

OHTAC Recommendation: Chronic Obstructive Pulmonary Disease (COPD)

Ontario Health Technology Advisory Committee

March 2012

Background

The Chronic Obstructive Pulmonary Disease Mega-Analysis series is made up of the following reports, which can be publicly accessed on the MAS website at: http://www.hqontario.ca/en/mas/mas_ohtas_mn.html.

- Chronic Obstructive Pulmonary Disease (COPD) Evidentiary Framework
- Influenza and Pneumococcal Vaccinations for Patients With Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Smoking Cessation for Patients With Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Community-Based Multidisciplinary Care for Patients With Stable Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Pulmonary Rehabilitation for Patients With Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Long-term Oxygen Therapy for Patients With Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Noninvasive Positive Pressure Ventilation for Acute Respiratory Failure Patients With Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Noninvasive Positive Pressure Ventilation for Chronic Respiratory Failure Patients With Stable Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Hospital-at-Home Programs for Patients With Acute Exacerbations of Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Home Telehealth for Patients With Chronic Obstructive Pulmonary Disease (COPD): An Evidence-Based Analysis
- Cost-Effectiveness of Interventions for Chronic Obstructive Pulmonary Disease Using an Ontario Policy Model
- Experiences of Living and Dying With COPD: A Systematic Review and Synthesis of the Qualitative Empirical Literature

The Toronto Health Economics and Technology Assessment (THETA) collaborative has produced an associated report on patient preference for mechanical ventilation. For more information, please visit the THETA website: <http://theta.utoronto.ca/static/contact>.

Conclusions

Influenza and Pneumococcal Vaccinations

Influenza Vaccine

- High quality evidence showed a significant reduction in episodes of influenza-related acute respiratory illnesses (ARIs) in the vaccinated group compared with the placebo group.
- Low quality evidence showed nonsignificant reductions in influenza-related ARI hospitalizations and the need for mechanical ventilation in the vaccinated group compared with the placebo group.
- Low quality evidence showed a significant increase in local adverse reactions, swelling, and itching in the vaccinated group compared with the placebo group; there was no significant difference, however, in the incidence of systemic reactions between the 2 groups.

Pneumococcal Vaccine

- High quality evidence showed a significant decrease in the incidence of pneumococcal pneumonia in the vaccinated group compared with the placebo group; there were no significant differences, however, in incidence of global pneumonia, episodes of global pneumonia, first episodes of community-acquired pneumonia (CAP), or time to first episode of CAP between the groups.
- Low quality evidence showed no significant differences in hospitalizations due to CAP or hospital length of stay between the vaccinated group and the placebo group.
- Low quality evidence showed no local or systemic reactions as a result of the vaccine, and the vaccine had no impact on mortality rates.

Smoking Cessation

- Moderate quality evidence showed a statistically significant increase in abstinence rates in the intensive counselling (≥ 90 minutes) group and the intensive counselling (≥ 90 minutes) and nicotine replacement therapy (NRT) group compared with the usual care group.
- Moderate quality evidence showed a statistically significant increase in abstinence rates in the NRT group and the antidepressant bupropion group compared with the placebo group.
- Low quality evidence showed no significant differences between the minimal counselling (< 90 minutes) plus antidepressant group and the minimal counselling plus NRT plus antidepressant group compared with the usual care group.
- Intensive counselling and intensive counselling plus NRT are dominant cost-effective strategies; that is, they are cheaper and more effective than usual care.
- NRT and bupropion are dominant cost-effective strategies; that is, they are cheaper and more effective than placebo.

Community-Based Multidisciplinary Care

- Moderate quality evidence showed that multidisciplinary care significantly improves the following health system outcomes compared with usual care: all-cause and chronic obstructive pulmonary disease (COPD)-specific hospital admissions, and COPD-specific emergency department visits.
- Low quality evidence showed that multidisciplinary care significantly improved health-related quality of life (HRQOL) compared with usual care.

- Very low quality evidence showed that multidisciplinary care significantly improved lung function at 1 year of follow-up compared with usual care.
- Low and very low quality evidence showed that multidisciplinary care led to a nonsignificant reduction in mortality and all-cause emergency department visits, respectively, compared with usual care.
- Multidisciplinary care is cost-effective at \$14,000 per quality adjusted life year (QALY) (range, \$0–\$51,000 per QALY) compared with usual care.

Pulmonary Rehabilitation

Stable COPD

- Moderate quality evidence showed that pulmonary rehabilitation, including at least 4 weeks of exercise training in persons with COPD, led to clinically and statistically significant improvements HRQOL as measured by Chronic Respiratory Questionnaire (CRQ) domains and the St. George's Respiratory Questionnaire (SGRQ) domains compared with usual care.
- Moderate quality evidence showed that pulmonary rehabilitation also led to a clinically and statistically significant improvement in functional exercise capacity compared with usual care.

Following Exacerbations

- Moderate quality evidence showed that pulmonary rehabilitation after acute exacerbation (within 1 month of hospital discharge) significantly reduced hospital readmissions and led to statistically and clinically significant improvements in HRQOL compared with usual care.
- Pulmonary rehabilitation within 1 month of hospital discharge is cost-effective at \$18,000 per QALY (range, \$0–\$40,000 per QALY) compared with usual care.

Maintenance Programs

- Low quality evidence showed no significant differences between pulmonary rehabilitation maintenance programs and usual care for HRQOL, hospital admissions, and length of stay in the hospital.
- Low quality evidence showed a statistically but not clinically significant effect of pulmonary maintenance programs on exercise capacity. A subgroup examining the higher quality study with a more intense maintenance program showed a statistically and marginally clinically significant improvement in exercise capacity in the pulmonary maintenance programs group compared with the usual care group.

Long-Term Oxygen Therapy

Severe Hypoxemia ($PaO_2 \leq 55$ mm Hg)

- Low quality evidence showed a borderline significant reduction in mortality in the long-term oxygen therapy (LTOT) group compared with the no-LTOT group.
- Very low quality evidence showed a significant improvement in forced expiratory volume in 1 second (FEV₁) in the LTOT group compared with the no-LTOT group.
- Low to very low quality evidence showed a significant improvement in HRQOL as measured by some domains of the SGRQ and the CRQ in the LTOT group compared with the no-LTOT group.
- Low quality evidence showed an increase in hospitalizations in the LTOT group compared with the no-LTOT group, but there was no difference in hospital length of stay between the 2 groups.
- LTOT for severe hypoxemia is cost-effective at \$39,000 per QALY compared with no LTOT.

Mild-to-Moderate Hypoxemia ($55 \text{ mm Hg} < PaO_2 \leq 74 \text{ mm Hg}$)

- Low quality evidence showed no difference in mortality in the LTOT group compared with the no-LTOT group at 3 and 7 years of follow-up.
- Very low quality evidence showed nonsignificant improvements in percent predicted FEV₁, endurance time, and dyspnea in the LTOT group compared with the no-LTOT group.

Noninvasive Positive Pressure Ventilation for Acute Respiratory Failure

Noninvasive Positive Pressure Ventilation Plus Usual Medical Care Versus Usual Medical Care for First-Line Treatment of Acute Respiratory Failure Due to Acute Exacerbations of COPD

- Moderate quality evidence showed that noninvasive positive pressure ventilation (NPPV) plus usual medical care (UMC) significantly reduced the need for endotracheal intubation, in-hospital mortality, and mean length of hospital stay compared with UMC.
- Low quality evidence showed a lower rate of complications in the NPPV plus UMC group compared with the UMC group.
- NPPV plus UMC is a dominant cost-effective strategy: that is, it is cheaper and more effective than UMC alone.

NPPV Versus Invasive Mechanical Ventilation for Treatment of Acute Respiratory Failure in Patients Who Have Failed UMC

- Because of inconsistent and low to very low quality evidence, there was insufficient evidence to draw conclusions on the comparison of NPPV versus invasive mechanical ventilation (IMV) for patients who have failed medical treatment.

NPPV for Weaning COPD Patients from IMV

- Moderate quality evidence showed that weaning COPD patients from IMV using NPPV results in significant reductions in mortality, nosocomial pneumonia, and weaning failure compared with weaning with IMV.
- Low quality evidence showed a nonsignificant reduction in mean length of stay and mean duration of mechanical ventilation in the NPPV group compared with the IMV group.
- NPPV for weaning COPD patients from IMV is a dominant cost-effective strategy: that is, it is cheaper and more effective than weaning using IMV.

NPPV for Treatment of Recurrent Acute Respiratory Failure in COPD Patients After Extubation from IMV

- Low quality evidence showed a nonsignificant reduction in rate of reintubation in the NPPV group compared with the UMC group; however, there was inadequate evidence to draw conclusions on the effectiveness of NPPV for the treatment of acute respiratory failure in COPD patients after extubation from IMV.

NPPV for Chronic Respiratory Failure

- Moderate quality evidence showed nonsignificant differences in mortality, lung function after 3 months, functional exercise capacity (6 Minute Walking Test [6MWT]) after 3 months, and hospitalizations between the NPPV and usual care groups.
- Low quality evidence showed clinically and statistically significant improvements in functional exercise capacity (6MWT) for the first 3 months of treatment and a beneficial impact on dyspnea in the NPPV group compared with the usual care group.

- There was insufficient evidence to draw conclusions about the impact of NPPV on HRQOL.

Hospital-at-Home Programs for Acute Exacerbations of COPD

- Low quality evidence showed no significant difference in hospital readmissions between the hospital-at-home and inpatient care groups, but days to hospital readmission were increased in the hospital-at-home group compared with the inpatient care group.
- Very low quality evidence showed no significant differences in mortality, HRQOL, or patient and caregiver satisfaction with care between the hospital-at-home and inpatient care groups.
- There was insufficient evidence to determine the impact of hospital-at-home compared with inpatient care on lung function and length of stay.

Home Telehealth for COPD

Home Telemonitoring

- Low quality evidence showed that time free of exacerbations and time to emergency department visits and hospitalizations were significantly improved in the home telemonitoring group compared with the usual care group. However, no significant differences were observed in terms of number of exacerbations and emergency department visits.
- Low to very low quality evidence showed conflicting results for HRQOL and hospitalizations, with some studies showing significant benefits in the home telemonitoring group compared with the usual care group, and other studies showing no significant differences between the 2 groups.
- Low quality evidence showed no significant differences in mortality and length of stay between the home telemonitoring and usual care groups.
- There is substantial clinical heterogeneity between the trials, and since home telemonitoring is largely dependent on local information technologies, infrastructure, and personnel, the generalizability of these findings may be low.

Telephone-Only Support

- Low quality evidence showed a significant reduction in emergency department visits and a significant improvement in HRQOL measured by the Chinese Self-Efficacy Scale for the telephone support group compared with the usual care group.
- Low quality evidence showed no significant differences in hospitalizations and hospital length of stay between the telephone support group and the usual care group.
- Due to concerns regarding the generalizability of these results, additional research is required.

Experiences of Living and Dying with COPD

- Many patients initially misunderstand terms such as *COPD*, *chronic obstructive pulmonary disease*, or *exacerbation*. Patients may not realize that COPD is incurable and fatal; some physicians themselves do not consider early COPD a fatal disease.
- Patients use many means—social, psychological, medical, organizational—to control what they can, and to cope with what they cannot. Economic hardship, comorbidities, language barriers or low health literacy can make coping more difficult.
- Increasing vulnerability and unpredictable setbacks make COPD patients dependent on others for practical assistance, but functional limitations, institutional living, or self-consciousness can isolate patients from social connections and from health care.
- Patients may not always attribute repeated exacerbations to advancing disease, instead seeing them as temporary setbacks caused by activities, environmental factors, faltering self-

management, or infection.

- The divergent meanings of palliative care and its goals in COPD lead to confusion about responsibility for such services.
- The flux of needs in COPD calls for service continuity and flexibility to allow health care providers, like patients, to respond to the unpredictable yet increasing demands of the disease over time.

Preferences for Ventilation Among COPD Patients

- A significant proportion of COPD patients were willing to forgo a potentially life-saving intervention, particularly when it was framed as an indefinite procedure.
- COPD patients who were willing to forgo either IMV or NPPV could not be reliably predicted by known covariates (such as age, quality of life).
- COPD patient preferences for ventilation were not stable, but varied depending on how the intervention was described. Many COPD patients also altered their preferences when asked to consider ventilation under different hypothetical health states.

Decision Determinants

A decision-making framework has been developed by the Ontario Health Technology Advisory Committee (OHTAC) that consists of 7 guiding principles for decision-making and a decision-making tool, called the Decision Determinants tool. When making a decision, OHTAC considers 4 explicit main criteria: overall clinical benefit, value for money, feasibility of adoption into health system, and consistency with expected societal and ethical values. For more information on the decision-making framework, please refer to the *Decision Determinants Guidance Document* (http://www.health.gov.on.ca/english/providers/program/mas/pub/guide_decision.pdf).

Based on the Decision Determinants criteria, OHTAC recommended the use of those technologies for which there was at least moderate quality evidence of effectiveness for either clinical/patient or health system outcomes. For those technologies for which there was only low or very low quality evidence, OHTAC decided that there was insufficient evidence to make recommendations at this time. However, for 1 technology (LTOT), OHTAC's consideration of the societal and ethical factors associated with the provision of oxygen outweighed the low quality of evidence and led to a positive recommendation.

OHTAC Recommendations

1. The Ontario Health Technology Advisory Committee (OHTAC) recommends that any provincial strategy on chronic obstructive pulmonary disease (COPD) address gaps in patient and public knowledge about this disease and its causes, management, and course. Effective interventions for improving lay understanding of COPD should be identified.*

*In implementing this recommendation, Health Quality Ontario should communicate regarding the inadequate public recognition of this disease with Public Health Ontario, which is working with Cancer Care Ontario on a blueprint for management of the burden of chronic disease in the province. The under-recognition of COPD extends to health professionals, and this should be communicated to relevant training bodies.

Recommendations Regarding Secondary Prevention

2. OHTAC recommends maximizing the use of pneumococcal and influenza vaccines in patients with COPD, ensuring that vaccination reflects the established guidelines and recommendations for immunization.

OHTAC recommends that any barriers to making the pneumococcal vaccine easily available through physician offices be removed, thereby making the pneumococcal vaccine more accessible to patients.

Other opportunities to optimize access to influenza and pneumococcal vaccines, including patients with acute exacerbations of COPD admitted to hospital, should be explored.

3. OHTAC strongly endorses evidence-based strategies aimed at encouraging smoking cessation in patients with COPD.

Intensive counselling (≥ 90 minutes) is the most effective and cost-effective strategy, and should continue to be encouraged.

OHTAC recommends that consideration be made to providing training programs to health care professionals involved in providing intensive counselling.

OHTAC recommends bupropion or nicotine replacement therapies for smoking cessation.

Recommendations Regarding Stable COPD

4. OHTAC recommends ongoing access to existing community-based multidisciplinary care for the management of moderate to severe stable COPD.
5. OHTAC recommends ongoing access to existing pulmonary rehabilitation for the management of moderate to severe COPD in stable patients.
6. OHTAC recommends that long-term oxygen therapy continue to be provided to COPD patients with severe resting hypoxemia (≤ 55 mmHg).
7. OHTAC does not recommend the use of noninvasive positive pressure ventilation (NPPV) for chronic respiratory failure in stable COPD patients due to its lack of clinical effectiveness.

Recommendations Regarding Acute Exacerbations of COPD

8. OHTAC recommends the use of pulmonary rehabilitation in patients following an acute exacerbation (within 1 month of hospital discharge).
9. OHTAC recommends the use of NPPV as an adjunct to usual medical care as a first-line treatment for patients with acute respiratory failure due to acute exacerbations of COPD who do not require immediate access to invasive mechanical ventilation (IMV). NPPV should be made widely available, with appropriate support systems and human resources for this indication.
10. OHTAC recommends the use of NPPV to wean COPD patients who have failed spontaneous breathing tests following IMV.
11. OHTAC recommends that patient preferences regarding mechanical ventilation be sought prior to acute respiratory decompensation, and should serve as a guide for the provision of this service.

Recommendations Regarding Palliative Care for COPD

12. In making palliative care services available, the fluctuating physical, psychosocial, spiritual, and information needs should be considered, without necessarily forgoing acute care or hope of improvement during and following severe exacerbations.

Recommendations Regarding Opportunities for Further Research

There was insufficient evidence for OHTAC to make recommendations on the following COPD treatment strategies:

- hospital-at-home for the treatment of acute exacerbations
 - pulmonary rehabilitation maintenance programs
 - home telemonitoring
 - telephone-only support
 - NPPV versus IMV for the treatment of acute respiratory failure in patients who have failed medical treatment
 - NPPV for recurrent respiratory failure (postextubation)
 - long-term oxygen therapy for mild-to-moderate hypoxemia
13. Due to substantial uncertainty arising from low/very low quality evidence of effectiveness and cost-effectiveness, but the potential for important health system and/or patient/clinical benefits, OHTAC recommends field evaluations for:
 - pulmonary rehabilitation maintenance programs
 - telemonitoring

As regards telemonitoring, OHTAC recommends that an evaluation of the proposed Ministry Telehomecare Expansion Project in partnership with Infoway, the Ontario Telemedicine Network, and the Local Health Integration Networks, which will encompass monitoring of patients with COPD, be undertaken and reported back to OHTAC upon completion.

Prior to expanding access to multidisciplinary care and pulmonary rehabilitation, OHTAC recommends field evaluation to evaluate long-term impacts of effectiveness and cost-effectiveness, optimal delivery of programs, characterization of patients most likely to benefit from these programs, and a survey of existing services.

14. Any primary research endorsed by OHTAC will include outcomes relevant to patient needs and perspectives, including patient preference, if applicable.

Implementation Considerations

In order to optimize the translation of the above recommendations into practice and to ensure high quality care, the formation of a provincial COPD Expert Panel to advise the health system and the Ministry of Health and Long-Term Care through Health Quality Ontario should be considered. This Expert Panel, representing patient and provider interests, should also inform OHTAC in an ongoing way of additional evidentiary requirements to further shape the COPD strategy.

Furthermore, opportunities to align these OHTAC recommendations to current funding strategies should be sought.

Feedback through public engagement expressed interest in pursuing other components of LTOT (oxygen assessment clinics, ambulatory oxygen therapy, and personal oximeters), OHTAC has reflected on this and regards these topics as out of scope of the existing overall mega-analysis on COPD, but these comments have been forwarded to the Assistive Devices Program (ADP). Similarly, through public engagement, OHTAC was made aware of the fact that there is a wide gap between the true costs of LTOT and the current funding level through ADP. This has also been forwarded to ADP.