ETHICAL CONSIDERATIONS THAT ARISE WHEN A HOME CARE PATIENT ON LONG TERM OXYGEN THERAPY CONTINUES TO SMOKE

A Report by the National Ethics Committee of the Veterans Health Administration

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National Center for Ethics in Health Care Veterans Health Administration Department of Veterans Affairs Founded in 1986, the National Ethics Committee (NEC) of the Veterans Health Administration (VHA) is an interdisciplinary group authorized by the Under Secretary for Health through the National Center for Ethics in Health Care. The NEC produces reports on timely topics that are of significant concern to practicing health care professionals. Each report describes an ethical issue, summarizes its historical context, discusses its relevance to VHA, reviews current controversies, and outlines practical recommendations. Previous reports have been useful to VHA professionals as resources for educational programs, guides for patient care practices, and catalysts for health policy reform. Scholarly yet practical, these reports are intended to heighten awareness of ethical issues and to improve the quality of health care, both within and beyond VHA.

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Executive Summary

For patients who smoke, long term oxygen therapy (LTOT) can offer both significant benefits and significant risks. LTOT is widely considered a substantially beneficial treatment for patients with chronic obstructive pulmonary disease (COPD), including active smokers, whose condition meets specific clinical criteria. However, LTOT also increases the risk of smoking-related fire because an oxygen-enriched atmosphere supports ignition at lower ambient temperatures and then hotter and faster burning. This report analyzes the ethical challenges encountered when a health care provider determines that a home care patient will benefit by receiving LTOT, but the patient continues to smoke. The report is organized around four questions:

- 1. What are the risks of smoking on LTOT in relation to the benefits?
- 2. Is the clinician who provides oxygen to a patient morally or legally responsible for any subsequent harm from fire?
- 3. What are the ethical requirements for providing LTOT to smokers?
- 4. Under what conditions does the risk of fire justify denying or withdrawing LTOT?

The Committee makes the following recommendations:

- 1. Clinicians should familiarize themselves with risks and benefits of LTOT, including the risks associated with smoking, so that they can appropriately support their patients in shared decision making.
- 2. Clinicians should thoroughly and accurately inform their patients of the risks and benefits of LTOT without minimizing or exaggerating the risks associated with smoking and document this in the medical record as per VHA Directive 2006-021, *Reducing the Fire Hazard of Smoking When Oxygen Treatment is Expected.*
- 3. When appropriate, Smoking and Oxygen Hazard Awareness: Home Safety Agreements should be used as a clinical technique to ensure that patients who choose to smoke on LTOT do so only with a full understanding of the dangers.
- 4. Clinicians must take care that discussions of the consequences for non-compliance with safety measure are informative but not unduly coercive.
- 5. Patients who chose to smoke on LTOT should be given the benefit of all applicable harm reduction techniques, including those required by VHA Directive 2006-021.
- 6. Termination of LTOT should only be considered in very extreme and exceptional cases after all reasonable and relevant harm reduction techniques have failed.
- 7. Termination of LTOT should only be considered in consultation with a multidisciplinary clinical committee or the facility's Ethics Consultation Service, as specified in VHA Directive 2006-021.
- 8. In deliberating referred cases, ethics committees, ethics consultants, or multidisciplinary review committees should consider the totality of all ethically relevant factors of the particular patient's situation.
- 9. Denial or withdrawal of LTOT is only justified when the risk to the patient and/or to third parties is so real, substantial, and immediate as to overshadow VHA's ethical **obligation to respect the individual**Veteran's desire to continue this treatment.
- 10. VA clinicians and decision-makers who diligently follow the recommendations suggested **in** this report should not be blamed for bad outcomes that may result from patients smoking in the presence of oxygen.

Ethical Considerations That Arise When a Home Care Patient on Long Term Oxygen Therapy Continues to Smoke

Introduction

For patients who smoke, long term oxygen therapy (LTOT) can offer both significant benefits and significant risks. LTOT is widely considered a substantially beneficial treatment for patients with chronic obstructive pulmonary disease (COPD), including active smokers, whose condition meets specific clinical criteria. However, LTOT also increases the risk of smoking-related fire because an oxygen-enriched atmosphere supports ignition at lower ambient temperatures and then hotter and faster burning (Ahearn, 2008).

Smoking and the need for LTOT are closely linked. COPD is the most common reason for LTOT prescriptions. An estimated 90% of COPD is a result of smoking-related lung damage (American Thoracic Society and European Respiratory Society, 2004). Smoking cessation is the most effective means to slow the progress of COPD. Unfortunately, however, many patients find it extraordinarily difficult to quit smoking (Jarvis, 2004). As a result, an estimated 20-40% of patients on LTOT continue to smoke (Ahearn, 2008; Lacasse, LaForge & Maltais, 2006). In 2008, according to the National Prosthetic Patient Database (NPPD), VHA provided 110,000 Veterans with home oxygen services. Thus, it is likely that at least 22,000 and perhaps as many as 44,000 VA patients on LTOT smoke.

Clinicians often feel morally conflicted when they are involved in providing a treatment which, though beneficial, carries a risk of serious harm to patients, their family members, health care workers who visit the patient's home, and possibly even others who are uninvolved in the care of the patient. This report aims to address this concern by providing guidance to clinicians who are directly involved in providing LTOT to home care patients, as well as guidance to multidisciplinary clinical committees or Ethics Consultation Services that may be asked to consult on particularly vexing cases involving patients on LTOT who continue to smoke.

VHA Directive 2006-021, *Reducing the Fire Hazard of Smoking When Oxygen Treatment is Expected*, requires that difficult or questionable cases be referred to a multidisciplinary review committee or for ethics consultation. Sections 4.a.(8) and (9) state:

- (8) When there is potential or identified conflict between the patient's right to smoke and/or the patient's continued smoking while using oxygen and the risk of harm to self or others, the provider(s) or others are to utilize a multidisciplinary review process, or request an Ethics Consultation, to address and resolve the situation.
- (9) All patients who fail to comply with oxygen therapy and smoking safety guidelines are referred to a multidisciplinary clinical committee or the facility Ethics Consultation Service for review to determine appropriateness of continued oxygen therapy, and how such therapy will be provided in ongoing care.

This report is organized around four questions:

1. What are the risks of smoking on LTOT in relation to the benefits?

- 2. Is the clinician who provides oxygen to a patient morally or legally responsible for any subsequent harm from fire?
- 3. What are the ethical requirements for providing LTOT to smokers?
- 4. Under what conditions does the risk of fire justify denying or withdrawing LTOT?

The first three questions will be most helpful to clinicians providing care to patients who may decide to smoke with LTOT; the last question is intended to provide some parameters for the deliberations of those committees and consultants faced with the more difficult cases.

What are the risks of smoking on LTOT in relation to the benefits?

<u>Risks</u> – Smoking at home puts one at risk of death or injury from fire. Smoking is the second leading cause of residential fires resulting in death. Residential fires resulted in death in 0.4% of incidents and in injury 2.2% of the time. In fires where death occurred, smoking was the cause 19.2% of the time (U.S. Fire Administration (USFA), 2008).

The presence of oxygen in a smoker's home increases the risk of fire. A review by the Fire Incident Data Organization (FIDO) showed that 7% of fatal victims whose smoking started the fire were using medical oxygen (USFA, 2006).

Moreover, when fire is related to home oxygen use, smoking is the principal cause. In fires involving home oxygen and resulting in burns that required treatment in a hospital emergency department, smoking caused the fire 73% of the time (Ahrens, 2008). (See Figure 1.) In a CDC study of fire incidents and home oxygen, 89% of deaths were incidental to people smoking while using oxygen (CDC, 2008). Other factors increasing the risk of fire for home care patients smoking with LTOT include living alone, a lack of working smoke detectors, the patient's cognitive impairment, the patient's history of smoking with oxygen, and flammable clothing (Joint Commission, 2001).

The most dangerous situation is smoking while actively using oxygen. A study of burn injuries related to oxygen use found that in 24 of 27 cases, the fire started while the patient was lighting a cigarette (Robb, et al., 2003). Another study showed that 89% of the injuries in these fires were facial burns (Ahrens, 2008). The tendency toward facial burns may be amplified because pure oxygen is heavier than air and so may accumulate in facial hair and upper body clothing.

Overall, however, smokers on LTOT account for only a small fraction of deaths in residential fires. A study of data from Maine, Massachusetts, New Hampshire, and Oklahoma between 2000 and 2007 found a death rate of 3.8 per 10,000,000 population per year from fire incidents related to smoking and LTOT. In comparison, the rate of death from all fires in the US between 1979 and 1992 was 265 per 10,000,000 per year (Federal Emergency Management Agency, 1997).

Likewise, fires caused by smoking at home while on LTOT account for a small portion of overall burn injuries. Barillo and colleagues (2000) retrospectively reviewed over 4,500 consecutive admissions to their burn center and found that only eight were related to simultaneous use of cigarettes and oxygen while at home.

Between 2005 to June 2007, seventeen fires occurring at the homes of LTOT patients were reported to VA's Patient Safety information database of events, with a patient death resulting in three cases (VA National Center for Patient Safety, 2007). If there are approximately 100,000 Veterans receiving home oxygen (NPPD) and 20 to 40% continue to smoke (Ahearn, 2008; Lacasse, LaForge & Maltais, 2006), then the annual rate of reported fire incidents was approximately 0.017% to 0.034% of the smokers on

LTOT, and the annual death rate of deaths was about 0.003% to 0.006%.

In summary, smoking at home substantially increases the risk for home fire, but the presence of oxygen in a smoker's home further increases the risk of fire only slightly. Almost 20% of all residential fires resulting in death are due to smoking, but only 7% of fatalities, when smoking started the fire, involve medical oxygen. Thus, the vast majority of smoking-related deaths from home fires (93%) do not involve medical oxygen. Extrapolating from these numbers, only about 1.3% of residential fires resulting in death are due to smoking with home oxygen.

<u>Perception of risk</u> – Actual risk can be very different from perceived risk. For example, the severity of the consequences of a home fire will tend to magnify the perception of risk that a fire will occur (Schneier, 2003). Reviewing the actual risks in relation to perception helps put the urgency of intervention into perspective.

Inherent psychological bias in risk perception may lead providers and patients to differ in their assessment of the true risks of smoking with LTOT. Two biases typical to most individuals when assessing risk may help explain this dissonance. First, people tend to perceive less risk when they control the situation and more risk when they do not; here, smokers control the use of cigarettes while the provider has little or no control over a patient's smoking. Second, people tend to perceive less risk when they choose the behavior, as when a person chooses to smoke. Familiarity also tends to decrease the perception of risk, such that LTOT patients who smoke without injurious consequences in the presence of oxygen may lessen their perception of the riskiness of that behavior (Ropeik & Gray, 2002).

Benefits – In general, the benefits of LTOT are substantial across all health measures. In their 2004 Standards for the Treatment of COPD, the American Thoracic Society (ATS) and European Respiratory Society (ERS) state that LTOT "improves survival, exercise, sleep and cognitive performance in hypoxaemic patients" (pg. 79). Once established, COPD tends to progress even in patients who successfully quit smoking, but Zielinski and colleagues (1998) found that, "Long-term domiciliary oxygen prolongs life in patients with COPD, despite inexorable progression of airflow limitation and of hypoxemia" (pg. 69). LTOT also provides relief from dyspnea (shortness of breath), a symptom which produces subjective distress similar to pain (Banzett, 2008). Significant improvement in health-related quality of life has also been found (Eaton et al., 2004).

The benefits of LTOT accrue to current smokers and non-smokers alike. The ATS and ERS (2004) standard for selection of pulmonary rehabilitation candidates states, "Current cigarette smokers are reasonable candidates for pulmonary rehabilitation and probably obtain similar benefits as non-smokers or ex-smokers" (pg. 105).

<u>Conclusion</u> – While smoking is a major risk factor for fire, the presence of oxygen only marginally increases the risk of fire from smoking. If a fire occurs, the harm can be substantial, even fatal for the patient and others nearby; nevertheless, LTOT significantly delays the inevitable decline associated with COPD and provides substantial subjective relief.

Is the clinician who provides oxygen to a patient morally or legally responsible for any subsequent harm from fire?

"Moral distress" is defined as feeling constrained from doing what is perceived as morally correct or, conversely, pressured into doing what feels morally incorrect (Jameton, 1984; Corley, 2005). A 2008

National Center for Ethics in Health Care (Ethics Center) National Ethics Teleconference on moral distress gave the following example:

A patient requires the use of home oxygen. Recently the patient attempted to turn on the stove while intoxicated and set his pajamas on fire. Eventually the nasal cannula also caught on fire and he burned his nose and mouth. The physician who prescribed the home oxygen was upset on learning about the patient's injuries. He was morally distressed that he would be putting the patient at risk by continuing to prescribe home oxygen, a therapy that is medically indicated. (http://www.ethics.va.gov/pubs/netsum.asp)

This example illustrates why clinicians are often conflicted over providing oxygen to patients who smoke. Even though oxygen is clearly beneficial to patients, clinicians may be concerned that the presence of oxygen violates *primum non nocere* ("First do no harm").

Smoking with LTOT presents several of the elements identified by Smith and Paradis (2008) as likely to create moral distress: there is a potential for significant harm; the therapeutic alliance may be strained because such patients are refusing to follow clinical advice; and the patient may perceive that the clinician is being controlling or demanding.

Attending to moral distress in VHA is essential. The experience of moral distress is sufficiently disturbing that professionals report feelings of burnout and even leave jobs or abandon careers because of its effects (Corley, 2005; Elpern, et al, 2005). Moral distress caused by worry that the provision of oxygen is causing harm to patients may explain the persistence of questions on this issue in VHA.

Answering the moral question – From an ethical perspective, VA clinicians are obligated to provide the best available treatment to patients, when clinically indicated, even to those patients who choose to incur risk through unhealthy behaviors. When patients do choose unhealthy behaviors, clinicians have an obligation to counsel the patient to discontinue those behaviors. In the present context, clinicians have a clear duty to encourage patients who require LTOT to stop smoking and to offer them enlistment in a smoking cessation program -- not only because smoking is detrimental to health but also because smoking creates a risk of fire, and because LTOT modestly increases that risk. If a patient with decision-making capacity decides to smoke while on LTOT even after being fully informed of the risks, the clinician is generally obligated to provide LTOT, nonetheless. From an ethical standpoint, under such circumstances, the person responsible for any harms due to smoking is the patient, not the clinician.

Answering the legal question. A complete discussion of the legal questions surrounding smoking and LTOT is beyond the scope of this report. However, a few points bearing on concerns about the legal liability of VA clinicians are worthy of some elaboration.

Under the Federal Tort Claims Act (FTCA), a clinician employed by VA cannot be held personally liable for damages suffered by a person resulting from action taken by the clinician within the scope of the clinician's employment. Accordingly, if a VA clinician provides LTOT to a patient as part of the patient's VA treatment, the clinician cannot be held personally liable for damages suffered by the patient or any other person as a result of the LTOT. Federal regulation (section 46.3, title 38, Code of Federal Regulations) and VHA Handbook 1100.17, National Practitioner Data Bank Reports (NPDBR), require that a VA practitioner be reported to the NPDB following a malpractice payment only if the majority of a medical malpractice payment review panel finds that the payment was related to the

practitioner's substandard care, professional incompetence, or professional misconduct.

A clinician's duty to exercise reasonable skill and care includes following the applicable standards of informed consent for prescribing LTOT as required by VHA Handbook 1004.01 and the responsibility laid out in VHA Directive 2006-021 to "discuss with the patient and/or the patient's surrogate, responsibility for complying with the terms agreed upon for safe administration of oxygen therapy when it is initiated." Under this latter policy, every facility is required to provide education and orientation to each patient and to make reasonable efforts to educate anyone else in the household who smokes about the hazards of smoking while oxygen is in use. Each facility is also required to provide the Veteran with a checklist or other cognitive aid to promote safe oxygen use. Some facilities have elected to use a written and signed home safety agreement as a tool for education and documentation. (These documents are available in the iMedConsent library).

What are the ethical requirements for providing LTOT to smokers?

Provision of LTOT to smokers has three ethical requirements:

- Ensure that the patient understands the risk;
- Avoid undue coercion inherent in the clinician's ability to withdraw oxygen; and
- Reduce the risk to greatest degree possible.

<u>Ensure understanding</u> – As part of the process of obtaining the patient's informed consent, ethical treatment requires ensuring that patients are informed of an intervention's risks and benefits before agreeing to receive the treatment. Information about an intervention given to patients should reflect the patient's actual situation. When a patient on LTOT chooses to continue smoking, that patient assumes the risks of smoking with stored oxygen in the home.

One technique for assuring that the patient has made a deliberate choice with full knowledge of the consequences is to use a written agreement such as the "Smoking and Oxygen Hazard Awareness: Home Safety Agreement," which is included in iMedConsent. While no printed and signed form can assure the patient's total understanding and compliance with safety requirements, the Agreement does provide documentation that the clinician has discussed the issue with the patient. Similar to an informed consent form, the Agreement acknowledges that the patient has decision-making capacity and understands the risks of smoking in conjunction with home oxygen therapy, that the provider has informed the patient of all relevant risks, and that the patient has not been coerced into signing (Beauchamp & Childress, 2008).

The Agreement is best understood as a clinical intervention and not a legally enforceable contract. The technique of formalizing the patient education discussion with a printed form that has the look and feel of a contract may increase patients' sense of responsibility for their behavior and its potential consequences, but clinicians should not assume that this alters their responsibility to ensure that the patient is capable of following safety guidelines. The purposes of the entire exercise are to heighten the patient's awareness of the dangers and to emphasize the seriousness with which the clinician treats the risk of fire from smoking in the presence of oxygen. Rigorous safety assessment and patient education must continue.

Capacity to sign safety agreement: Most patients who are able to function at home will have the decision-making capacity to sign the agreement. From an ethical perspective the mental capacity required to be considered an autonomous decision maker is related to the complexity of the decision under consideration – in this case, to agree to follow safety procedures. The standard for assessing capacity in this situation should be similar to other situations; thus, persons are considered to have decision-making capacity unless there is a specific indication that they do not.

Avoid coercion – VHA is committed to providing the best available care to Veterans even when they make unhealthy lifestyle choices. Still, VA clinicians have the authority to determine that it is too dangerous to provide oxygen in the patient's home and so to deny or withdraw LTOT. While clinicians should offer patients help to change unhealthy behaviors, patients should not be coerced into change. Coercion exists when the influence a clinician uses to bring about healthy behavioral change is undue or unfair, often signaled by the patient's discomfort (Olsen, 2003). Coercion is ethically problematic because it unduly reduces or eliminates the patient's freedom to choose (Beauchamp & Childress, 2008).

Clinicians need to be aware of the potential for coercion inherent in the authority of their positions and its effect on patient perception. Patients clinically qualifying for LTOT are severely impaired and dependent on health care. Oxygen may be providing these patients substantial relief from suffering. Therefore, the possibility that oxygen could be removed may be perceived by these patients as a significant threat.

In addition, because of the power differential between patients and clinicians, the clinician's actions can be construed as coercive or threatening even when that is not intended. Perhaps the greatest danger of this perception is its effect on the clinical relationship. Patients feeling coerced may become less forthright about their feelings and behavior and create an added danger by smoking in secret. Patients who hide smoking are defined as "high-risk patients" in VHA policy (VHA Directive 2006-021).

When considering the removal of oxygen because of the patient's unsafe behavior, deliberation and good judgment are needed. Patients should be accurately informed about VA policy and procedures that pertain to providing oxygen to patients who smoke. Rather than threatening to withdraw oxygen, clinicians should express concern for the patient and the potential consequences of continued unsafe behaviors, including concern about the possibility that a multi-disciplinary committee might decide that VA can no longer provide oxygen.

<u>Harm reduction</u> – When LTOT patients decline to quit smoking, good practice demands that clinicians work to reduce the risk presented by smoking. Harm reduction is a model of treatment which seeks to lessen the impact of a negative behavior on the health of a person who will not abandon the behavior.

Harm reduction was first postulated in the Netherlands for treating heroin addiction (Hartgers, et al., 1991). Since then harm reduction principles have been used to address risk from other types of IV drug use (Brettle, 1991), drinking and driving (Monti, et al., 1999), at-risk drinking (Marlatt & Witkiewitz, 2002), and sexual behavior (Parsons, et al., 2005). The following are the principles of harm reduction as posted by the Harm Reduction Coalition and adapted to the situation of reducing risks associated with smoking and home oxygen use:

- People choose harmful behavior; risk reduction seeks to minimize the degree of harm.
- Health behavior is a complex, multi-faceted phenomenon on a continuum where some

behaviors are safer then others.

- Quality of life, not compliance, is the criterion of success.
- Non-judgmental, non-coercive provision of services assists patients in reducing risk.
- Patients are the primary agents of reducing risk; risk reduction seeks to empower patients to meet needs as they perceive them
- Poverty, class, racism, age, and social isolation affect both people's vulnerability and their capacity for effectively dealing with behavioral change.
- The *real* threat of smoking with oxygen must not be minimized or exaggerated. (http://www.harmreduction.org/index.php)

The harm reduction approach is as much a change in perspective as a change in procedure. The advantage of the approach is that it promotes therapeutic relations as the clinician and the patient work together to reduce risk. This may convey a tone of concern toward the patient; such a tone is more difficult when the issue is framed as a decision regarding denial of a wanted treatment. The goal of the harm reduction approach is to bypass an adversarial power struggle played out through a legalistic attention to rights and so to refocus on a relationship where the goal is the patient's welfare, on the patient's terms.

Still, harm reduction is controversial on several grounds. There remains a known increased risk to third parties who share living space with smokers receiving home-based LTOT. The provision of oxygen to an active smoker always involves a determination that the risk is outweighed by the benefit to the Veteran. The line where benefit is felt to outweigh risk is based on values and not mathematical calculation; the determination that the benefit typically trumps the risk is based in the value VHA places on delivering high quality care to Veterans. But the risk remains, and clinicians should be aware that because of the character of this risk-benefit decision – the benefit of LTOT outweighing the low probability of an event which, if it does occur, can have devastating consequences – there is potential for second-guessing, especially after such an adverse event.

Another fear related to harm reduction is that by tolerating the risky negative behavior, one is encouraging it. Thus, helping to mitigate rather than eliminate an unhealthy behavior sends patients mixed messages, covertly endorsing the behavior. It might be feared that patients who would have quit smoking under the pressure of a more aggressive approach will continue to smoke if there is an atmosphere of toleration. This criticism emerged in discussions of needle exchange programs and condom use campaigns (Allan & Wright, 2004). However, there is good evidence that many harm reduction campaigns are effective (Pauley, 2008).

<u>Harm reduction strategies</u> – VHA Directive 2006-021, Reducing the Fire Hazard of Smoking when Oxygen Treatment is Expected, requires measures that fit well in a harm reduction perspective. These measures include:

- Fire risk assessment and reassessment with any change in prescription
- Educational and/or warning information every 6 months
- Assessment of compliance at least every six months
- Working smoke detectors
- Educational and/or warning information for patient and others
- Counseling for non-compliant patients

- Documentation of all close calls and adverse events
- Referral to ethics consultation and multidisciplinary consideration for difficult cases

Other forms of harm reduction might include self-extinguishing cigarettes; safe ash trays; fire retardant clothing, furniture, and bedding; use of smokeless tobacco; advance notification of the local fire department and other appropriate public safety officials; and the use of warning stickers. Enlisting family or caregiver support can also be effective. Harm reduction for non-smoking related hazards, such as candles and gas stoves, should also be used with all LTOT patients, smokers and non-smokers alike. These are just a few examples of possible strategies; the most effective harm reduction will take place in a shared decision-making environment between individual patients, their families, and clinicians who know them and specialize in the treatment of pulmonary disorders. Harm reduction is an attitude and not simply a set of interventions. It will be most effectively practiced by clinicians who adopt the perspective.

Under what conditions does the risk of fire justify denying or withdrawing LTOT?

According to VHA Directive 2006-021, patients with a "conflict between the patient's right to smoke and...the risk of harm to self or others" (Section 4.a.(8)) and "patients who fail to comply with oxygen therapy and smoking safety guidelines" (Section 4.a.(9)) must be referred for a multidisciplinary review or an ethics consultation "to address and resolve the situation" (Section 4.a.(8)) and/or "to determine appropriateness of continued oxygen therapy, and how such therapy will be provided in ongoing care" (Section 4.a.(9)).

The consultants or committees asked to consider these difficult cases should act cautiously when considering removal of LTOT. Terminating LTOT, a physiologically and subjectively beneficial treatment, is only justified if all reasonable efforts to reduce the risk to acceptable levels have failed and there is evidence that the risk of fire is substantial and immediate. "Substantial and immediate" means that the benefits of LTOT are outweighed by the high likelihood of fire-related injury, and that the immediacy of risk to persons other than the patient is far greater than usual, based on the specific events of the case.

Risk considerations – One troubling aspect of smoking with LTOT is that the risk extends to persons other than the patient. Family, home care providers, informal caregivers, and other persons in a multi-unit building could all be harmed in a fire. While the probability of fire is low, the potential degree of harm is great, and this magnifies the subjective sense of risk. While there are many risk factors for fire in a patient's overall environment, the only germane risk is the increase in risk resulting from the presence of oxygen and not the risk of smoking itself.

Denial or withdrawal of LTOT is only justified when the risk outweighs VHA's obligation to provide this beneficial treatment that would otherwise be considered medically necessary. Although definitive numbers are not available, the increased risk from the oxygen would seem of the similar magnitude as other fire hazards, such as candles, drinking and smoking, or gas stoves. Accordingly, LTOT should not be denied based solely on the increased risk of fire caused by the presence of oxygen. Denial based on risk to third parties may be justified if there are other factors demonstrating immediate substantial risk, such as repeated disregard of safety measures, advanced dementia and irresponsible supervision, or perverse non-compliance, i.e., deliberate provocation. These factors need to be analyzed on a case-by-case basis.

The following is a list of legitimate factors in considering the denial or withdrawal. No single factor is dispositive. Rather, the answer to each factor moves the argument some degree toward or away from denial of LTOT on the basis of that factor's particular risk. The final decision must be made on the totality of the assessment. The list is not exhaustive but is intended to provide examples of the matters that an ethics consultation committee could address when faced with this decision (See Figure 2.):

- Patient's mental acuity
- Other mental state factors, e.g., depression, thoughts of suicide
- Patient's self-care ability, e.g., visual acuity
- Patient's cooperation with safety measures
- Responsibility of caregiver
- Caregiver's willingness to accommodate patient's smoking
- Availability of caregiver(s) for supervision
- Single or multi-family dwelling
- Other risk factors for fire in the home
- Degree of benefit to the patient
- Patient's clinical need for LTOT
- Patient's perception of improved quality of life from LTOT
- Potential risk to health care workers entering the home
- Number of other family members in the home
- Children in the home
- Family members' willingness to accept risk from patient's smoking
- Prior history of fire-related events or close calls
- Patient's reactions to these prior events

<u>Proven high risk situations</u> – A determination of high risk carries an obligation to decrease that risk. LTOT should only be terminated or denied after thorough review of the evidence and the determination, based on that evidence, that there is a substantial and immediate risk of fire that cannot be mitigated by harm reduction techniques. Once that determination is made, then VHA must terminate the therapy.

In conclusion, VHA clinicians should never stop a beneficial treatment without the strong justification that the treatment creates a serious enough risk to outweigh the benefit of this treatment to Veterans. Denial or removal of LTOT should be a last resort after all other interventions have been tried without success, and should be reserved for extreme cases given the low risk of fire due to smoking, relative to the health benefits of oxygen therapy.

SUMMARY AND RECOMMENDATIONS

Smoking with home-based LTOT is to be expected because most LTOT is prescribed for disorders resulting from many years of smoking. Smoking is highly habit-forming and very difficult to quit. Smoking is a risk factor for fire, and the presence of oxygen increases the risk because it enhances

combustion, though oxygen itself neither burns nor explodes. Still, although an exact figure such as fires injuries per oxygen-day is not available, the overall risk of injury-causing fire is very low.

VA has an obligation to provide the best treatment available, regardless of patients' lifestyle choices, and LTOT significantly enhances length as well as quality of life for many patients. When patients receiving LTOT choose to smoke, the best treatment is to reduce the risk of fire as much as possible. Indeed, efforts to help the patient smoke more safely may reduce the risk of fire, even in the presence of oxygen, below the risk presented by "unmanaged" smoking in the absence of LTOT.

Substantial, immediate danger of fire is the chief justification for removal or denial of this beneficial treatment and should be considered a last resort after all harm reduction techniques have failed. Still, the best and therefore the most ethical treatment of the patient, as well as one way to address the moral distress of clinicians reluctant to provide a potentially dangerous intervention, requires going beyond the dichotomy of providing or denying oxygen. Harm reduction is a valuable approach that allows continued care and treatment for patients who do not fully cooperate with our recommendations.

Recommendations

When clinically indicated, the best available smoking cessation treatment must be offered to Veterans. When smoking cessation is not achieved, Veterans should still receive LTOT when it is clinically beneficial. The clinician is responsible to provide all pertinent information about the choice to smoke with LTOT, to remain available to assist the patient with cessation, and to reduce the risk of smoking as much as possible. Respect for a patient's autonomous decision requires that the patient be allowed to accept responsibility for the risk of unhealthy choices.

- 1. Clinicians should familiarize themselves with risks and benefits of LTOT, including the risks associated with smoking, so that they can appropriately support their patients in shared decision making.
- 2. Clinicians should thoroughly and accurately inform their patients of the risks and benefits of LTOT without minimizing or exaggerating the risks associated with smoking and document this in the medical record as per VHA Directive 2006-021, *Reducing the Fire Hazard of Smoking When Oxygen Treatment is Expected*.
- 3. When appropriate, Smoking and Oxygen Hazard Awareness: Home Safety Agreements should be used as a clinical technique to ensure that patients who choose to smoke on LTOT do so only with a full understanding of the dangers.
- 4. Clinicians must take care that discussions of the consequences for non-compliance with safety measure are informative but not unduly coercive.
- 5. Patients who chose to smoke on LTOT should be given the benefit of all applicable harm reduction techniques, including those required by VHA Directive 2006-021.
- 6. Termination of LTOT should only be considered in very extreme and exceptional cases after all reasonable and relevant harm reduction techniques have failed.
- 7. Termination of LTOT should only be considered in consultation with a multidisciplinary clinical committee or the facility's Ethics Consultation Service, as specified in VHA Directive 2006-021.
- 8. In deliberating referred cases, ethics committees, ethics consultants, or multidisciplinary review

- committees should consider the totality of all ethically relevant factors of the particular patient's situation.
- 9. Denial or withdrawal of LTOT is only justified when the risk to the patient and/or to third parties is so real, substantial, and immediate as to overshadow VHA's ethical obligation to respect the individual Veteran's desire to continue this treatment.
- 10. VA clinicians and decision-makers who diligently follow the recommendations suggested in this report should not be blamed for bad outcomes that may result from patients smoking in the presence of oxygen.

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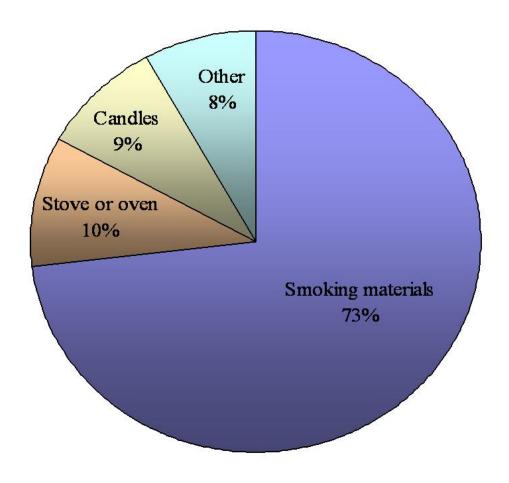
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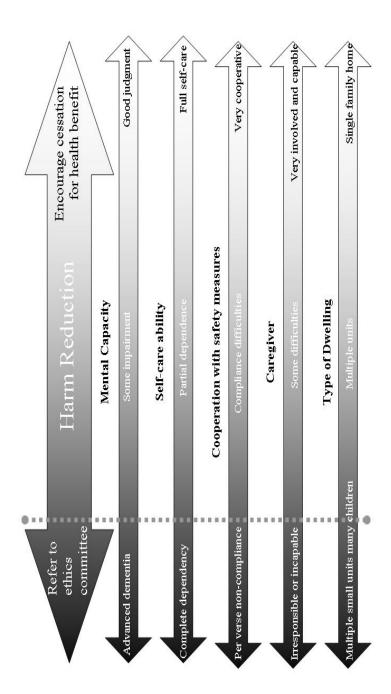
Heat Source in 2003-2006 Medical Oxygen-Related Burns Seen at Hospital Emergency Rooms

FIGURE 1



From: CPSC's National Electronic Injury Surveillance System in Ahrens, M. (2008). Fires and Burns Involving Home Medical Oxygen. National Fire Protection Association. http://www.nfpa.org/assets/files/PDF/OS.Oxygen.pdf

FIGURE 2



Note: This diagram is intended to convey the multi-factorial nature of the situation, where factors occur on a continuum and no single factor is determinative. The decision to refer to a multidisciplinary clinical committee or the facility's Ethics Consultation Service for consideration of denial is a threshold to be approached cautiously.