

OxyMask for delivering oxygen therapy

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is OxyMask. It is used for delivering oxygen therapy.
- The **innovative aspect** is the novel design, which is intended to improve the efficiency and convenience of oxygen therapy.
- The **intended place in therapy** is uncertain because of the wide range of settings and clinical conditions in which oxygen therapy is prescribed. Specialist commentators suggested that it might be particularly suitable for people who need varying flow rates.
- The **main points from the evidence** summarised in this briefing are from 3 studies in the US and Canada. Based on small numbers of patients, they suggest that OxyMask is at least as effective at delivering oxygen as a non-rebreather mask or a venturi mask.
- **Key uncertainties** are that the evidence base is still developing and currently lacks quantity and quality. Further studies comparing oxygen use and patient experience of OxyMask with current masks in NHS oxygen therapy pathways would be particularly valuable. There are no published studies in children.
- The **price** of OxyMask is £2.40 per unit. Current oxygen masks range from £0.41 to £1.31 (both excluding VAT). Using OxyMask would be more expensive than current masks but this may be offset if less oxygen is needed to deliver the needed oxygen concentration.

The technology

OxyMask (Southmedic) is an open mask that uses an innovative pin and diffuser system to deliver oxygen therapy. The mushroom-shaped pin is designed to redirect and concentrate the oxygen flow while the diffuser directs the flow towards the nose and mouth. There are openings in the mask that allow room air to mix with the delivered oxygen when a person inhales. The company claims that, compared with standard masks, OxyMask results in a more consistent prescribed concentration of oxygen. The openings in the mask are also designed to minimise the risk of carbon dioxide rebreathing. The overall design of the mask is also intended to be more convenient and comfortable for patients, allowing communication and eating and drinking.

The OxyMask is designed to deliver a wider range of oxygen concentrations (from 24% to 90%) and flow rates (from 1 litre to more than 15 litres per minute [litres/min]) than standard masks. It is available in adult and child sizes.

Innovations

OxyMask has novel design features that are intended to improve the delivery of oxygen therapy and be more convenient for patients.

Current care pathway

Oxygen therapy is used to help people with a range of health conditions, such as severe long-term asthma, pulmonary hypertension and cystic fibrosis. It is most commonly used to treat chronic obstructive pulmonary disease.

Oxygen therapy is most commonly delivered through either nasal cannulae or a face mask connected to an oxygen cylinder or concentrator machine by a flow regulator. Nasal cannulae are usually preferred for delivering long-term oxygen therapy. Simple masks are not recommended for patients who need low-flow oxygen because of the risk of carbon dioxide rebreathing. Other masks that can also be used are a venturi mask and a non-rebreather (also known as reservoir) mask. A venturi mask is used when a fixed concentration of oxygen is needed. The non-rebreather mask is used mainly in emergency situations for acute respiratory conditions.

The following publication has been identified as relevant to this care pathway:

- NICE clinical knowledge summary on [breathlessness](#) (based on the [British Thoracic Guideline for oxygen use in adults in healthcare and emergency settings, 2017](#)).

Population, setting and intended user

The optimum place in treatment for using OxyMask is currently uncertain because of the wide range of people in whom oxygen therapy is prescribed and the range of care settings in which it is used. Specialist commentators have suggested that it might be particularly suitable for people who need varying flow rates to achieve target oxygen saturation.

It would be prescribed by healthcare professionals as part of an oxygen therapy pathway.

Costs

Technology costs

Each OxyMask costs £2.40 excluding VAT; bespoke pricing arrangements, including through NHS supply chain, are available; this is likely to reduce the unit cost.

Costs of standard care

Prices of current oxygen masks, including the simple mask, venturi, non-rebreather and rebreather masks, range from £0.41 to £1.31, excluding VAT (NHS supply chain). The paediatric masks are at the higher end of the range. The unit price is often reduced when masks are purchased in bulk.

Resource consequences

If OxyMask is being used continuously or as part of a per-hospital oxygen therapy device protocol then it should be replaced every 10 days. If it is only used occasionally then it should be replaced every 30 days or at the first sign of wear.

Using OxyMask would cost more than standard masks. The additional costs could be offset if it improved patient outcomes, reduced the amount of oxygen used or enabled better stock management. The Northern Ireland Ambulance Service recently did clinical studies using OxyMask. A summary of the studies' results reported that the annual delivery cost of using OxyMask was £126,321 compared with £132,900 for traditional oxygen masks. It concluded that there could be £32,895 in cost savings over 5 years.

OxyMask is currently being used by 1 ambulance service and 4 NHS trusts and is at various stages of service evaluation and implementation in these and other organisations.

Regulatory information

OxyMask is a CE marked class IIa medical device.

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).

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

There are 3 studies summarised in this briefing; other technical evidence was excluded because the studies used mannequins rather than people.

There is 1 retrospective before-and-after evaluation of safety and cost, 1 unblinded crossover trial and 1 pilot-randomised, single-blind crossover trial. All studies were done in the US or Canada.

The retrospective study does not report how many people's data were reviewed, but based on the reported number of oxygen masks it is estimated at more than 9,000. The other studies included 36 adults, 10 of which were healthy volunteers.

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence for the effectiveness of OxyMask for delivering oxygen therapy is limited in quality and quantity. None of the studies reported their methods and results in detail. The variety of outcomes reported across all studies make it difficult to draw conclusions from the evidence.

All of the studies were done in the US or Canada so the results may not be generalisable to the NHS. The protocols for delivering oxygen therapy may differ to those used in the NHS but the company have confirmed that the devices are the same and have the same flow restrictions and capabilities as those available in the UK.

Table 1 Summary of selected studies

<u>DeJulio et al. (2018)</u>	
Study size, design and location	A retrospective before-and-after evaluation of the safety and cost of oxygen therapy from data collected at a 395-bed acute care hospital in the US over a 2-year period.
Intervention and comparator(s)	Intervention: OxyMask. Comparator: traditional oxygen mask devices including simple oxygen masks, adult 3-in-1 oxygen masks, partial rebreathing masks, non-rebreathing masks, tracheostomy masks, nasal cannulae.
Key outcomes	There were fewer 'unusual occurrence' reports after the introduction of OxyMask (after: 0 versus before: 4).
Strengths and limitations	It is not reported how many people were included, but based on the reported number of oxygen masks used it is estimated to be over 9,000 (around 3,800 for traditional oxygen masks and around 5,500 for OxyMask). It is not defined what is meant by an 'unusual occurrence'. 2 clinical areas continued to use traditional oxygen delivery devices up to 5 months after the introduction of OxyMask. It is not reported how many patients this would have affected but it means that this is not a simple before-and-after study.
<u>Paul et al. (2009)</u>	
Study size, design and location	An unblinded crossover trial in 10 healthy adults in Canada.

Intervention and comparator(s)	Intervention: OxyMask. Comparator: venturi mask.
Key outcomes	The oxygen flow rate needed to maintain a high saturation was claimed to be significantly lower in OxyMask compared with the venturi mask (2.1 versus 12.2 litres/min) and the PiO_2 at the lip was claimed to be significantly higher (323 versus 257 mmHg).
Strengths and limitations	Only 10 adults were recruited into the study. The methods section gives details of how the OxyMask was delivered but there are no details for the venturi mask. This study is at high risk of reporting bias. The study received funding from the company that makes OxyMask. There is no p value reported to support the claims of significance.
<u>Beecroft and Hanly (2006)</u>	
Study size, design and location	A pilot-randomised, single-blind, crossover trial of 26 adults with chronic pulmonary disease who were using supplemental oxygen in Canada.
Intervention and comparator(s)	Intervention: original OxyMask (trialled by 13 adults) and modified OxyMask (trialled by 13 adults). Comparator: venturi mask (Hudson RCI).
Key outcomes	Oxygen flow rate was significantly lower when using OxyMask compared with the venturi mask (at low saturation 1.8 versus 5.2 litres/min; at high saturation 4.4 versus 10.8 litres/min; $p < 0.001$). Inspired PO_2 was significantly higher (at low saturation 217.3 versus 189.4 mmHg; at high saturation 323.5 versus 257.4 mmHg, $p < 0.001$) and expired PO_2 was significantly lower (at low saturation 162.6 versus 182.1; at high saturation 216.7 versus 245.5, $p < 0.001$). There was no significant difference in minute ventilation and expired PCO_2 . Ratings of mask comfort tended to be higher for OxyMask (6.7 versus 4.9) but the difference was not significant ($p = 0.09$).

Strengths and limitations	Only 13 adults trialled the modified OxyMask. This is a small sample size. The results reported for the original OxyMask are not relevant as that mask design is different to the current mask design and is no longer in use. The methods of randomisation are not reported so the study is at risk of selection bias. The authors hypothesise that OxyMask delivers oxygen more efficiently and more comfortably than the venturi mask but they do not state how these outcomes will be measured and assessed. Two authors of the paper have received financial support from the company that makes OxyMask: 1 to perform the study and the other to present data from the study at an international scientific meeting.
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Abbreviations: EtCO₂, end tidal carbon dioxide; FiO₂, fraction of inspired oxygen; NRBM, non-rebreather mask; PCO₂, partial pressure of carbon dioxide; PiO₂, partial pressure of inspired oxygen; PO₂, partial pressure of oxygen; VE, minute ventilation.

Recent and ongoing studies

No recent or ongoing studies were identified.

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.

Only 1 of the 3 specialists had used this technology before in their clinical practice.

Level of innovation

One specialist thought that OxyMask was an innovative technology. Two specialists thought that it was only a minor variation to current standard mask designs.

Potential patient impact

Two specialists thought that OxyMask would be more convenient because the mask would not need to be changed if the flow of oxygen needed to change.

One specialist said using OxyMask would improve comfort, which would lead to better compliance. They said other benefits would be that patients would be able to drink liquids and there would be less condensation and feelings of claustrophobia, and a reduced risk of carbon dioxide retention. One specialist did not think that there was evidence to support any benefit to patients.

Potential system impact

One specialist said OxyMask may lead to reductions in oxygen flow rates, which would lead to cost savings, but did not think that there was enough evidence to support this. One specialist said that a patient would be monitored in the same way as they are now but there would be a reduced need for multiple venturi masks as the oxygen could be titrated through the 1 OxyMask. Two specialists thought that using OxyMask would cost more than using current standard care masks.

General comments

One specialist noted that OxyMask is not widely used in the UK. Another specialist said at their hospital they trialled OxyMask on people who needed high-flow oxygen therapy (above 4 litres) and those being actively weaned off non-invasive ventilation. The results of the pilot were positive so the hospital is now using OxyMask in people who use high-flow oxygen.

One specialist said that more evidence was needed on actual inspired oxygen concentration at different inspiratory flow rates and different oxygen flow rates so that conclusions can be made about clinical effectiveness.

Specialist commentators

The following clinicians contributed to this briefing:

- Niall O'Keeffe, clinical lead cardiothoracic anaesthesia and intensive care, Manchester Royal Infirmary. Did not declare any interests.
- Pamela Sweeney, lead respiratory clinical nurse specialist, University Hospitals Birmingham NHS Trust. Did not declare any interests.
- Thida Win, consultant chest physician, East and North Hertfordshire NHS Trust. Did not declare any interests.

Additional reviewer:

- Paul Thomas, Association for Respiratory Technology and Physiology. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. 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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