NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

Assessment report overview

The Thopaz+ portable digital system for the management of chest drains

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the External Assessment Centre (EAC) report. It includes **brief** descriptions of the key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the Committee may wish to discuss. It should be read along with the company submission of evidence and with the EAC assessment report. The overview forms part of the information received by the Medical Technologies Advisory Committee when it develops its recommendations on the technology.

Key issues for consideration by the Committee are described in section 6, following the brief summaries of the clinical and cost evidence.

This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional bodies
- Appendix C: Comments from patient organisations
- Appendix D: Company claims and decision problem from scope

1 The technology

Thopaz+ (Medela UK) is a portable digital chest drain system that provides regulated negative pressure (at a level set by the managing healthcare professional) close to the patient's chest and continuously monitors the air leak and the fluid drainage. The digital display provides objective air leak and fluid loss data in real time as well as in historical graphs, to track therapy progress. The Thopaz+ system consists of an in-built, regulated suction pump with digital display, rechargeable battery, tubing to connect to any standard chest drain catheter and a Thopaz+ disposable fluid collection canister. Thopaz+ is compact and lightweight (223 x 255 x 95 mm and 1 kg) and has an early warning alarm to alert users if safety issues arise, such as a full canister, blocked tubing or a low battery.

The Thopaz+ system received a CE mark in 2014 as a class IIb medical device. The predecessor system, Thopaz, was first CE marked in 2008. Thopaz+ is identical to Thopaz but has a digital measure of fluid drainage. The system is intended to be used by suitably trained healthcare professionals in hospital operating theatres, intensive care and high dependency units as well as recovery wards.

2 Proposed use of the technology

2.1 Disease or condition

An injury to the chest wall or a hole in the lung can cause the pleural space between the wall of the chest cavity and the lung to fill with air, causing the lung to collapse. This can happen after thoracic surgery or after trauma to the chest cavity. Symptoms include a sharp, stabbing chest pain when breathing and a dry, hacking cough. Prognosis varies with cause but in most cases, once healed, there is no long-term effect on health. Treatment is via insertion of a chest drain for the drainage of air and fluid from the pleural cavity and to encourage re-inflation of the lung. Chest drains are kept in place until the lung has re-inflated, fluid drainage has reduced and air drainage stopped

2.2 Patient group

Thopaz+ is indicated for all people who receive a chest drain, such as those requiring thoracic drainage from the pleural and mediastinal cavities in circumstances including recovery after cardiac or thoracic surgery, pneumothorax, thorax injury, pleural effusion, pleural empyema or other related conditions. In England in 2014-15, there were 31,710 episodes of insertions of tube drains into the pleural cavity, 10,853 drainages of the pleural cavity and 6,633 episodes requiring attention to tube drains into the pleural cavity.

2.3 Current management

Insertion of chest drains is recommended in the NICE guideline for major trauma in the management of chest trauma in pre-hospital and hospital settings, but chest drain management is not covered by NICE guidance.

The British Thoracic Society (BTS) 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. Underwater seal chest drains 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 or may not be needed depending on the patient's condition, but can be provided with underwater seal drains usually using a wall suction unit.

2.4 Proposed management with new technology

After a chest drain is inserted (by a surgeon or physician) the drain is attached to the Thopaz+ drainage system, usually by a nurse. Air leak and fluid drainage is monitored using a readout on the digital display. All other aspects of the use of Thopaz+ are the same as standard care.

3 Company claimed benefits and the decision problem

The decision problem and claimed benefits are described in Appendix D.

The company submission was aligned to the scope decision problem however there were two partial variations:

- The cost model included the pulmonary resection population only
- The subgroup analysis omitted data from paediatric populations

The EAC attributed the latter variation to lack of available evidence.

4 The evidence

4.1 Summary of evidence of clinical benefit

The company assessed a total of 15 full text studies for eligibility and excluded 12 studies as they were conference abstracts with insufficient data. The company submission included 3 studies (Pompili et al. 2014, Tunnicliffe and Draper 2014, Rathinam et al. 2011). The EAC considered the company searches were not adequate and it undertook further searches which identified 13 studies, including 2 studies presented by the company. The EAC excluded the other study presented by the company (Rathinam et al. 2011) as out of scope. The studies are summarized in Table 1.

EAC critical appraisal of the clinical evidence

The EAC critically reviewed the evidence and concluded the evidence base for Thopaz+ was quite strong overall with 9 comparative studies, 6 of which were RCTs (see appendix C of the Assessment report). One RCT was of excellent quality with a well designed protocol and appropriate minimization of bias in terms of concealment of random allocation, sample size calculation and full reporting of results (Pompili et al. 2014). None of the trials could be

blinded because the comparator devices were obviously of physically different appearance. Three further RCTs were of good quality with clear protocols and results (Gilbert et al. 2015, Lijkendijk et al. 2015, Jablonski et al. 2013, and Marjanski et al. 2013). Mier et al. (2010) was a non-randomised trial of lower quality with no clear hypothesis but had well matched comparative groups of patients and clearly reported results. 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, which avoids some biases (see appendix C of the assessment report). Pompili et al. 2011 was of excellent methodological quality with well matched participant groups, patient selection and study design to minimize bias and clear reporting of results and withdrawals. None of the comparative studies was undertaken in the UK NHS setting but Pompili et al. (2014) had one of four centres based in the UK. The EAC noted that it is likely all of the sites in the studies used different local protocols for the insertion and removal of chest drains which may make the results more generalisable as they may reflect differences in chest tube drainage procedure protocols across different NHS hospital sites.

Eight out of the 9 comparative studies were on patients who underwent pulmonary resection and were treated postoperatively with Thopaz+. All of the comparative devices were conventional analogue drainage units using wall suction. The results show that most of these patients had a shorter duration of chest tube drainage compared with conventional analogue drainage (7/8 studies reporting this outcome: Gilbert et al. (2015), Lijkendijk et al. (2015), Pompili et al. (2014), Miller et al. (2016), Pompili et al. (2011), Shoji et al. (2016) and Mier et al. (2010)) and a shorter length of stay compared with conventional analogue drainage (4/6 studies reporting this outcome: Lijkendijk et al. (2015), Pompili et al. (2014), Miller et al. (2016) and Pompili et al. (2011)). Only one study reported a non-significant longer length of stay for Thopaz+ (Marjanksi et al. 2013). No studies reported a longer duration of chest tube drainage with Thopaz+.

Two studies on patients with pneumothorax were identified, one of which was comparative (Jablonski et al. 2013). This showed that both the duration of chest drainage and length of hospital stay are significantly shorter with Thopaz.

A single study compared patient satisfaction between Thopaz+ and traditional drainage in patients undergoing pulmonary resection (Pompili et al. 2014). This study showed that patients treated with Thopaz+ had an improved ability to arise from bed, improved perceived system convenience, felt more comfortable being discharged home with the device if needed and fewer felt they would want to change the system compared with those treated with a traditional drainage device.

The incidence of drain re-insertion was reported in 4 comparative papers and was non-significantly lower for Thopaz+ compared to traditional drainage in 3 studies (Gilbert et al. 2015; Marjanski et al. 2013; Shoji et al. 2016). No drain re-insertions were reported in Lijkendijk et al. 2015 in either arm. The EAC found no quantitative, comparative evidence for staff time spent on chest drainage when using Thopaz+ or for fluid loss measurement.

EAC conclusions on the clinical evidence

The EAC considered the clinical evidence presents an unbiased estimate of the technology's treatment effect and is relevant to the specified decision problem. However, it noted the evidence is mainly in patients treated for postoperative use of Thopaz+ following pulmonary resection, making it difficult to draw conclusions on the effectiveness of Thopaz+ for pneumothorax. The company identified an ongoing UK based study looking at the use of Thopaz+ in pneumothorax (Randomised ambulatory management of primary pneumothorax (RAMPP) table 6 in the assessment report) and the EAC identified an unpublished completed study on manual aspiration versus a digital chest drainage system in spontaneous pneumothorax (table 7 in the assessment report). The results of these studies may provide more evidence on the use of Thopaz+ for the treatment of pneumothorax.

Additionally, the population identified in the scope was broad and the EAC found no evidence for Thopaz+ outside of postoperative use in patients undergoing pulmonary resection or for the treatment of pneumothorax. The EAC noted there was only one non-comparative study in a paediatric cohort (Costa Jr et al. 2016).

The EAC concluded that on the whole the quality of the evidence was strong with 6 randomised studies and 3 studies that used propensity-matched control cohorts.

Table 1 Clinical studies.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	Comments
Pulmonary resection (planned elective surgery, including lobectomy, segementectomy and wedge resection)						
Brunelli et al. (2013), Italy.	RCT comparing Thopaz+ in regulated suction mode and Thopaz+ in regulated seal mode	100 patients undergoing pulmonary lobectomy randomised (50 in each group)	Length of hospital stay, duration of chest tube drainage and complications.	No significant difference in the duration of chest tube placement or length of hospital stay between the two groups.	None.	One author is company consultant.
Gilbert et al. (2015), Canada	RCT comparing Thopaz+ and Pleur-Evac (analogue water sealed device); patients stratified according to presence or absence of air leak.	172 patients undergoing pulmonary resection Stratified: (Group 1, no air leak n=87; Group 2, air leak n=85) and then randomised (Group 1 Pleur-Evac n=43 and Thopaz+ n=44; Group 2 Pleur-Evac n=42 and Thopaz+ n=43).	Duration of drainage, length of hospital stay, number of chest tube reinsertions and complications.	No significant difference in length of stay, duration of chest tube drainage or postoperative complications in both air leak status groups. A non-significant number of chest tube reinsertions were required with Pleur-Evac (none for Thopaz+)	N=6 (post-operative ICU transfer n=4, returned to operating theatre n=2).	
Lijkendijk et al. (2015), Denmark.	RCT comparing Thopaz+ and Thora-Seal (Covidien),	105 patients having a lobectomy by thoracotomy or VATS were randomised	Chest drain duration, length of hospital stay and number of	No significant difference between the two groups for: optimal chest tube duration, actual chest tube	Four patients had their drainage system switched from Thopaz+. One	

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	Comments
	traditional drainage system.	(Thopaz+ n=55; Thora-Seal n=50). Thopaz+ set to -15 cm H_2O, whereas Thora-Seal used gravity pressure only.	chest tube reinsertions.	duration or length of hospital stay on an ITT or per protocol basis.	patient had a very long (35 day) length of stay due to a large necrotic tumour.	
Marjanski et al. (2013), Poland.	RCT comparing Thopaz+ to a Sherwood glass bottle with suction provided via a central wall suction system.	64 patients having a pulmonary lobectomy were randomised (32 in each group) Negative pressure set to -15 cm H_2O in each group for the first two days postoperatively, and then reduced to gravitational drainage.	Complication rates, number of chest tube reinsertions, drainage duration, and hospitalisation time after lobectomy.	Mean drainage and duration of hospital stay were not significantly different. Complication rates were significantly lower for Thopaz+. A non-significant number of chest drain re-insertions were required in the conventional group (none for Thopaz+).	None.	
Pompili et al. (2014). Multi-centre (Italy, UK, USA, China).	RCT comparing Thopaz+ and traditional “water seal” suction drainage.	325 patients having pulmonary lobectomy (n=320), segmentectomy (n=56) and bi-lobectomy (n=5) were randomised (Thopaz+ n=191; Traditional n=190). Both systems were set at -20 cm H_2O until the	Duration of chest tube placement, length of hospital stay and patient satisfaction survey.	Duration of chest drainage and postoperative hospital stay was significantly shorter for Thopaz+. The Thopaz+ group reported a significantly improved ability to arise from bed and perceived	A total of 6 patients did not receive their intervention (Thopaz+ n=2; Traditional n=4) due to ICU admission. 3 patients died	Three of the authors have financial relationship with Medela.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	Comments
		morning of post-operative day one. After this period, Thopaz+ was set to -8 cm H_2O during the day, and the traditional system had no suction.		improved system convenience. Fewer Thopaz+ patients would prefer to change with another system they observed. A mean difference of 2.6 days from air leak cessation to tube removal was observed and was similar in the two groups.	(Thopaz+ n=1; Traditional n=2). The final study number was 325 patients.	
Miller et al. (2016), USA.	Two-armed observational comparative study, using propensity matching analysis, comparing Thopaz+ with Oasis 3600 by Atrium analogue drainage system.	108 patients having VATS lung resection, (85% underwent lobectomy received chest drainage (Thopaz+ n=33; Oasis n=75). Patients were propensity matched and analysed (Digital n=20; Analogue n=40).	Duration of chest tube drainage, length of hospital stay, number of chest tube replacement procedures and complications.	The hospital stay and duration of chest tube drainage was significantly shorter for Thopaz+. Significantly fewer complications were observed for Thopaz+.	None.	Two of the authors declare financial relationship with Medela.
Pompili et al. (2011), Italy.	Observational comparative study, using propensity matching analysis, comparing Thopaz+	286 patients having a pulmonary lobectomy received chest drainage (Thopaz+ n=51; Traditional n=235). Thopaz+ patients were propensity matched with	Duration of chest tube drainage, length of hospital stay, complications	Mean duration of chest tube drainage and hospital stay were significantly shorter in the Thopaz+ group.	None.	One of the paper's authors has a consultant agreement with Medela.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	Comments
	with traditional suction drainage.	51 historical controls from a pool of 235 patients who received traditional drainage. Both systems were set to -15 cm H_2O during the night. During the day, Thopaz+ was set to -8 cm H_2O, and the traditional system had no suction.	and chest tube re-insertions.	No complications related to chest tube management were observed in either group. No chest drain reinsertions were required in either group.		
Shoji et al. (2016), Japan.	Prospective observational study with propensity score matched controls comparing Thopaz+ to an analogue chest drainage system, (ACS) using “water seal”.	233 patients having a pulmonary resection received chest drainage (Thopaz+ n= 112, ACS n=121). Thopaz+ patients were matched to historical ACS controls to give two groups of 86. Thopaz+ set to -13 cm H_2O in the presence of air leak, and reduced to -8 cm H_2O if there was no air leak present. All ACS set to -5 cm H_2O suction initially, and	Chest drain duration and complications.	Chest drain duration was significantly shorter in the Thopaz+ group than ACS group. There was no significant difference in patients requiring re-drainage.	Six Thopaz+ patients were switched over to ACS due to implausible air leak readings. None had an air leak. This was most likely an operator error in Thopaz+ setup.	The six DCS patients who were switched to ACS were not part of the propensity score matched cohort.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	Comments
		suction turned off if air leak not present.				
Mier et al. (2010), Spain.	Three-armed prospective, comparative case study comparing Thopaz+ to Digivent (digital chest drain system) and Pleur-Evac (analogue water-sealed device).	75 patients undergoing pulmonary resection for non-small cell lung cancer (Thopaz+ n=26; Digivent n=24; Pleur-Evac n=25).	Duration of chest tube therapy.	The mean number of days to chest tube withdrawal was significantly shorter with Thopaz+ than the comparators.	N=6 (2 from each group due to discharge home with a Heimlich valve).	Patients were not randomly allocated.
Linder et al. (2012), Germany.	Prospective, multicentre case series of patients undergoing postoperative chest tube management using Thopaz+.	80 patients undergoing pulmonary wedge resection, anatomic segmentectomy or lobectomy received chest tube therapy	Duration of chest tube therapy and post-operative hospital stay.	Length of chest tube therapy differed significantly across centres with an average of 4.9 days. Length of hospital stay did not differ significantly across centres with average of 7.7 days.	One patient excluded due to damage of the respective Thopaz+ log file.	Study funded by Medela. Four centres have different standard protocols for chest tube management.
Costa Jr et al. (2016), Brazil.	Prospective observational, non-comparative study of Thopaz+ in paediatric patients.	11 paediatric patients undergoing pulmonary resection.	Duration of drainage, length of hospital stay and complications.	The mean length of stay was 4.9 days, mean duration of drainage was 2.5 days and mean drainage	No withdrawals.	This study shows the use of Thopaz+ in a children.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	Comments
		Mean age 5.9y (SD ±3.3).		volume was 270.4 mL. Postoperative complications were observed in two patients.		
Pneumothorax (including primary, secondary and spontaneous pneumothorax)						
Jablonski et al. (2013), Poland.	RCT comparing Thopaz+ to a traditional suction (TS) drainage.	60 spontaneous pneumothorax with air leak patients randomized (Thopaz+ n=30, air leak monitored digitally; Group B TS system connected to wall port n = 30, air leak monitored subjectively by bubble observation in the water-seal column). Pressure set to -15 cm H_2O in each group	Duration of drainage and length of hospital stay.	The mean duration of drainage and length of stay was significantly shorter with Thopaz+	None.	All patients had air leaks assessed by Thopaz+ prior to randomisation.
Tunnicliffe and Draper (2014), UK.	Non-comparative observational case series (pilot study) on Thopaz+.	13 patients received chest drainage with Thopaz+. Four primary and nine secondary pneumothoraces.	Length of hospital stay, length of time device was used, complications and patient satisfaction of the device.	Median length of stay was 3.5 days and duration of chest tube drainage was 4 days. Patient satisfaction with Thopaz+ was high.	None.	One of the authors received payment from Medela.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	Comments
Company studies excluded by EAC.	**Design and intervention(s)**	**Participants**	**Outcomes**	**Results**	**Rationale for exclusion by the EAC**	**Comments**
Rathinam et al. (2011), UK.	End user assessment of Thopaz+ and feedback study from a single-armed retrospective case series.	120 undergoing elective bullectomy/pleurectomy, lung resection, or VATS lung biopsy or mastectomy patients received chest drainage	Patient feedback on the device.	Patients said Thopaz+ portable and light, which improved mobility and independence. They preferred the quietness and compactness compared to conventional drains and suction.	This study is out of scope as the focus is staff feedback on Thopaz+. There is patient feedback (in scope), but this is a single paragraph.	The patient feedback is narrative and the number of patients that the narrative summary is based on has not been noted.

4.2 Summary of economic evidence

The company submission did not identify any published economic studies. The EAC identified 2 studies: Southey et al. (2015) was excluded because it included patients discharged from hospital with their chest drains in situ. Pompili et al. (2011) was limited in detail but showed Thopaz+ to be cost-saving compared with conventional drainage, based on reduced hospital stay.

Company's cost analysis

The company model was a simple decision tree with one decision node for use of Thopaz+ or standard drainage with wall suction. The time horizon was the length of hospital stay. In this model it is assumed that the comparator cost of traditional drainage with wall suction is zero (consumables and training). Also it is assumed that staff time dedicated to drainage is equal between the interventions and that the only difference in outcomes between the interventions is length of stay. The company considers that these assumptions will result in a conservative estimate of cost savings for Thopaz+.

The model used inputs from the Pompili et al. (2014) study based on patients undergoing pulmonary resection only, which included centres from the UK, China, Italy and USA. The length of stay was 4.6 days for Thopaz+ and 4.9 days for the comparator based on the UK centre data. The duration of chest tube drainage was 3.6 days for Thopaz+ and 4.7 days for the comparator, based on the multicentre average.

EAC revisions to the model

The EAC agreed the company's simple model structure was appropriate. However, the EAC revised the clinical parameters by calculating a weighted average of the available data: The resulting length of stay was 5.4 days for Thopaz+ (based on 6 studies) and 5.8 days for the comparator (based on 3 studies). The duration of chest tube drainage for Thopaz+ was 3.5 days based

on 8 studies. The EAC also considered the incidence of chest drain reinsertion and calculated the prevalence as 0.017 from 9 studies.

The EAC revised the consumer costs and the training costs for Thopaz+. It also included costs for the comparator device and complications. Tables 10 and 11 in the assessment report detail the EAC revisions and additions to the model.

Results

The results from the company's base case show a total device cost per patient of £66.07 for Thopaz+ and zero cost for the comparator but overall the use of Thopaz+ results in a cost saving of £35.56 per patient due to the reduced length of stay. Further details are in table 3 of the assessment report. The company undertook a one-way deterministic sensitivity analysis varying the parameters in the model and identified the reduction in the length of stay as the key driver of the cost savings

The EAC results in table 3 show that Thopaz+ has a cost saving of £111.33 per patient compared with conventional wall suction devices over a time horizon of the length of hospital stay.

Table 3: EAC base-case results.

Cost category	EAC's base-case		
	Thopaz+	**Comparator**	**Difference***
Cost of technology per treatment/patient	£26.47	£0.00	-£26.47
Consumables per treatment/patient	£30.85	£35.45	£4.60
Complications (chest tube reinsertion)	£0	£3	£3
Training cost per patient	£5.29	£0.00	-£5.29
Total cost of device per patient	£62.61	£38.45	**+£24.16**
Cost of hospital stay	£1,829.20	£1,964.69	£135.49
Total cost per patient	£1891.81	£2003.14	**-£111.33**

The EAC carried out one-way sensitivity analysis and identified the main driver for cost savings as the reduced length of stay for patients with Thopaz+. Thopaz+ only became cost-incurring if the length of stay was set to 7.7 days,

based on the value reported in a non-comparative study by Linder et al. (2012). In this analysis, patients with Thopaz+ had a longer length of stay than those treated conventionally. This was observed in only one comparative study (Marjanski et al. 2013) and was not statistically significant. The EAC did not consider this to be clinically realistic and noted from a threshold analysis that Thopaz+ becomes cost saving where the reduction in length of stay is greater than 0.071 days or around 2 hours.

Parameter	Inputs		Results		Source of inputs
	Low	High	Low	High	
Length of stay (days): Thopaz	4.5	7.7	-£416.20	£667.77	Published studies
Length of stay (days): Conventional	5.5	6	-£9.71	-£179.08	Published studies
Device utilization	0.2	0.8	-£71.64	-£121.26	Base case ±30%.
Bed days cost (£)	302	423.7	-£96.52	-£145.32	NHS reference costs for thoracic procedures.

Subgroup and scenario analyses

The EAC explored the effect of purchasing, instead of renting a Thopaz+ device and the potential use in people with pneumothorax.

Buying a Thopaz+ device leads to greater cost savings (£124.76 per patient, £13.43 more than the base case) compared with rental, assuming a 5 year lifespan for the device and that the consumables and device maintenance costs remain the same.

The use of Thopaz+ in patients with pneumothorax leads to much greater potential cost savings of £550.90 per patient, because of the greater reduction in length of stay found in this group of patients (5.1 days for Thopaz+, 7 days for standard chest drainage). The EAC notes that modelling for pneumothorax is based on length of stay data from a single study (Jablonski et al. 2014).

5 Ongoing research

The company identified 5 ongoing clinical studies, 1 in pulmonology and 4 on the use of Thopaz+ in cardiothoracic surgery. The pulmonology trial is ongoing in the UK:

Randomised ambulatory management of primary pneumothorax (RAMPP), MRC funded, 286 patients, recruiting 17/6/15 to 31/12/17, to report by December 2018.

6 Issues for consideration by the Committee

Clinical evidence

- In the absence of UK-based studies is the observed reduction in length of hospital stay generalizable to the NHS
- There are 2 included studies on pneumothorax, only one of which is comparative. Does the limited evidence for people with a pneumothorax allow any definitive conclusions for this population?
- The EAC considered the evidence for including staff time savings, reduced rates of chest X-rays and reduced rates of complications for Thopaz+ was not sufficient to include in the clinical case or economic model.

Cost evidence

- Cost savings for purchase of the Thopaz+ device show a small increase for purchase over rental but there are uncertainties in whether these costs are realisable.
- Potential cost savings in the pneumothorax population are significant but based on less certain clinical evidence. Is the evidence strong enough to support a statement on possible savings for pneumothorax?

7 Authors

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NICE Medical Technologies Evaluation Programme

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Appendix A: Sources of evidence considered in the preparation of the overview

Details of assessment report:

- The Thopaz+ portable digital system for the management of chest drains, Evans J, Ray A, Morgan H et al. August 2017

Submissions from the following sponsors:

- Medela UK

Related NICE guidance

- Major trauma: assessment and initial management. NICE clinical guideline NG39 (February 2016) Available from https://www.nice.org.uk/guidance/ng39

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Appendix B: Comments from professional bodies

Expert advice was sought from experts who have been nominated or ratified by their Specialist Society, Royal College or Professional Body. The advice received is their individual opinion and does not represent the view of the society.

- Mr Kostas Papagiannopoulos, Consultant Thoracic Surgeon, Leeds NHS Foundation Trust, no conflicts of interest declared.
- Mrs Catherine Plowright, Consultant Nurse Critical Care, Medway NHS Foundation Trust, no conflicts of interest declared.
- Mrs Jenny Mitchell, Senior Advanced Nurse Practitioner, Oxford University Hospital NHS Trust, received teaching fees from Medela UK in September 2016.
- Dr Kamlesh Mohan, Respiratory Consultant, Liverpool Heart and Chest Hospital NHS Foundation Trust, no conflicts of interest declared.

Expert adviser comments

Comments on this technology were invited from clinical experts 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 use Thopaz+ with their patients. One commentator's team has had substantial experience with the system, with over 8,000 uses over 9 years.

Level of innovation

All commentators felt that Thopaz+ was an innovative device, because it provides regulated suction and accurate, digital measurement of a patient's air leak. This improves on traditional underwater seal systems, which provide unregulated suction which is subject to large variations and a patient's air leak can only be estimated via visual assessment of bubbles exiting the drainage tube. Digital measurement of air leak using Thopaz+ systems improves the

accuracy of clinical assessment and reduces interobserver variation. One commentator highlighted that is could also detect intrapleural pressures and fluid drainage. One commentator also highlighted the device's safety alarms that detect blockage or sudden changes to readings, which are not available in traditional systems. One commentator stated there was no other similar technology available at present.

Potential patient impact

Three commentators noted that the portable nature of Thopaz+ allows patients with chest drains to be fully mobile, compared with traditional wall suction systems where patients are restricted to the bed. Thopaz+ encourages early mobilisation, which benefits patients by promoting lung expansion, reducing the risk of deep vein thrombosis and offers greater dignity and wellbeing and may be associated with earlier discharge.

Two commentators advised that the accurate air leak data provided by Thopaz+ aids clinical assessment as to when to remove a chest drain. This can prevent uncertainty, allowing decision-making to be delegated to junior doctors and nurses, promoting the timely and safe removal of chest drains.

Two commentators highlighted that the alarm functions of Thopaz+ could improve patient safety, because they allow 24/7 monitoring of patients with chest drains. This was especially useful for wards with limited nursing resources, junior doctor cover after hours or for patients in single rooms.

Two commentators felt that the regulated pressure provided by Thopaz+ is a gentler and more accurate method of treating the pleural cavity, allowing faster lung healing. Thopaz+ prevents excessive pressure being applied to the lungs, minimising the risk of damage and applies only the correct negative pressure if extra pressure is required. One commentator stated that Thopaz+ allows suction to be stopped earlier.

Two commentators noted that Thopaz+ could reduce x-ray exposure to radiation on the ward, as it allows patients to be sent to radiology without a nurse escort, instead of using portable x-rays.

One commentator reported that Thopaz+ can help identify air leaks during endobronchial valve insertion in patients with persistent air leaks.

No commentators reported any safety concerns with Thopaz+.

Potential system impact

All commentators agreed that training is needed to use Thopaz+, but one noted that this would be no more onerous that that required to use underwater seal drains. Another commentator stated that Thopaz+ was simple to use and training could be delivered easily in in a few hours, and was provided free of charge by the company. Two commentators highlighted that Thopaz+ allows timely and safe removal of chest drains and mobilises patients sooner, potentially reducing the length of inpatient stay and freeing up beds.

Three commentators stated that Thopaz+ may allow patients to be discharged home with a chest drain in place, allowing monitoring at home, which may also reduce length of stay and hospital visits. Another commentator noted that it was possible to discharge patients home with other ambulatory chest drains, such as Rocket, Atrium and Pleurex, but they were aware of only 1 centre that discharged patients home with a Thopaz+ drain.

Two commentators noted that the ability of Thopaz+ to electronically record data will improve understanding of pleural management and allow for national standardised protocols for chest tube management, improving care across the NHS. One commentator stated that reducing uncertainty in chest drain management may reduce unnecessary imaging.

Three of 4 commentators agreed that Thopaz+ could lead to cost savings for the NHS. One commentator noted that the difference in price between underwater chest drains and Thopaz+ is only around £20, and as water seal

bottles need changing several times, there would be no difference in cost to the NHS.

General comments

Two commentators remarked that the ability to retrospectively review electronic clinical data using Thopaz+ was useful, without relying on medical records and could be used as a teaching or research tool.

One commentator noted that Thopaz+ provided better handling of patient fluids and improved infection control.

One commentator stated that Thopaz+ could have future benefits in wireless remote monitoring of chest drains, which could enhance care in primary or community settings.

Appendix C: Comments from patient organisations

Advice and information was sought from patient and carer organisations. Please see the patient expert statements included in the pack for full details.

Representatives from the following patient organisations contributed to this briefing:

- Pulmonary Fibrosis Trust
- Roy Castle Lung Cancer Foundation.
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The Pulmonary Fibrosis Trust noted that Thopaz+ provides a significant change to the way chest drainage is carried out, which may improve patients' quality of life by reducing hospital stay. The Trust identified patients with pulmonary fibrosis or other interstitial lung diseases as a subgroup who may particularly benefit from Thopaz+ when compared to current management. The Trust also consulted patients who have had chest drainage, who would recommend any technology that can shorten hospitalisation.

The Roy Castle Lung Cancer Foundation stated that if Thopaz+ could reduce chest drain time by a few days it could reduce post-operative length of stay, which is beneficial to patients. Colleagues who were specialists in thoracic surgery noted that Thopaz+ brings a more scientific basis to drain management, specifically drain removal, than the 'art form' it currently is.

Appendix D: decision problem from scope

Patient benefits:	• Reduced chest tube duration • Reduced length of hospital stay • Reduced rates of patient complications • Higher patient satisfaction
Healthcare system benefits:	• Reduced hospital costs • Increased convenience for doctors and nursing staff • Improved chest drain management • Better prediction of patient outcomes
Sustainability benefits:	• Less plastic consumable waste as 0.3L, 0.8L and 2.0L canisters available: the volume of disposed plastic can be tailored to the patient. Those with least fluid need can have the smallest canister, resulting in less disposable plastic and less risk of contamination and spray health issues.

	Scope issued by NICE
Population	People requiring a chest drain, including for example those needing thoracic drainage from the pleural and mediastinal cavities for pneumothorax, post-operatively after cardiac or thoracic surgery, following thoracic injury, pleural effusion, pleural empyema or other related conditions.
Intervention	Thopaz++
Comparator(s)	• Underwater seal chest drains • Chest drains using a flutter valve or any other recognised valve mechanism
Outcomes	The outcome measures to consider include: • duration of chest tube placement • incidence of drain re-insertion • fluid loss measurement • length of hospital stay • rates of complications and device-related adverse events • staff time • patient satisfaction (including measures of patient discomfort)
Cost analysis	The intervention and comparators for the cost analysis are described above. Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared.

	Sensitivity analysis will be undertaken to address uncertainties in the model parameters.	
Subgroups to be considered	Use in children. Specific indications: • pneumothorax (differentiating spontaneous and other air leaks) • post-operative use after cardiac or thoracic surgery • patients with pleural disease • thoracic trauma or injury	
Special considerations, including those related to equality	No equality issues were identified. People undergoing thoracic surgery as a result of a long-term condition may be classed as disabled under the Equality Act 2010.	
Special considerations, specifically related to equality issues	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No