



TYM smartphone otoscope for imaging and videoing the external ear canal and eardrum

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is the TYM smartphone otoscope. It is used for the imaging and videoing of the external ear canal and eardrum.
- The **innovative aspects** are that it allows the user to capture images and videos of the external ear canal and eardrum. These can then be shared between healthcare professionals and stored in the patient's record.
- The intended **place in therapy** would be as a replacement for standard otoscopes in adults and children who need an ear examination. It would most likely be used in primary care.
- The **main points from the evidence** summarised in this briefing are from 1 validation study in Nepal including a total of 56 patients in an outpatient screening setting. This study found the TYM smartphone otoscope to be as effective as standard otoscopes in helping decide whether to refer the patient to an ear, nose and throat specialist.

- **Key uncertainties** around the evidence are that it is based on 1 small non-UK study including a population with high prevalence of ear disease. There may also be issues around data sharing and IT infrastructure that would need to be considered.
- The **cost** of the TYM smartphone otoscope is £107.50 per unit (excluding VAT), with an additional £0.06 in consumables per examination. The user can provide their own compatible Apple iOS smartphone or purchase a refurbished one for £141.70. The **resource impact** could be an increased cost to the NHS but this might be offset if the device provides quicker diagnoses and fewer referrals from primary to secondary care.

The technology

The TYM smartphone otoscope (Cupris) uses an iOS smartphone to let users capture images and videos of the external ear canal and eardrum. These can then be reviewed and shared securely with other healthcare professionals through the Cupris app.

The TYM smartphone otoscope package consists of 5 specula (4.25 mm), a proprietary smartphone case and an otoscope attachment.

To use the device, the user places their smartphone in the case and slides the otoscope attachment over the lens of the phone camera. A speculum is then screwed onto the attachment until locked into place. Images and videos are captured using the smartphone's camera linked to the Cupris app.

The Cupris app can be downloaded from the [Cupris website](#). The images and video captured using the device are stored on a secure and encrypted cloud system and can be viewed on the iPhone, Mac or Windows PC computer.

The TYM smartphone otoscope can only be used with compatible Apple iOS devices. Compatibility for Android smartphones is planned by mid-2018.

Innovations

The TYM smartphone otoscope differs from standard otoscopes by allowing images and videos to be captured and stored in the patient's record, and by allowing these images and videos to be shared securely between healthcare professionals. It also differs from most otoscopes in that it does not need any additional equipment.

Current NHS pathway or current care pathway

Standard, non-digital otoscopes are usually for people presenting to primary care services with difficulty in hearing or other ear-related symptoms. Information from the otoscopy is used to inform decisions about care. The GP may refer the patient to an ear, nose and throat (ENT) consultant or audiologist if appropriate. Referrals usually provide only a written description of the signs and symptoms. The patient must then wait for the ENT or audiology appointment, and it is usually necessary for them to travel to the appointment.

Audiologists and ENT consultants also routinely use digital video otoscopes in secondary care. ENT specialists also do microscope otoscopy.

The NICE guideline on [otitis media with effusion in under 12s](#) suggests that assessment should include a clinical examination focusing on otoscopy, upper respiratory health and general developmental status. British Academy of Audiology [guidelines for the direct referral of adults with hearing difficulty to audiology services](#) state that a full medical history and a full ear examination must be done before any referral to an audiologist.

Population, setting and intended user

The TYM smartphone otoscope would most likely be used by GP or other health professionals in primary care (instead of standard otoscopes), or by ENT specialists in secondary care (instead of digital otoscopes). It would be used in people of all ages who need an ear examination. The company states that no additional training is needed for staff already familiar with standard otoscopy.

Costs

Technology costs

The device costs £107.50 per unit (excluding VAT), not including a compatible iOS smartphone. A smartphone is needed to use the device. One speculum must be used per patient at a cost of £0.06 each. The Cupris app is free to download.

Table 1 Cost of the TYM smartphone otoscope (excluding VAT)

Description	Cost	Additional information
TYM smartphone otoscope package	£107.50	This includes 5 specula, the otoscope attachment, a phone case and an instruction manual
4.25 mm speculum (disposable)	£0.06	One used per patient; based on £49.79 for 850
Refurbished iPhone 5 with 12-month warranty	£141.70	Distributed by Cupris

Costs of standard care

A standard, non-digital otoscope with handle and charger costs £53.81. A digital video otoscope costs £333.57 ([NHS Supply Chain](#)). One speculum must be used per patient at a cost of £0.06 each.

Resource consequences

Introducing the TYM smartphone otoscope would increase costs, but this may be offset if its use resulted in fewer unnecessary referrals to secondary care. The costs may be further offset if the device enables image and video capture by non-specialist clinicians.

Implementing the device may need some changes to infrastructure because of the use of the Cupris app, the need for Wi-Fi and charging points for the smartphones.

This device is currently used in 27 NHS organisations.

Regulatory information

The TYM smartphone otoscope was CE marked as a class I. The CE mark applies to the otoscope only and not the associated Cupris app.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Ear infections are more likely in young children, or in people with learning difficulties or autism or Down's syndrome. Age and disability are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises 1 cross-sectional validation study that included 56 patients.

Table 2 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The only publically available evidence is a study done at a surgical hospital in a remote region of Nepal, which screened people attending a rural outpatient clinic for ear disease. Being a screening study, patients were recruited regardless of otological history. Because of this, and the study setting, it has limited generalisability to UK care pathways in which assessment and diagnosis is done in primary care.

Evidence is being generated to assess the resource impact of using the device in the NHS in ear, nose and throat (ENT) clinics, care homes, GP clinics and audiology home visits, with results expected by the end of 2018.

Table 2 Summary of selected studies

<u>Mandavia et al. (2017)</u>	
Study size, design and location	56 patients (12 children and 44 adults). Within-subject cross-sectional validation study, screening for ear disease in a surgical outpatient clinic in Nepal.
Intervention and comparator(s)	Intervention: TYM smartphone otoscope. Comparator: assessment with standard otoscope by 1 UK-trained ENT consultant.
Key outcomes	The overall prevalence of ear disease of any type was 35%. Concordance in primary diagnosis (TYM versus standard assessment) was 95%. TYM had sensitivity, specificity, and positive and negative predictive values for diagnosing any ear disease of 0.94, 0.96, 0.91 and 0.97 respectively. Concordance in decision to refer for ENT consultation treatment (TYM versus standard assessment) was 100%.
Strengths and limitations	Patients were assessed by a UK-trained clinician, but the sample was non-UK patients with a high prevalence of ear disease. Four patients were excluded because the TYM smartphone otoscope images were inadequate.

Recent and ongoing studies

A pilot study of the TYM smartphone otoscope was done in 1 NHS trust between April 2016 and November 2016, including 275 patients in the ENT clinic, care home, GP clinic and audiology home visit settings. Peer-reviewed publication is planned for 2018.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Three of the 4 specialist commentators were familiar with this technology and 2 stated they had used it before.

Level of innovation

All 4 specialist commentators thought that the TYM smartphone otoscope was innovative, mainly because the otoscopy can be done using a smartphone instead of having to use a dedicated piece of equipment. None of the commentators thought that the device had yet been superseded or replaced, but all stated they were aware of other competing technologies with a similar function.

Potential patient impact

All commentators thought that using the TYM smartphone otoscope could provide patient benefits, specifically: better care decisions, GPs being able to make faster referrals to ear, nose and throat (ENT) specialists, and an increase in informed decision-making by patients (because they would be able to see the images themselves). The specialists disagreed as to whether the quality of the images when viewed remotely would be as good as seeing them in person. Two also noted that the device may provide an opportunity for remote ENT consultations in the community. One specialist commentator stated that the images could be stored in patients' medical records, which may be more robust documentation than descriptions written by clinicians. They also thought that this would be useful for monitoring symptoms over time.

Three commentators thought that the TYM smartphone otoscope may be particularly useful for people with chronic ear conditions, children, people with learning difficulties, and people who struggle or are unable to attend outpatient appointments.

Potential system impact

Opinion was split on the device's potential effect on the care pathway. Two commentators

felt that changes to the pathway were likely if nurses and healthcare assistants could do ear examinations and have expert opinion delivered remotely. However, the other 2 specialists felt that change was unlikely because ENT consultants generally prefer direct clinical observation; that it may be difficult to assess the extent of middle ear problems without the use of sophisticated equipment in the ENT clinic, or having access to detailed patient history. One specialist commentator thought that using the device could lead to an increase in referrals related to unclear images, which might not be offset by the number of referrals prevented through using the device. Another noted that audiology assistants routinely do standard otoscopies in secondary care.

All 4 specialists agreed that adopting the TYM smartphone otoscope would cost more than standard care, especially if compatible smartphones need to be purchased. Other factors may be subscription costs for the platform (if there were an inter-professional use fee) or if a data contract is needed (some NHS sites do not always have access to Wi-Fi). None of the specialist commentators thought that using the device would lead to a large resource impact in terms of staffing. However, staff training in its use and an update to information governance protocols would be needed to ensure that data transmission was encrypted and confidential.

None of the commentators was aware of any safety concerns or regulatory issues surrounding the device.

General comments

Three specialists thought that the TYM smartphone otoscope would most likely be used in addition to standard care, whereas 1 thought it could replace it. One also had concerns that the specula may not be compatible with those available on NHS supplies, and noted that maintaining charge on a smartphone is more complex than replacing batteries or using chargers for otoscopes. The commentators thought that more research was needed, with 1 suggesting an audit specifically evaluating changes in the level of inappropriate specialist referrals from trusts currently using the device.

Specialist commentators

The following clinicians contributed to this briefing:

- Tim Husband, head of service for audiology, Novus Health. No relevant conflicts of interest.
- Dr Keith Grimes, GP. No relevant conflicts of interest.
- Prof Douglas Hartley, associate professor in Otolaryngology and ear, nose and throat (ENT) consultant, Nottingham University and Nottingham University Hospitals NHS Trust. No relevant conflicts of interest.
- Matthew Hopkins, senior audiologist, Aneurin Bevan Health Board. No relevant conflicts of interest.

Development of this briefing

This briefing was developed for NICE by Cedar. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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