Executive summary

Health Council of the Netherlands. Population Screening Act: tuberculosis screening. The Hague: Health Council of the Netherlands, 2012; publication no. 2012/06.

In this advisory report the Health Council's Committee on Population Screening assesses a licence application for tuberculosis screening. In accordance with the Population Screening Act, a licence is required for population screening involving ionising radiation, which is used for the X-ray photographs in screening for tuberculosis. The Minister of Public Health, Welfare and Sport requested the Health Council for an advisory report on the application submitted by the Dutch Municipal Health Services' umbrella organisation, GGD Nederland, for an extension of the licence for tuberculosis screening, and on the transition from analogue to digital X-ray photography in tuberculosis screening. The Health Council's last advisory report on screening for tuberculosis was in 1999. Limited to the significance for tuberculosis screening, the Committee has checked the application, the Minister's request and developments since 1999 against the statutory criteria of the Population Screening Act, specifically scientific soundness, compliance with statutory rules on medical procedures, and the benefit and associated risks for the individuals to be screened.

Background to the application

Tuberculosis is rare in the general population of the Netherlands; the annual number of Dutch incident cases of tuberculosis is 5 to 7 per 100,000. Consequently, since 1999, only risk groups have been screened.

Tuberculosis is a transmissible disease caused by *Mycobacterium tuberculosis*. Therefore, the main aim of tuberculosis screening is to prevent the transmission of infections in the general population. This so-called third-party interest adds an extra dimension to the government's responsibility to protect the population against tuberculosis.

Implementation framework

Tuberculosis screening is carried out by the Municipal Health Services (GGDs). The umbrella organisation, GGD Nederland, applies for the licence on behalf of the individual GGDs. The Committee on Practical Tuberculosis Control (CPT) of the Tuberculosis Fund (KNCV) and the Centre for Infectious Disease Control (CIb) of the National Institute for Public Health and the Environment (RIVM) inspect and evaluate tuberculosis screening. The CPT regularly submits proposals for changes to tuberculosis screening, ensures quality assurance and regularly presents figures on the results of tuberculosis screening.

Scientific soundness

The Committee judges that the scientific soundness of tuberculosis screening for risk groups is satisfactory.

Determination of risk groups

In general two types of risk groups are identifiable for tuberculosis screening. Firstly, groups of people are screened who are at an increased risk owing to actual or possible contact with a tuberculosis patient. The source and contact investigation results in a high return of traced cases and helps prevent further transmission of tuberculosis.

Secondly, the risk of certain groups of people having tuberculosis is higher than average owing to their background. These groups are identified using the rule of thumb that tuberculosis in a risk group must occur ten times more often than in the general population; so the cut-off point for the Netherlands has been set at 50 per 100,000.

Tuberculosis screening appears to contribute to tuberculosis control in both groups. Moreover, the risk group policy in tuberculosis screening has international support.

Tests

X-ray photographs and the skin test (Mantoux) are the main screening tests. However, there is a high likelihood of false positive skin tests if a patient has previously been infected with tuberculosis or has been vaccinated. Most groups are therefore mainly tested using X-ray photography. The skin test continues to be the main screening test for children because radiation may have more and longer term consequences for children.

To prevent many false positives from being treated for tuberculosis, the X-ray photograph or skin test is generally followed up by bacteriological analysis. In some cases, e.g. children, it may be necessary not to wait for the results of this analysis and to start treatment immediately.

The GGDs are gradually switching from analogue to digital X-ray photography and the Minister requested advice on this issue specifically. The Committee is of the opinion that digital X-ray photography may offer advantages, provided strict protocols are drafted and enforced. However, the Committee takes the view that the transition from analogue to digital X-ray photography should be evaluated in accordance with a similar transition in population screening for breast cancer.

There have also been other developments since 1999 in the tests used in tuberculosis screening. For example, there are tests which focus on proteins which are supposedly specific to tuberculosis bacteria (Interferon gamma release assays or IGRA). The Committee is of the opinion that there is insufficient evidence to warrant introducing IGRA in tuberculosis screening.

Each strain of *Mycobacterium tuberculosis* has a unique DNA pattern on which the DNA fingerprinting technique focuses. It is used to identify clusters of *Mycobacterium tuberculosis*, to enable faster and more efficient control of tuberculosis outbreaks. The Committee is of the opinion that DNA fingerprinting contributes to identify clustering in contact investigation.

Internationally, there are already quite a few countries with an increasing occurrence of strains of *Mycobacterium tuberculosis* resistant to more than one drug. Multiresistant tuberculosis is increasing in the Netherlands but remains rare. The Committee sees no indications (in the short term) that resistance in the Netherlands will become a major issue in tuberculosis screening.

Compliance with statutory rules on medical procedures

The GGDs have a large amount of information material but it lacks coherence and some essential information is absent. The course of the consent procedure is

unclear. And it is unclear whether proper provisions for submitting complaints are available everywhere and how communication on this subject takes place with those concerned. The Committee therefore concludes that the provision of information, the consent procedure and the complaints procedure do not meet the requirements of the Population Screening Act.

Owing to the third-party interest, compulsory tuberculosis screening may be justified but always only after voluntary participation has been refused and possible alternatives have been considered. Even in the case of compulsory screening, the person screened has the right to complain. There is a lack of clarity about the way of dealing with voluntary participation versus compulsory tuberculosis screening and the right to complain about it.

Benefit and risk

The Committee concludes that the benefit outweighs the risk of tuberculosis screening, provided restricted access to screening is maintained. Screening does not affect the treatment of tuberculosis and the treatment's success. However, a screened person who is a member of a risk group benefits more than the average Dutch citizen from the prevention of outbreaks. The risk of a screened person invalidly receiving treatment for tuberculosis is small.

Special groups of immigrants, such as those from Surinam and European Union countries are not covered by the foreign nationals policy but would qualify for screening. Other immigrants who return for a long period to a country of origin with a high incidence of tuberculosis would qualify for active traveller’s advice. The Committee recommends investigating whether these groups could be offered voluntary screening.

The Committee supports the policy adopted for children: caution with regard to screening but – as the hazards of tuberculosis are much greater for children – prophylactic treatment if there are sufficient grounds for suspecting tuberculosis. Screening may also be indicated after vaccination against tuberculosis and the Committee therefore recommends checking whether tuberculosis screening after vaccination has taken place.

The positive predictive value of X-ray photography in respect of tuberculosis is low, and so the number of false positives and secondary findings is relatively high. The Committee sees this as a cause for concern, especially because the applicant is unable to provide data on secondary findings and the referrals to which they could lead.

Advisory report with conditions and recommendations

The Committee is of the opinion that tuberculosis screening fails to comply with various parts of the statutory criteria of the screening act. It therefore recommends the Minister to grant GGD Nederland a licence for tuberculosis screening for one year, after which it must meet the conditions set out in the advisory report. In addition to several others these conditions concern, changes to the protocols for (digital) X-ray photography, the registration and evaluation of the transition to digital X-ray photography and the way in which false positives and secondary findings are handled. Furthermore, there are conditions concerned with the content of the procedures for information, consent, complaints, and the implementation of compulsory screening.