introduction</td>
<td>All</td>
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<tr>
<td></td>
<td>Opening remarks</td>
<td>Dr Mark Rosenberg, Dr Paul Emerson, Dr Dirk Engels</td>
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<td></td>
<td>Global situation yaws and update activities</td>
<td>Dr Kingsley Asiedu, Dr Patrick Lammie</td>
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<td></td>
<td>Coalition for Operational Research on NTDs (COR-NTD)</td>
<td>All</td>
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<tr>
<td>10:30–11:00</td>
<td>Break</td>
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<tr>
<td>11:00–12:30</td>
<td>Pilot implementation of the WHO Morges yaws eradication strategy in 2013 – achievements, results and lessons learnt</td>
<td>Ghana Mr Aziz Abdulai, Vanuatu Dr Jacob Kool, Discussion All</td>
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<td>Ghana</td>
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<td>Vanuatu</td>
<td>Dr Jacob Kool</td>
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<td></td>
<td>Discussion</td>
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<td>12:30–14:00</td>
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<tr>
<td>14:00–15:30</td>
<td>Results of research activities carried out in Ghana and Vanuatu – achievements, results and lessons learnt</td>
<td>Ghana and Vanuatu Dr Ron Ballard, Discussion – Operational research needed for yaws eradication All</td>
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<td>Dr Ron Ballard</td>
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<td></td>
<td>Vanuatu</td>
<td>All</td>
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<td></td>
<td>Discussion</td>
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<td>16:00–17:30</td>
<td>Discussion of key issues (see background document)</td>
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<td>11:00–12:30</td>
<td>Development of a global strategic plan for yaws eradication (cont.)</td>
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<td>13:30–15:00</td>
<td>Conclusions, recommendations and closure</td>
<td>Dr Dirk Engels, Dr Mark Rosenberg</td>
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ANNEX 3A. ALGORITHM FOR ASSESSMENT OF A POTENTIAL YAWS-ENDEMIC AREA

Potential yaws-endemic area
- Historical epidemiological information
- Current reported cases

Yes

Rapid integrated assessment of children ≤ 6 years
- Luminex multiplex (treponemal-specific antibody)
- Treponemal test
- Dual treponemal and non-treponemal

≥ 1%

Full assessment

STEP 1

Clinical and etiological assessment in communities
- Clinical evaluation of suspected yaws-like lesions
- Rapid test (DPP dually-positive)
- PCR (if available) on suspected lesions

Serosurveys in primary schools
- Rapid test (DPP dually-positive) ≥ 1%

Confirmed yaws-endemic

Country-specific strategic plan for MDA?

STEP 2

With age breakdown this “snapshot” will indicate if there is ongoing transmission
ANNEX 3B. ALGORITHM FOR ASSESSMENT OF MASS DRUG ADMINISTRATION AFTER IMPLEMENTATION IN TARGETED COUNTRIES

**Routine/Sentinel surveillance**
- Primary health care clinics
- Ulcers with dual seropositivity (DPP)
- Rx & Contact tracing/Rx

**One year follow-up**
Should be 1 year to prevent bias due to seasonal variations

**Full assessment**

**Clinical and etiological assessment in communities**
- Clinical evaluation of suspected yaws-like lesions
- Dual rapid test (DPP)
- PCR (if available) on suspicious lesions

**Surveys in primary schools**
- Clinical evaluation of suspected yaws-like lesions
- Dual Rapid Test (DPP)
- Oversample aged ≤ 6–7 yrs (first year in school)
- PCR (if available) on suspected lesions

**Confirmed yaws cases detected by PCR (if available) or by dual rapid test (DPP)**

**Surveys in primary schools**
- Confirmed yaws cases detected by PCR (if available) or dual seropositive (DPP)
- > 0% dual seropositive (DPP) in children age ≤ 6–7 yrs

**Continuing yaws transmission**

**Second round of MDA**
(Criteria for TTT to be determined)
ANNEX 4A. GROUP DISCUSSION

GROUP 1: EPIDEMIOLOGY AND MAPPING

WHAT WE KNOW

1. Yaws is a focal disease
2. Some 100 countries have ever reported yaws, of which:
   - 13 countries are confirmed endemic since 2000 (≥ 1 confirmed case)
   - 2 countries have reported yaws elimination and are awaiting certification
   - 85 countries have ever reported yaws, but the current status is unknown
3. Not all yaws-like lesions are yaws.

WHAT WE NEED TO KNOW

1. Definitions of a yaws case
2. Whether a country is endemic or not
   a. Are all yaws cases reported since yaws is no longer a reportable disease?
   b. Explore existing opportunities for dried blood-spot collection
   c. What is the cut-off level to determine non-endemic? This may need modelling.
3. An estimate of the (i) populations at risk and (ii) total burden of the disease worldwide and in the 13 known endemic countries in particular, to estimate the amount of azithromycin and other resources that will be needed.

HOW DO WE FIND OUT?

1. A central data repository
2. Modelling
3. Epidemiology studies
   a. Prioritize the 13 countries that are known to be endemic since 2000 based on the number of cases reported annually.
   b. In parallel (but of lower priority), start assessing the 85 countries with previous history of yaws to confirm that these countries are no longer endemic.

WHAT NEEDS TO BE DONE

The group identified the following high-priority areas to be addressed:

1. Agree on relevant definitions: case (suspected case, clinical case, laboratory case [current infection, past infection, latent infection, reinfection]), prevalence, endemicity [indigenous vs imported], interruption of transmission, criteria to start and stop MDA, criteria to start and stop targeted treatment, criteria to start and stop ICM, M&E indicators during treatment phase and during surveillance phase, and eradication criteria. Definitions from the Morges report (pages 4 and 5) and the 2014 Yaws National Programme Managers Guide (draft document) can be used as a starting point, but some need to be updated.
2. Yaws should be a notifiable disease

3. Defining the evaluation unit for baseline estimates of the population at risk. Suggest district level (50,000–200,000 people) for full assessment. Village level may be too intensive. For impact assessment, a different unit may be appropriate.

4. Define the treatment unit, which may or may not be the same size as the evaluation unit.

5. Study the spatial distribution: spatial heterogeneity of infections. Intensive mapping in 3–4 different countries, gathering extremely detailed information within a district to fully understand spatial distribution. These data would allow determination of appropriate evaluation unit, implementation unit, sampling strategy, age group. Clinical, serology and PCR. (Mapping would also need to be done post-MDA to identify the effect of mass treatment on the distribution of the disease.)

6. Survey methodology: baseline prevalence is not necessarily needed because where there is at least one case an intervention will be required. Given that the immediate results of confirmed cases will not be known (pending PCR), the survey could be designed around the need to identify, with some level of certainty, that there are 1 or more cases.

<table>
<thead>
<tr>
<th>Implementation phase</th>
<th>Post-zero phase</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Suspected case</strong></td>
<td>Individual with clinical signs consistent with yaws</td>
</tr>
<tr>
<td><strong>Confirmed case</strong></td>
<td>DPP dually-positive or TPHA + RPR</td>
</tr>
<tr>
<td><strong>Past infection</strong></td>
<td>Clinically yaws lesion healed + DPP results showing non-reactive non-treponemal line</td>
</tr>
<tr>
<td><strong>Treatment failure</strong></td>
<td>Persistent clinical lesions 8 weeks after azithromycin treatment and confirmed by PCR despite being serologically dually-positive</td>
</tr>
</tbody>
</table>
GROUP 2: INTERVENTIONS: DIAGNOSTICS, TREATMENT AND SYNDROMIC MANAGEMENT

2.1 DIAGNOSTICS

WHAT WE KNOW

We have diagnostics that we can use to move forward.

WHAT WE NEED TO KNOW

1. What diagnostic to use at what point in time and in what sequence (i.e. a diagnostic strategy and diagnostic algorithms)
2. What are the causes of ulcers that are not yaws and not caused by H. ducreyi?

HOW DO WE FIND OUT?

1. Operational research studies (parallel approaches)
2. Prospective sampling (bio bank)

WHAT NEEDS TO BE DONE

1. Diagnostic framework: comprehensive review of available diagnostics, prices, strategies to reduce costs (pool multiple samples into one test), projected volumes (how many tests will be procured, manufacturers want to know this), who can do what (partners in diagnostics), what (combinations of) diagnostics will be used during phase 1, before treatment (to guide decisions about starting MDA), phase 2, during treatment (to guide decisions about whether to continue or stop MDA and/or ICM), phase 3 (surveillance after treatment), identify reference laboratories, quality assessment and quality control structures.
2. Piggyback operational research studies (parallel approaches) and sampling strategies on existing control efforts to get the samples needed to do diagnostic evaluation studies
   a. Prevalence of dual positives (DPP can be added to the Global Trachoma Mappint Project)
   b. First Luminex and then age breakdown in endemic and control populations, previously endemic areas

2.2 TREATMENT

WHAT WE KNOW

1. Azithromycin is an effective treatment for yaws at a single dose of 30 mg/kg
2. Yaws-like lesions respond well to cleaning with salt water and applying dressings
WHAT WE NEED TO KNOW

1. If 20 mg/kg would be enough, we would need 33% less drugs compared to 30 mg/kg
2. Treatment strategies, combinations of sequential MDA and/or targeted treatment.
3. What are non-yaws or non-\textit{H. ducreyi} causes of ulcers? What treatment can be given for those ulcers?
4. What is more accurate: height-based dosing or age-based dosing?

HOW DO WE FIND OUT?

1. Review evidence base
2. Design studies
3. Conduct parallel studies
4. Review evidence base to explore what doses people actually receive, and if and what kind of study is needed to compare 20 mg/kg to 30 mg/kg.
5. Longitudinal studies for causes of ulcers (is it yaws, \textit{H. ducreyi} or something else?). What is the incidence of infection and reinfection? Are these ulcers? Ulcer etiology studies can be piggybacked on mapping and impact assessments. Take swabs from ulcers to determine what causes ulcers.

WHAT NEEDS TO BE DONE

1. Draft a guide for programme managers (national NTD coordinators) with (generic, locally adaptable) key elements: MOP (manual of procedures) SOPs (standard operating procedures), work instructions, best practices, communication materials. The 2014 Yaws National Program Managers Guide can be used as a starting point. Laboratory manuals, IEC (information, education, communication) materials and training modules must be developed.
2. Address regulatory issues. Azithromycin is not registered for treatment of yaws. Is off-label use of azithromycin allowed? WHO recommendations are based on evidence. Waivers for off-label use can be issued by individual country health ministries.
3. Study efforts need to be integrated and coordinated with existing mapping control efforts.
4. Need to design appropriate sampling strategies to get the correct samples to answer the questions identified.
5. Answer several biological and medical questions:
   a. What is the ideal strategy for management of the other ulcers? Ulcers caused by organisms not susceptible to azithromycin may become relatively more prevalent as yaws cases decline. Syndromic management (combination therapy to cover all causes of ulceration may be needed).
   b. Bio bank swabs now (prospectively) to get baseline status, metagenomics, sample collection ready for (i) interpreting and evaluating new assays, and (ii) 'look back' studies with historical samples.
   c. What is more accurate: height-based dosing or age-based dosing?
   d. Treatment strategy
      i. How many rounds of MDA?
      ii. MDA and/or targeted treatment (ICM)?
      iii. Frequency, interval, lessons learnt from India programme
      iv. Identify best practices to deliver treatment
2.3 SYNDROMIC MANAGEMENT

WHAT WE KNOW

1. Azithromycin has collateral benefits
2. There are other causes of ulcers in yaws-endemic areas, clinically indistinguishable from yaws
3. Symptomatic treatment for ulcers is available and relatively easy to provide

WHAT WE NEED TO KNOW

1. What are other causes of ulcers? How do we diagnose?
2. What are appropriate treatments for ulcers?
3. How do we inform communities so that they are aware that some ulcers (not due to yaws or susceptible to azithromycin) may remain in the population after MDA so that they do not consider MDA a failure.

HOW DO WE FIND OUT?

1. Parallel studies (as described above).

WHAT NEEDS TO BE DONE

1. Start providing case management of ulcers (cleaning with salt water and applying dressings) when identified during mapping and/or studies.
2. Develop an approach to inform and engage the community (review existing experiences).
3. Coordinate efforts with those under way for mapping and conduct longitudinal studies to better understand ulcerative disease and its natural history.
4. Identify the causes of ulcers.
5. Consider studies to determine the involvement of flies in transmission.
6. Consider studies on non-human reservoirs.
GROUP 3: OPTIMAL DELIVERY AND PREFERRED PRACTICES

WHAT WE KNOW

1. A single dose of azithromycin is as effective as the current standard
2. Up to 30% of children reported gastrointestinal events (using age-based dosing, on an empty stomach, as opposed to weight based-dosing not on an empty stomach)
3. Everyone (all ages) living in an area endemic for yaws requires azithromycin treatment at least once
4. Productivity varies between individuals distributing MDA
5. There must be training on MDA, coupled with a supply chain system
6. For infants and small children, a paediatric oral solution may be preferable over crushed tablets.

WHAT WE NEED TO KNOW

1. What should the dose be based on height and weight? Dosing schedule brackets with therapeutic range (20–40 mg/kg).
2. Coverage of the ‘de facto’ population (i.e. those who are present during the MDA, not only those who were present during the census taking).
3. What is the strict pyramidal hierarchy of authority/accountability to ensure consistency across individuals?

HOW DO WE FIND OUT?

1. Paper-based datasets and an algorithm
2. Conduct studies in parallel in several sites to test different approaches and obtain fast results
3. Monitoring travel in endemic villages; presence in the village and dedicate village volunteer (e.g. Yaws Intelligence Service).

WHAT NEEDS TO BE DONE

1. Build a treatment algorithm
2. Identify the best strategy to treat everyone at least once (e.g. MDA at time 0 and MDA at time 1 month, or mop up). Different demonstration sites running different approaches: 1 MDA with mop up; 2 MDAs; 1 MDA with active surveillance (targeted treatment/ICM, as for the pilot project in Ghana and Vanuatu).
GROUP 4: GLOBAL YAWS EFFORT – PARTNERSHIPS

WHAT WE KNOW

1. This is not the first time that yaws eradication has been attempted, but it must be the last.
2. There is potential to integrate yaws with the other PC-NTD control efforts, in particular trachoma
   a. Mass treatment is warranted, and therefore yaws should be classified as a PC-NTD, but yaws should still also be
      classified as an ICM-NTD
3. There is co-endemicity of yaws and chancroid, yaws and trachoma, and yaws and other NTDs
4. There must be a syndromic approach to treatment of ulcers.
   a. Yaws-like ulcers can be caused by organisms other than TPP (H. ducreyi, unknown organisms). The mapping
      efforts are a unique opportunity not only to identify patients with ulcers but also to provide some basic treatment
      such as dressings and wound cleaning.
   b. Treatment campaigns with azithromycin alone may not be enough; another drug may have to be co-administered
      to target the other organisms associated with yaws-like lesions.
5. A comprehensive strategy and plan is called for that includes:
   a. A roadmap
   b. A strategy
   c. A projection of the resources needed to ensure a sustainable effort to reach the target of eradication of yaws
      by 2020
      i. Human
      ii. Knowledge
      iii. Financial
      iv. Azithromycin
6. Political will and governmental buy-in
7. Advocacy and community mobilization
   a. Global advocacy
   b. Local advocacy
   c. Rotarian dermatologists
8. Communication and web-based information (knowledge management)
   a. Social media
   b. Continually updated maps of endemicity/cases/resource needs
   c. Online overview/repository of relevant documents and resources
9. Integration and coordination
   a. Integration into the health system, from the beginning
   b. WASH should be included in the strategy and the WASH community should be engaged
10. Operational research will be needed to guide and optimize the programme.
WHAT WE NEED TO KNOW

1. How best to structure the programme
2. How to handle requests for medicines
3. Can volunteers be mobilized (for community surveillance, 1.3 million Rotarians)
4. How to form a partnership with Pfizer
   a. What is needed to get a commitment?
   b. How do we start?
   c. Predicting demand via mapping
   d. Do we also get generic medicines?
5. How to advocate at different levels
6. Who are our allies for syndromic approach?
   a. Lymphatic filariasis, leprosy, Buruli ulcer, visceral leishmaniasis, morbidity management and disability prevention (MMDP) efforts
   b. Take cues form sexually-transmitted infections (chancroid, syphilis)

HOW DO WE FIND OUT?

1. Engage with, and use knowledge and experience from, other disease eradication programmes and/or NTD programmes.
2. Conduct operational research to demonstrate effective strategies.

WHAT NEEDS TO BE DONE

1. WHO classification of yaws as a both a PC-NTD and an ICM-NTD
2. Funding and commitment of interest from BMGF
3. Draft a roadmap
   a. High-level policy and advocacy document ‘YAWS 2020’ that outlines the goal, plan and needs to achieve 2020 goals (compare ’2020 INSight’ for trachoma)
   b. High-level technical document that reviews the evidence base and lessons learnt from Ghana, India and Vanuatu, from the 1950s to the present, and outlines a proposed strategy. This meeting report published in PLoS or Proceedings (open access) can serve as that document.
3. Estimate the amount of azithromycin that will be needed
   a. Clarify treatment strategy
   b. Forecast supply of drugs
4. Estimate all resources needed
   a. For the eradication of yaws by 2020
   b. For the pilot studies
5. Establish a knowledge management structure
   a. Programme manager guide
   b. Build a website for knowledge management and advocacy
6. Establish structures and coalitions
   a. Yaws Expert Committee, or YEC
   b. International Coalition for Yaws Eradication, or ICYE, uniting all partners (compare ICTC, or International Coalition for Trachoma Control, for trachoma) to advocate and coordinate
7. Draft an operational research agenda
8. Explore potential partnerships and opportunities for coordination and integration
   a. Demonstration/collaborative improvement
   b. Build in WASH
   c. Health education.
## ANNEX 4B. WHAT NEEDS TO BE DONE

<table>
<thead>
<tr>
<th>Epidemiology and mapping</th>
<th>Interventions diagnosis, treatment and syndromic management</th>
<th>Optimal delivery and preferred practices</th>
<th>Global yaws effort – partnerships</th>
<th>Lead partner</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO reinstate yaws as a notifiable disease</td>
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<td>Research question</td>
<td>Epidemiology and mapping</td>
<td>Interventions, diagnostics, treatment</td>
<td>Syndromic management</td>
<td>Optimal delivery and preferred practices</td>
<td>Knowledge management</td>
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<td>Are seropositive cases without skin lesions infectious?</td>
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<td>Can azithromycin treatment alone eliminate latent or subclinical infection?</td>
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<td>Estimate the amount of azithromycin that will be needed (range)</td>
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<td>Work out supply of azithromycin</td>
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<td>Estimate all resources needed for the pilot studies</td>
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<tr>
<td>Draft operational research agenda</td>
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YAWS STRATEGY DEVELOPMENT

REPORT OF A MEETING, 27-28 OCTOBER 2014, ATLANTA, GA, USA