NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation document

Thopaz+ portable digital system for managing chest drains

The National Institute for Health and Care Excellence (NICE) is producing guidance on using Thopaz+ in the NHS in England. The medical technologies advisory committee has considered the evidence submitted and the views of expert advisers.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the draft recommendations made by the committee. NICE invites comments from the public. This document should be read along with the committee papers.

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical effectiveness and resource savings reasonable interpretations of the evidence?
- Are the provisional recommendations sound, and a suitable basis for guidance to the NHS?
- Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?

Note that this document is not NICE's final guidance on Thopaz+. The recommendations in section 1 may change after consultation. After consultation the committee will meet again to consider the evidence, this document and comments from public consultation. After considering these comments, the committee will prepare its final recommendations which will be the basis for NICE's guidance on the use of the technology in the NHS in England.

For further details, see the medical technologies evaluation programme process guide and medical technologies evaluation programme methods guide.

Key dates:

- Closing time and date for comments: 17:00 13 November 2017
- Second medical technologies advisory committee meeting: 8 December 2017

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

1 Draft recommendations

1.1 The case for adopting Thopaz+ for managing chest drains is supported by the evidence. Thopaz+ can reduce drainage time and length of stay in hospital, and improves safety for people with chest drains. Its use may also improve clinical decision-making through continuous, objective monitoring of air leaks and fluid loss.

1.2 Thopaz+ should be considered for people who need chest drainage after pulmonary resection or because of a pneumothorax. The system can increase patient mobility because it is portable. Staff find it more convenient and easier to use than standard wall suction.

1.3 Cost modelling indicates that Thopaz+ is cost saving compared with standard wall suction in people who need chest drainage after pulmonary resection. The estimated saving is £111.33 per patient over their stay in hospital. These savings are mainly achieved through reduced length of stay in hospital.

2 The technology

Description of the technology

2.1 Thopaz+ (Medela UK) is a portable digital chest drain system that provides regulated negative pressure close to the patient's chest

and continuously monitors and records air leak and fluid drainage. The system comprises an in-built, regulated suction pump with digital display, rechargeable battery, tubing that connects to any standard chest drain catheter and a Thopaz+ disposable fluid collection canister. Sensors in the system turn the pump on and off to ensure the pressure level set by the healthcare professional is precisely maintained.

2.2 The rental cost of Thopaz+ stated in the company's submission is £115 per month. It can also be purchased for £3,400.

2.3 The claimed benefits of Thopaz+ in the case for adoption presented by the company are:

- reduced chest tube duration
- reduced length of hospital stay
- reduced rates of patient complications
- higher patient satisfaction
- reduced hospital costs
- increased convenience for doctors and nursing staff
- improved chest drain management
- better prediction of patient outcomes
- reduced plastic consumable waste.

Current management

2.4 Chest drains are regularly used for a number of clinical indications to allow drainage of air and fluid from the pleural cavity and to allow re-inflation of the lung. The NICE guideline on major trauma recommends chest drains for managing chest trauma in pre-hospital and hospital settings, but chest drain management is not specifically covered by NICE guidance.

2.5 The British Thoracic Society guidelines on pleural disease state that chest drains should include a valve mechanism to prevent fluid or air entering the pleural cavity. This may be an underwater seal,

flutter valve or other recognised mechanism. Chest drains with underwater seals appear to be the standard of care in the NHS and consist of a water seal, suction control and drainage collection bottle. These drains collect fluid and prevent backflow into the pleural cavity, while at the same time allowing a subjective assessment of air leaks and fluid loss. The drainage bottle must be placed below chest level and kept upright. Suction may be needed depending on the patient's condition and can usually be provided using a wall suction unit.

3 Clinical evidence

Summary of clinical evidence

3.1 The evidence for Thopaz+ assessed by the external assessment centre (EAC) comprises 13 studies (n=1,632), including 9 comparative studies. Six of the studies were randomised controlled trials (n=826) although no blinding was possible because the devices used look very different. There was 1 non-comparative study in children (Costa et al. 2016) and the remaining studies were in adults. Only 1 study centre in 1 multicentre trial (Pompili et al. 2014) was in the UK: the 12 other studies were done in Europe, Asia and North America. For full details of the clinical evidence, see section 3 of the assessment report.

Main points from the EAC's analysis of the clinical evidence

3.2 The EAC considered that of the 6 randomised controlled trials:

- Pompili et al. (2014) was well designed and reported, and of excellent quality
- 4 were of good quality with clear protocols and results (Gilbert et al. 2015, Lijkendijk et al. 2015, Jablonski et al. 2013, Marjanski et al. 2013)

- Mier et al. (2010) was of lower quality with no clear hypothesis but had well matched comparative groups of patients.

The EAC also noted that 3 observational comparative studies (Pompili et al. 2011, Miller et al. 2016 and Shoji et al. 2016) were of high quality using propensity-matched control cohorts.

3.3 The EAC considered that all of the sites in the studies were likely to have different local protocols for inserting and removing chest drains, which may make the results more reflective of the likely variation in chest tube drainage protocols across the NHS.

3.4 All but 1 (Jablonski et al. 2013) of the comparative studies were on the use of Thopaz+ after pulmonary resection. All of the comparators were standard analogue drainage units using wall suction. The results showed that Thopaz+ was associated with shorter drainage times (7 of 8 studies) and a shorter length of stay (4 of 6 studies) compared with standard drainage.

3.5 Two studies including patients with pneumothorax (collapsed lung) were identified, 1 of which was comparative (n=60; Jablonski et al. 2013). Results from the comparative study showed that both drainage time and length of hospital stay are significantly shorter with Thopaz+.

3.6 Chest drains needed to be reinserted in 4 of the comparative trials. Rates of reinsertion were non-significantly lower for Thopaz+ than standard drainage.

3.7 The EAC found no published quantitative, comparative evidence for staff time spent on chest drainage when using Thopaz+ or for fluid loss measurement.

Summary of economic evidence

3.8 The company's economic submission was a simple decision tree with 1 decision node for the use of Thopaz+ or standard drainage

with wall suction, based on inputs from Pompili et al. (2011). The time horizon was the length of hospital stay. For full details of the economic evidence, see section 3 of the assessment report.

EAC's analysis of the economic evidence

3.9 The EAC agreed that the company's simple model structure was appropriate, but it made some changes to better reflect the evidence and current NHS practice. These changes comprised:

- adding costs for consumables and training associated with standard drainage
- using a length of hospital stay of 5.4 days for Thopaz+ (based on a weighted average from 6 studies) and 5.8 days for standard drainage (based on 3 studies)
- using a drainage time of 3.5 days for Thopaz+(based on 8 studies)
- adding the cost of chest drain reinsertion and complications (reinsertion prevalence was calculated as 0.017 from 9 studies)
- revising the consumer and training costs for Thopaz+.

For full details of these changes, see section 4.4 of the assessment report.

3.10 The company's base case resulted in a cost saving per patient of £66.07 for Thopaz+ compared with standard drainage over the length of hospital stay. After the EAC's changes this cost saving increased to £111.33 per patient.

3.11 The main driver of the cost savings for Thopaz+ is shorter length of hospital stay. The device remained cost saving throughout all realistic one-way sensitivity analyses.

4 Committee discussion

Clinical effectiveness

4.1 The committee noted that the evidence presented for Thopaz+ was mainly for its use in patients after pulmonary resection. The clinical experts confirmed that this reflected their experience in the NHS. The committee considered that Thopaz+ has clear clinical advantages compared with standard drainage using wall suction in patients after pulmonary resection, including a shorter drainage time and a shorter length of stay in hospital.

4.2 The committee recognised that the evidence to support the use of Thopaz+ for chest drains placed after a pneumothorax was relatively limited. Nonetheless, the studies available appeared to be consistent with the clinical benefits observed after pulmonary resection. One clinical expert noted that audit data from their NHS hospital had indicated that Thopaz+ showed similar clinical advantages in both patient populations. The committee therefore concluded that the clinical benefits of the technology are likely to be generalisable to patients with pneumothorax.

4.3 The committee considered the use of Thopaz+ in other patients who need chest drainage. None of the experts had experience of using the technology in children, but they did report the use of Thopaz+ in other patients needing chest drainage (such as after cardiac surgery and trauma). The clinical experts explained that if devices are available on wards they may be used safely for a broad range of patients who need chest drainage, but evidence to support clinical or system benefits in these circumstances is currently lacking.

4.4 The clinical experts stated that there are other potential benefits that may not be reflected in the published evidence. They described improved decision-making because Thopaz+ can

objectively measure the rate of air leakage and total fluid drainage. The clinical experts also advised that Thopaz+ is portable and easy to manage, allowing increased mobility which aids recovery and patient satisfaction. The committee concluded that there may be additional advantages for patients not captured in the published studies.

NHS and system impact considerations

4.5 The clinical experts explained that using Thopaz+ allows for treatment across wards to be standardised, because it provides objective measurements of air leakage and fluid loss. These data make it easier to assess and record patients' progress. This in turn may help clinicians determine when is best to remove the chest drain. One clinical expert explained how the use of Thopaz+ had helped them redesign the logging system for chest drain management.

4.6 The committee heard that managing chest drains with Thopaz+ is easier than with standard drainage and this has may release nurse time. Patients may need fewer chest X-rays with the use of Thopaz+.

4.7 The clinical experts explained that using Thopaz+ improves patient safety. The system has in-built alarms that warn users of potential problems such as a blocked tube, full canister or low battery. When visiting the X-ray department, people may be safely accompanied by non-nursing staff because of the alarm. If the device is accidentally switched off, it changes to a normal, single-way valve chest drain. The committee concluded that the safety features of the technology increase staff confidence in managing chest drains.

Cost savings

4.8 The committee noted that the estimated cost savings with Thopaz+ of £111.33 per patient in people after pulmonary resection was

largely attributable to a reduced length in hospital of up to 1.5 days (average 0.4 days) per patient compared with standard drainage. The committee considered the implications of this reduced length of stay and whether it was realisable in practice. The clinical experts explained that the continuous, objective monitoring possible with Thopaz+ helps reliable decision-making and encourages earlier chest drain removal and discharge. The committee noted that Thopaz+ remained cost saving even with a difference in length of stay of only 0.071 days.

4.9 The EAC explored device utilisation in a sensitivity analysis. In its base case, the company assumed 50% device utilisation. The committee heard from 2 clinical experts who use Thopaz+ that device utilisation in their own units was closer to 100%, and that once introduced it rapidly became the standard of care for patients with chest drains. The committee concluded, therefore, that the device utilisation in the company's base case was conservative.

4.10 The committee considered the different options through which Thopaz+ is available (that is, purchase or rental). It noted the EAC sensitivity analysis based on a £3,400 purchase price resulted in increased savings of £124.76 per patient. However, including the purchase of 5-year warranties reduced the cost savings by £2.13 per patient. The company stated that leasing arrangements are available and that volume purchasing discounts are available; for example, buying over 20 devices would reduce the individual purchase price to £2,700.

4.11 The committee also noted that given the potential additional savings in staff time that had not been captured either in the published evidence or cost model (such as through non-clinical staff escorting patients to X-ray), the estimated total savings were likely to be conservative. Furthermore, the model did not include

additional factors such as improved clinical decision-making based on objective data monitoring and reduced rates of complications.

4.12 The committee concluded that cost savings are also likely in people with pneumothorax. It noted that the company's base-case cost saving of £550.90 per patient was based on a single comparative study. This reported a larger difference in length of hospital stay between Thopaz+ and standard draining in people with pneumothorax compared with people after pulmonary resection (1.9 days compared with 0.4 days). The clinical experts clarified that shorter drainage times and lengths of stay were plausible in this patient group. The committee concluded that Thopaz+ is likely to be cost saving in people with pneumothorax, but that the evidence is more uncertain than in people after pulmonary resection.

4.13 The committee concluded that using Thopaz+ is likely to lead to significant clinical and system benefits compared with standard drainage using wall suction in people who need chest drainage after pulmonary resection or for pneumothorax.

Peter Groves
Chair, medical technologies advisory committee
October 2017

5 Committee members and NICE project team

Committee members

This topic was considered by the medical technology advisory committee which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal) and a technical adviser.

Paul Dimmock
Technical analyst

Bernice Dillon
Technical adviser

Jae Long
Project manager

ISBN: