





consequence and of no consequence. Those who fall under the “leprosy of consequence” (i.e. non-self-healing leprosy) need to be detected early. But while over-detection is easy to confirm, assessing potential under-detection is always a challenge. Generally, in the field it is difficult to label a case as “active” just based on a one-time examination. In the eighties Dr. Noordeen had the opportunity to follow up on a survey after 20 years and found 95% self-healing: Cases with one or few patches had developed into self-healed cases with and without residual evidence, but also into cases with disabilities. To set up a comprehensive longitudinal survey therefore is highly desirable, focusing on much more than merely on “diagnosis”.

He said that such a project (with a four year timeline seeming reasonable) could perfectly supplement the planned study on new case detection which is going to be carried out soon by the Government of India. Dr. Shah who was in a preparatory group meeting in Nainital said that the meeting report and the accompanying e-mail received from Gol support this judgement. Therefore it seems to be the right direction that NFSD wants to help develop better, evidence-based methodologies for assessing the leprosy situation and monitoring progress with the purpose to improve leprosy control, taking a very broad approach. The synergies between these two projects can be quite high, as the global NFSD initiative will need a strong institutional basis in the particular countries. For a big country like India this would probably mean the involvement of several local research organizations and their selection should be done in close consultation with the Gol, with a very likely overlap to the institutions involved in the Gol study project.

To make some progress in clarifying what is scientifically feasible Dr. Oskam (KIT, Amsterdam) reflected on her preliminary input regarding design and methodology, which she had put together in October and sent around in advance of the meeting. She acknowledged the contribution of Professor Cairns Smith (Aberdeen) to this draft outline. In the discussion it was noted that the study design will need to include defining the paths and methods of improvement in health services in general and early case finding in particular, directing the attention to parameters which indicate the case detection delay as well as the reasons for it. It was also noted that an appreciable number of surveys with total population screenings is nearly unachievable (to reach 98% of a population 7-8 visits per household were estimated to be necessary). As the rapid-village survey methodology may not be reliable enough and that other “lean” methodologies would need to work also in low-endemic areas, further deliberation is needed particularly on appropriate sampling methods, after consultation with statisticians.

With case detection delay being a special focus of the project the discussion emphasized on the relation of surrogate markers for possible under-detection. Mrs. Shah pointed to WHO’s informal consultation meeting on 17 September 2008, recommending disability grade 2 among new cases as a marker for under-detection to monitor progress, which over the coming years would lead to a globally standardized data set as a valuable reference point for various study efforts which could relate to this indicator. From his rich experience in the field of grade 2 disabilities not only in India but also in Sri Lanka Dr. Shah pointed to the fact that already this relatively simple marker offers a lot of practical challenges. For instance, though it ordinarily cannot be missed, in Sri Lanka the disability rate had fallen to almost 2



% just because charting of the disabilities had not been practiced by the health services. The rate went up to almost 8% after training of the health workers. Similarly, once a patient with grade 2 is operated, he may no longer remain in grade 2, thus complicating the survey where the record will show him as grade 2, whereas upon reevaluation after operation he will be in grade 1.

Grade 2 disability tends to be a crude indicator to monitor progress (time from infection to grade 2 disability varies between patients and may be as long as 5 to 10 years). As the goal is to develop valid measures of delay that are reliable and easy to use between different countries and over time, the relations to other possible markers should be interesting to be looked at. It would be important to show which markers in which combination are indicative of early detection. More refined analyses based on classification could include grade 1 disability as a possible marker, as well as social parameters determining the health seeking and treatment behavior. The discussion stressed the difference between patient related and health system related parameters, which could lead to research into the relative importance of these two major causes of diagnostic delay.

Dr. Lunau reminded to the fact that the current study effort is a global one and that preparatory activities regarding the envisaged first round of surveys in India should therefore not be restricted to reviewing India-related research results only. This in mind, it was discussed that questions to be answered next could include: "What is known about the current situation and about factors that may be helpful for our study?" (based on existing, also grey literature) and/or: "What trend did the disease burden follow in the past and how did it relate to the trend of various potential markers?" (based on existing data sets that have not yet been analyzed for this purpose). Considerations should also include potential markers such as serology.

Dr. Noordeen further suggested that Indian research institutions need to be identified as soon as possible, which will cover the particular geographical areas where the study will be carried out. He said Linda's draft could be discussed with them for their input and finalization.

#### Next Steps

In the iterative process of developing a study design (which at the moment is still in its infancy) Dr. Oskam will prepare a new draft and include further input from Prof. Smith as well as comments from Dr. Noordeen and Dr. Shah before the draft is presented to potential partners and collaborators.

Dr. Leisinger will keep contact to Dr. Joshi and Dr. Pannikar with regard to further collaboration in the research initiated by NFSD, envisaging a meeting with Dr. Joshi (in the context of the Gol survey planning meeting) in the 1st week of January 2009.

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