NICE National Institute for Health and Care Excellence

2022 exceptional surveillance of tuberculosis (NICE guideline NG33)

Surveillance report

Published: 17 January 2022

www.nice.org.uk

Contents

Surveillance decision

We will update the NICE guideline on tuberculosis. The update will focus on improving adherence: case management including directly observed therapy and the use of video observed therapy (VOT).

Reasons for the decision

The NICE guideline currently recommends directly observed therapy (DOT) as part of enhanced case management, for those at high risk of poor adherence, but does not recommend VOT. New evidence indicates that VOT was a more effective approach to observation of tuberculosis treatment than DOT.

Exceptional surveillance review summary

Reason for the exceptional review

To examine the impact on the NICE guideline of a published NIHR funded study, Management and control of tuberculosis control in socially complex groups: a research programme including 3 randomised controlled trials (work package 5, pages 39 to 46 and work package 6, pages 48 to 50). The findings on VOT versus DOT are also published in the Lancet, Smartphone-enabled video-observed versus directly observed treatment for tuberculosis.

Methods

The exceptional surveillance process consisted of:

- Considering the development of the NICE guideline on tuberculosis.
- Considering the new evidence that triggered the exceptional review.
- Feedback from topic experts.

We decided that full updated literature searches were not needed because the information we had from the new evidence and topic experts was enough to establish whether an

update to the guideline was needed.

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Information considered in this exceptional surveillance review

How the guideline was developed

The NICE guideline does not currently recommend VOT as there was limited relevant evidence available at the time of development.

DOT versus VOT study methods

The study authors report that their research was the first randomised controlled trial comparing the level of treatment observation for DOT and asynchronous VOT (where video clips are recorded by patient and forwarded for later viewing by a healthcare professional).

The NIHR study (work package 5) was a multicentre, analyst-blinded, randomised controlled superiority trial comparing the efficacy of asynchronous VOT with clinic-, home- or community-based DOT in supporting adherence in patients with active tuberculosis (across 22 clinics in England).

DOT was delivered by following the recommendations in the NICE guideline, which involved treatment observation 3 to 5 times per week, with any remaining daily doses self-administered. For VOT, patients were trained to record and send videos of every dose ingested 7 days per week using a smartphone app (smartphones with data were provided to patients free of charge). The smartphone app automatically sends encrypted, time/date-stamped videos to a secure server via mobile or wifi network.

The primary outcome of the study was greater than or equal to 80% of scheduled observations successfully completed during the first 2 months following randomisation. The main secondary outcome also considered the scheduled observations successfully completed in the 2 months following randomisation and throughout treatment, but as a proportion of scheduled observations on a continuous scale rather than dichotomous as per the primary outcome. Primary analysis was by intention to treat.

The NIHR study also completed an economic comparison of costs of VOT versus DOT (work package 6). The analysis from the perspective of the NHS, included DOT observations costs per week at 2015 to 2016 prices. VOT costs included fixed costs of infrastructure set up (including smartphone, video storage and system licence) and nurse analysis of videos.

For further information on the study methods see the NIHR report and Lancet publications.

NIHR study results

The study randomly assigned 226 eligible patients to VOT (n=112) or DOT (n=114). A total of 131 (58%) patients had social risk factors (history of homelessness, drug use, imprisonment, alcohol or mental health problems), with no significant differences at baseline between the allocated groups.

For the primary outcome, greater than or equal to 80% scheduled observations successfully completed during the first 2 months following randomisation:

- for VOT this was achieved by 78 (70%) out of 112 patients,
- for DOT this was achieved by 35 (31%) out of 114 patients (partially adjusted odds ratio 5.48, 95% confidence interval 3.10 to 9.68; p<0.0001).

For the main secondary outcome, proportion of scheduled observations (on a continuous scale) successfully completed in the 2 months following randomisation and throughout treatment:

- VOT completed 5,091 (79%) of 6,474 scheduled observations, compared with 1,774 (45%) of 3,922 on DOT.
- The mean proportions of doses observed per patient were 78% (standard deviation [SD] 41%) for VOT and 36% (SD 31%) for DOT (adjusted mean difference in proportions 42%, 95% confidence interval 29 to 53; p<0·0001).

The authors also note that VOT not only supports professional treatment observation but can also be more convenient for patients than in-person DOT.

Economic study

The NIHR study provides cost estimates based on various scenarios, for example:

observation of a 6 month course of treatment with daily VOT cost £1,645 per patient (for a VOT service that covers 50 patients) compared to £5,700 for 5 observations per week for DOT. In a smaller VOT service which covers 25 patients VOT would cost £2,600 per patient.

The economic analysis from the NIHR study of VOT versus DOT identified VOT is cheaper than DOT if service capacity is not below a particular threshold, given the fixed costs of VOT. Although a threshold analysis was not provided, the available data indicates that a VOT service that covers 10 patients would have similar costs to a DOT service which provides 5 observations per week over 6 months (£5,500 for VOT versus £5,700 for DOT).

The report concludes that for settings with sufficient demand for tuberculosis treatment support, VOT is cheaper for the NHS than DOT and has superior outcomes, and therefore VOT dominates DOT.

Topic expert feedback

In this exceptional review we engaged with topic experts who were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty. We sent online questionnaires about the new evidence that is relevant to the guideline and received feedback from 6 topic experts comprising of 3 lead tuberculosis nurses, 2 consultant microbiologists and 1 health protection consultant. All 6 agreed that the recommendations about DOT in the section on improving adherence: case management including directly observed therapy should be updated based on the new evidence. Experts also acknowledged a general move to video consultations to help manage social distancing and appointment backlogs, thereby indicating that assessment of VOT was appropriate and timely.

Equalities

As noted by 1 topic expert, treatment completion in patients with complex social needs could be improved by offering VOT, which would help reduce inequality. It was also noted that some patients may be digitally excluded from VOT; for example, where they are not familiar with or have a physical or sensorial disability which excludes them from using smartphone technology.

Overall decision

The NICE guideline does not make recommendations on remote VOT as an alternative approach to DOT as there was insufficient good quality evidence at the time of guideline development.

This exceptional review considered smartphone-enabled video-observed versus directly observed treatment for tuberculosis, a UK based randomised control trial. The findings of the trial may support the use of VOT as it enabled higher levels of treatment observation for patients with tuberculosis throughout treatment, than DOT. An economic analysis attached to this trial indicated that the asynchronous VOT approach is also cheaper than DOT in circumstances where there is sufficient demand.

There is also potential for practical benefits, for professionals and patients, as the remote, asynchronous VOT approach allows for more flexibility, lower costs and is less inconvenient than DOT, for example having to attend therapy appointments.

Following consideration of the results from the trial and economic analysis, as well as topic expert feedback, the new evidence may have an impact on the guideline.

ISBN: 978-1-4731-4416-3