Towards zero leprosy

WHO Global Leprosy Strategy (GLS) 2021-2030

Lepra Review

We will beat leprosy together

1. Introduction

The World Health Organisation (WHO) recently launched the Global Leprosy Strategy (GLS) 2021-2030: Towards Zero leprosy. Lepra appreciated WHO's inclusion of NGOs, ILEP members and the wider leprosy community in consultations preceding the publication of the final version of the strategy.

As expressed in our earlier written feedback, we are happy to see that the GLS has substantially improved its content compared to previous versions and we recognise the value of a GLS 2021-2030 as a guiding document for leprosy control. Specifically, we are glad to see that a health system and early detection rationale has been incorporated throughout the GLS, and in particular active case finding.

However, we remain concerned over many points raised in previous consultations that have not been taken on board, such as target and process indicators that have been left open to interpretation rather than made SMART. Additionally, we feel that GPZL's agenda of promoting vaccines and PEP, which are still at the evidence generating stage, have greatly influenced this document. In this context, we would like to restate our reservations as they may affect our engagement with and support of WHO's Global Leprosy Strategy.

2. Reservations

2.1 Goal

Although we understand the attractiveness of "Zero leprosy" as a public relations tool, Lepra is uncomfortable with the terms ***"Elimination"*** and *"Zero Transmission"* on epidemiological and science grounds.

Given that leprosy cases can incubate for up to twenty years, the bacteria can survive outside the human body for 4-5 months and transmission and susceptibility are still not fully understood – the building blocks for *"Zero Transmission"* are at best still under development[1].

We feel, therefore, that this terminology is overambitious and does not serve us as professional health organisations. Moreover, the misuse and inevitable misinterpretation of "elimination" and "eradication" leads to operational challenges whereby many countries see attainment of public relations based targets as reason to close leprosy services and reduce capacity and priority.

We propose the term *"Leprosy Control"* instead. This more accurately describes our shared ambition to significantly reduce the number of cases with the knowledge and means available.

1. Global consultation of National Leprosy Programme managers, partners and affected persons on Global Leprosy Strategy 2021–2030. https://www.who.int/publications/i/item/9789290228226

2.2 Targets

As we have already mentioned in our feedback to the WHO survey on the 2030 targets for leprosy, the proposed targets generally lack supporting evidence, notably around baselines and process indicators, making progress hard to judge and the targets difficult to verify.

More specifically, for the following reasons we do not support the targets proposed as stated, for the following reasons:

- The target on autochthonous cases is highly confusing and very difficult to verify.

» It assumes countries can achieve "elimination" by having imported cases but not home-grown leprosy. Following this rationale, the USA, for example, will never achieve this target because they have continuing zoonotic transmission from armadillos.

» It also ignores the fact that non-autochthonous cases can be MB and so lead to autochthonous cases in following years in the host country.

» Thirdly this target assumes strong and reliable national health information systems with the ability to appropriately differentiate autochthonous and imported cases. In Bangladesh for example, many new cases come from the bordering area with India, where migration patterns are complex and even the most reliable national health information systems would struggle.

» Fourthly, as a civil society organisation, given all of the above we cannot see the logic of differentiating migrants and refugees from others, unless there is a well-defined medical and epidemiological need. If migrants and refugees suffering from leprosy are to be mentioned in potentially divisive targets and indicators, they should also be mentioning in the context of thereby deserving of extra services and specialised tailored care compared to the host population.

- The target of a 70% reduction in the new cases of leprosy appears based on the promotion and expectations of preventive chemotherapy roll-out that has been adopted heterogeneously across some countries, NGO's and other key stakeholders[2,3].

» The evidence shows that the effects of post exposure prophylaxis do not last permanently, therefore requiring successive implementation rounds, nor does it have a notable impact on infectious LL cases. This last aspect fundamentally undermines the targets proposed.

» In addition, the rationale is partly founded on the 'population at risk' concept that is still not well understood. For example, it is commonly understood that approximately 95% of a human population is effectively not at risk for leprosy for little understood immunological reasons.

» The target is also based on the assumption that resources (e.g. case finding activities) will be maintained or even expanded over time. We think this assumption does not take into consideration the reality of operational limitations in endemic countries, such as sustainability, quality, health workforce, finances and implementation barriers. Indeed, the lack of any demonstrable public health thinking makes judgement around these targets in general difficult.

» It is also uncertain how the significant and often unrecorded numbers found by the private sector will be added to the baseline estimations and how they will be adjusted for under-reporting. One study in India estimated that around 80% of private sector dermatologists see leprosy patients but, among them, only 29% report such cases[4]. In this context, we recommend engaging private dermatologists in all key countries to better recognise leprosy and that governments should make it a reportable disease at a national statistical level.

» The review of achievements section points to the reduction in new cases, but fails to recognise the

2.Leprosy post exposure prophylaxis with single-dose rifampicin: Nepalese dermatologist's dilemma (plos.org)
3.Leprosy post-exposure prophylaxis risks not adequately assessed - The Lancet Global Health
4. The dermlep study part 2: Results of a nation-wide survey of dermatologists' access to quality leprosy services at their clinics and hospitals in India https://www.idoj.in/article.asp?issn=2229-5178;year=2020;volume=11;issue=6;spage=895;epage=903;aulast=Rao

drop in technical capacity and active case finding that went alongside this. Thus currently putting baselines around new cases is seriously under question.

» The 90% reduction in Grade-2 disability can only make sense if sustained and quality Active Case Finding (ACF) plus early treatment is conducted in highly-endemic countries. However, field experience suggests not only that Grade-2 disability is significantly under-reported as authorities are asked to hit targets in reduction, but that ACF activities are also diminishing in quality terms. Evidence shows that a great number of new cases are missed every year[5,6]. In sum we find that Grade-2 disability rates are in inverse proportion to the investment in quality ACF activities and this needs to be factored into the target.

» Empirical evidence and transparency around the denominators of the targets proposed is lacking. Most recent baselines around new case finding are unreliable, making targets unrealistic, particularly in highly-endemic settings where active case detection activities have been barely implemented and where they have been implemented inconsistently. We do not recommend using 2020 baselines as they are compromised and suppressed by the low quality of active case finding activities in recent years, lack of reporting from the private sector and COVID-19 lockdowns[7]. We suggest regular validation/verification studies particularly in highly endemic countries, and to estimate indicators accordingly.

» The 2019 report suggests under-detection among women: 38.9% of all cases were found to be female whereas quality active case finding in India found this to be closer to 50% i.e. similar to the percentage of women in the general population. Women in many societies have poorer access to health services and in poorly executed active case finding are often further missed. A more useful indicator for successful capacity building of health services would be a percentage of women among new cases. Indeed, it is potentially a more helpful indicator of progress in leprosy control than the focus on autochthonous cases.

2.3 Key research areas

- We do not understand what has been the criteria to narrow down and prioritise the research priorities apparently previously raised by LRI and GPZL. We recommend further consultation on the prioritisation process with the wider leprosy community who are not members or have different priorities to these two organisations.
- We suggest adding treatment of drug resistance as one of the key areas of research.
- Apart from indicators on post-MDT disability development we suggest to add new, optimised post-MDT follow-up models of care.
- Standardised nerve function assessments and the training of practitioners to do them routinely is known to be a good predictor of disability. Further research in this area to set the standards may be helpful.

2.4 Progress and key indicators for strategic pillars

We highly appreciate the incorporation of a health system strengthening (HSS) and active case finding rationale into the progress indicators. This is a major improvement compared to previous versions. We understand that finding the right indicators may be an arduous task. However, we think the indicators are not yet sufficiently SMART[8], compromising comparability and momentum. We propose further consultation and continued work around the targets and mechanisms for reporting on them.

5. https://www.leprosy-information.org/resource/missing-millions-threat-elimination-leprosy
6. https://www.leprosy-information.org/resource/enhanced-active-case-finding-identifying-leprosy-cases- missed-recent-detection-campaigns
7. COVID-19 and leprosy new case detection in India. https://leprosyreview.org/article/92/1/20-21008
8. Specific. M Measurable. A Achievable. R Realistic. T Time-bound

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- **Pillar 1: Implement integrated, country-owned zero leprosy roadmaps in all endemic countries**

» Political commitment. Most countries can easily report they have established national partnerships without really improving the situation. We need to capture and define what this means as a means of effective engagement. With regards to the increasing share of the leprosy budget, we know that hypothecated leprosy budgets are likely to continue to decrease over the next few years. It is a good idea to measure political commitment around budgets, but it should be further defined.

» Zero leprosy roadmaps. National roadmaps need not align with GLS 2021-2030, especially as it implies adoption of the unproven and disputed effects of LPEP. Strong M & E systems and accountability need to be assured and captured in quality measures. Having roadmaps in place will not capture the real progress to targets. There is a need to clearly link roadmaps to agreed SMART indicators.

» Capacity building. This is a major issue and so needs to be more specific. For example, we recommend focusing on the detailed needs of those elements that need to be addressed, especially the training and logistical support of front line workers.

» Surveillance and data management. What does functioning mean? With regards to digital-case based data collection we agree this is a good indicator.

» AMR/ADR (resistance and adverse reactions) monitoring. We suggest including existing lab capacity for AMR testing across countries.

» Research. This should relate to the research priorities established. We suggest working around the existing organisations/academia/labs working on leprosy.

- **Pillar 2: Scale-up leprosy prevention alongside integrated active case detection**

» Contact tracing. This is good, indeed vital, but it needs to capture the quality around coverage targets. There needs to be a way to ensure and capture performance in the indicators.

» Active case finding. This relates to highly endemic countries only. Ideally, this indicator should be verified on annual baselines. The indicator needs further tweaking as it is still not capturing progress as it is. We think the direction is positive though.

» Number of women (females) found through active case finding, as an indicator of appropriate, quality active case finding and a benchmark for passive case reporting for men and women.

- **Pillar 3: Manage leprosy and its complications and prevent new disability**

» **Access to referral system**. Referral facilities available is too general and it is not adding value. Referral facilities should be specified to the service delivered/needed. An idea may be merging this indicator with *"management of reactions and disabilities"*.

» **Management of reactions and disabilities.** Too many complications are merged here, affecting the value of this indicator. Reactions, ulcers, neuropathic pain, eye-related problems, etc. are all different disabilities that are treated differently according to the patient´s needs. The reality however, is that these indicators have been misreported over the last decade because there are often no monitoring systems in place capable of registering complications. If WHO aims to capture bottom level results, work needs to be done to ensure statistical accuracy and reliability. We suggest going back to performance indicators, such as countries with monitoring systems to register and/or treat ulcers/ reactions/etc. and proportion of people registered with reactions treated with steroids. In addition, there is a need to consider all cases managed in the private sector.

2.5 Strategic pillars and key components

- In general, we agree on most key components under pillars 1-4. However, we feel that the document overlooks the operationalisation of such components. It is difficult to think that countries will achieve "elimination" (sic) by endorsing these pillars without assuring quality service implementation first. The whole strategy for zero leprosy seems to be based on the assumption that resources will be maintained or even increased over time. This is unrealistic without prioritising quality performance and ensuring accountability. More specifically, the COVID-19 situation has heavily affected the allocation of leprosy resources, making targets and roadmaps even more challenging.

- Pillar-1 recommends the implementation of country-owned zero leprosy roadmaps. It is also stated that country-led roadmap processes will be supported by both WHO and the Global Partnership for Zero Leprosy (GPZL). However, presumably GPZL and WHO do not necessarily align on everything regarding leprosy control. Furthermore, given the significant and serious questions that remain around LPEP and the role of GPZL in promoting it, is this a prudent approach? It is therefore uncertain how roadmaps would align and how countries would endorse what part of them. In addition, ILEP and other civil society input and support can be overlooked in this process, which is unwise, as they often bring a more bottom-up approach and are key players in health system strengthening.
- Under pillar-2, WHO still prioritises the scale-up of preventive chemotherapy through Leprosy post exposure prophylaxis (LPEP). However, the findings from the MALTALEP study with regards to the increase of MB leprosy cases after patients were given Single Dose Rifampicin (SDR) as prophylaxis, have been ignored, creating potential safety concerns. The shortcomings of this study were published elsewhere[9,10]. Further concerns come from the lack of evidence on the safety of administration of rifampicin in the context of LPEP[11].
- We are happy to see that Active Case Finding (ACF) is specifically recommended under pillar-2. It is however, mainly promoted under the umbrella of preventative chemotherapy through contact tracing. Whilst we recognise that continuing contact tracing is a good public health intervention, we strongly recommend that Active Case Finding is promoted independently and not merged with preventative chemotherapy, not least because the latter may pose severe risks. For instance, experiences from India show that new cases are systematically not being reported during the administration of single-dose rifampicin found through contact tracing activities. Therefore, it is important to have ACF recognised as a major area in itself for leprosy control, without merging with PEP.
- Conflating contact tracing with ACF is also misleading. The majority of cases of leprosy do not come from contacts, so the differentiation is essential if one wants to control leprosy. They are different processes using different methods and often different staff.
- Under pillar-2, we recommend excluding any speculative comment around possible vaccines that have not yet shown effectiveness or finished clinical trials. It may create confusion and possible frustration. Rather for interventions still in trials or associated with controversial evidence (LPEP) it would be prudent to consider key research areas to investigate them further.
- Likewise, we suggest that slit skin smear testing is strengthened as this does identify infectious patients, rather than speculating around diagnostic tests of infection.
- In pillars 1-3, WHO recommends integrated skin-NTD strategies where feasible. Although this may be true in many settings, leprosy work has also proven to be efficient when integrated with other diseases, such as tuberculosis. A flexible pragmatic approach from country to country seems prudent.
- Skin-NTDs are being promoted within the context of early case detection activities. Whilst we recognise this is an attractive approach, we need to ensure that leprosy does not lose out from

9. https://www.leprosy-information.org/resource/effectiveness-single-dose-rifampicin-after-bcg-vaccination- prevent-leprosy-close-contacts
10.https://www.leprosy-information.org/resource/single-dose-rifampicin-and-bcg-prevent-leprosy
11. Safety in administering medicines for neglected tropical diseases (who.int)

incorporation into Skin-NTDs, but the added value is well defined. For example, in a recent integrated active case study one District (Jharkhand) of Bihar State in India, led to only 11 new cases of leprosy in an area where dozens of new cases might have been expected.

- To bolster earlier case detection, under active case finding consider including an indicator on self-care / self-support groups contributing to the referral system. Community members can be a key component for recycling information on symptoms and appropriate health seeking behaviour.
- Although the diagnosis and management of leprosy reactions is one of the key components of pillar-3, we still feel the narrative around reactions is weak. We suggest the importance of providing reaction treatment to the people in-need be raised together with the assessment of nerve damage at diagnosis and during and after treatment.
- We also recommend adding neuropathic pain as a complication of leprosy under pillar-3.
- In pillar 3, it may be important to differentiate leprosy complications, rather than group them all together. For example, there is a lot of difference between pain, depression and an Erythema Nodosum Leprosum (ENL) reaction.
- Capacity is mentioned across pillars and more specifically, under major challenges. Nevertheless, it is not apparent how recognition of this challenge has been factored into our understanding of the true scale of the problem and the true numbers of new leprosy cases.
- Strategic pillar-4 uses the term "stigma." We prefer the term "prejudice" as the word stigma puts the emphasis on the feelings of the person as if it were their fault, as opposed to the source and cause of the problems which is the prejudice of others.

3. Conclusion

Lepra finds the final WHO Global Leprosy Strategy 2021-2030 to be a significant improvement upon what has gone before. We applaud the direction, especially the recognition of ACF in all pillars and within research proprieties, and the demonstrated willingness to consult with stakeholders in the drafting process.

We therefore believe that our feedback can help provide a good basis for active engagement with WHO's partners and stakeholders, and also aid eventual evaluation of the strategy.

Lepra 12 October 2021