Most of the large quantity of data on noninvasive ventilation (NIV) in acute respiratory failure is from patients who want all possible treatments and life-support. Few data are available on NIV in patients who have elected specific limits on life support and treatments (eg, patients with do-not-intubate [DNI] orders) and patients who are near the end of life and will receive comfort measures only (CMO). The most critical issue regarding NIV in DNI and CMO patients is informed consent. The patient must be informed of the risks and potential benefits of NIV, and must consent to NIV. We have few data on patients’ attitudes about NIV at end of life. Data from cancer patients at end of life suggest that they want to maintain control over care decisions and may want treatment that delays death long enough that they can put their affairs in order. If informed consent and control of care decisions are assured, then NIV can be appropriate in DNI and CMO patients to reverse an acute respiratory failure that is not necessarily life-terminating, or to improve patient comfort, or to delay death. Key words: respiratory failure, mechanical ventilation, noninvasive ventilation, do not intubate, do not resuscitate, comfort measures only, acute respiratory failure, end of life, death. [Respir Care 2009;54(2):223–229. © 2009 Daedalus Enterprises]
failure (ARF) has focused on patients who want all possible life support and treatments. Randomized controlled trials have described the settings where NIV is effective. Many patients who set limits on life support and treatments have had poor experiences with intubation and have chronic disease and a poor prognosis. CMO patients desire only to minimize discomfort and ease the dying process. Clearly, the goals of therapy differ in the 3 care categories.

I will focus on patients who elect not to receive certain treatments (eg, intubation) and CMO patients who might benefit from NIV. NIV for patients who want all possible life-support and treatments are discussed in the other papers in this conference and elsewhere.

### What Do Patients Want?

The vast majority of the data on patients’ concerns at end of life are from patients with cancer. Their primary concern is “a loss of autonomy over the circumstances of their dying.” These patients fear feeling powerless over treatment decisions that might prolong their life. Clark et al wrote that “patients at the end of life are replacing the fear of death with a fear of dying.”

Steinhauser et al conducted a series of focus groups with terminally ill cancer patients and asked about their concerns and fears at end of life. Those patients indicated that a “good death” would allow them to the opportunity to plan for death and determine what therapies they want and don’t want at end of life. Most of all the patients wanted clear clinical management decisions before the time of death to determine where they would die, to plan the funeral, to get personal and financial affairs in order, to obtain closure in personal relationships, and to say goodbye to their spouses, children, and extended family. They did not want to burden their families emotionally or financially with an extended period of end-of-life care. They also expressed a desire to somehow contribute to and assist others who would follow them in the same situation. These patients wanted to give their death meaning and described a “bad death” as lacking the opportunity to plan ahead, to make advance treatment decisions, to put their affairs in order, to say goodbye, and to avoid burdening their families.

### Ethical Issues

The main ethical concern about NIV for ARF in DNI and CMO patients is informed consent, which is necessary but can be problematic, because not all patients with terminal diseases have discussed end-of-life issues with their physicians, and many physicians are reluctant to discuss advance directives with their patients. Morrison et al sent questionnaires regarding advance directives to 460 internal medicine physicians, 277 (60%) of whom responded. They found that the physicians lacked certain understandings about and had some erroneous beliefs about advance directives, which were barriers to initiating discussion about advance directives.

Johnston et al surveyed 329 adult out-patients, 282 residents, and 272 practicing physicians (response rates 75%, 76%, and 65%, respectively) for their opinions about advance directives. The patients believed that discussions regarding advance directives should occur earlier in the course of disease and earlier in the patient-physician relationship than did the physicians (Fig. 1). Both physician...
and patients thought it was the physician’s responsibility to initiate the discussions about advance directives.24

Despite literature that indicates patients’ desire to discuss advance directives25–26 and a mandate by regulatory agencies,27 many patients with end-stage disease, and the elderly, have not formalized their treatment wishes with advance directives.28 Many patients at end of life who are transferred to acute-care hospitals do not have advance directives.29 Pekmezaris et al29 reviewed the medical records of 93 deceased nursing home residents. Forty-three of the residents had died in the nursing home. Fifty died after transfer to an acute-care hospital. In the majority of the patients’ charts the only advance directive was do not resuscitate. Other directives included DNI (24.7%), do not artificially feed (17.2%), do not artificially hydrate (9.7%), and do not transfer to an acute-care hospital (12.9%). The demographics, severities of illness, and racial and religious backgrounds were similar in the group who died in the nursing home and the group who died in the acute-care hospital. However, the frequency of having all 5 of the above advance directives was much higher in those who died in the nursing home (P < .01).

Since standard advance directives are not commonly found in patients’ medical records, it can be difficult to know if a patient at end of life has discussed NIV. Recent statements about palliative care from societies whose focus is patients with chronic pulmonary diseases do not discuss NIV in the sections on the standard of care for patients with cardiopulmonary disease at end of life.30 Thus, it is up to the clinician to determine if the patient has consented to NIV. The patient should be educated to the fact that NIV is a form of life support, but is noninvasive, and that the patient can discontinue NIV at any time. Ideally, discussion about NIV should occur long before the patient is near the end of life. The discussion should occur in the physician’s office, during a period of medical stability, so that the patient can contemplate the choices well before confronting the end of life. Some institutions have added do/do-not-use-NIV to their list of advance directives. The ideal is to provide precise direction to all caregivers regarding the patient’s wishes. NIV is an ethical approach to managing a patient at end of life if the patient provides informed consent.

Outcome of Interest

The outcomes expected from NIV in DNI and CMO patients are not the same as when applying NIV with a patient who is to receive all possible life-support and treatments. In the majority of patients who receive NIV for ARF, avoiding intubation and death are the outcomes of interest. With DNI and CMO patients, intubation is not an option. With DNI patients, avoiding death from ARF may be the outcome of interest. NIV may reverse the ARF and allow the patient to be discharged from the acute-care facility. This may not be possible for some patients, but, as with the CMO patients, increasing patient comfort by decreasing shortness of breath and avoiding opiates to reduce dyspnea may be the outcome of interest. NIV should not be administered to a CMO patient unless the objective and outcome is increased comfort. It is inconceivable that a patient who requires restraints to maintain NIV would be more comfortable with it than without it.

In both CMO patients and patients with advance directives that disallow specific treatments, NIV may be applied to delay death if the patient so desires, to give, for instance, a geographically distant family member enough time to travel to the hospital to be at the patient’s side before death, to allow the patient to be transferred home to die, or to give the patient enough time to settle personal or financial matter. The clinician’s role is to try to meet the patient’s needs so that the final hours or days of life are as comfortable as possible.

NIV for DNI and CMO patients is not without controversy. Bach argued that “palliative care is uninformed euthanasia when patients are not offered noninvasive lifesustaining options.”31 That argument was made in reference to patients with neuromuscular and neurologic diseases, but it is also true in patients with chronic obstructive pulmonary disease (COPD), chronic heart failure, or end-stage cancer. Bach pointed out that the decision to use or not use NIV is totally up to the patient and family, after appropriate education about the risks and potential benefits. It is solely the patient’s decision (not the clinician’s) whether the quality of life with NIV is acceptable. Others have argued that the ethical and economic costs of using NIV to delay an inevitable death are too great.32 Some have opined that, since we do not have long-term outcome data or detailed data on patient comfort and satisfaction.

**Fig. 1.** Survey responses to the question, “Who should initiate discussions regarding advance directives?” (From Reference 24, with permission.)
with NIV, it should not be used in DNI or CMO patients. Although I agree that this information is needed, to me it does not seem reasonable to withhold a therapy that could benefit an individual and is desired by the individual simply because long-term outcome data are not available. The critical issue is informed consent. As long as the patient fully understands the risks and potential benefits and is comfortable with NIV, even if only for a short period, the treatment should be administered.

Applying Noninvasive Ventilation in Do-Not-Intubate and Comfort-Measures-Only Patients

The literature on the application of NIV to DNI and CMO patients is limited, and there have been no randomized controlled trials. The first documented use of NIV in DNI and CMO patients was by Benhamou et al., who applied NIV to 17 COPD patients in ARF and for whom intubation was contraindicated because of age, physiologic condition, or family wishes. NIV was successful in 10 of these patients. Eight of the 17 died in the hospital.

Two years later, Meduri et al reported on the application of NIV in 11 DNI patients in ARF. NIV was successful in 7 patients (64%), all of whom survived the intensive care unit (ICU), and hospital mortality was 55%. In 1994 Freichels et al also used NIV in 3 DNI patients with COPD and ARF. All 3 patients died.

Farha et al reported on the Cleveland Clinic’s experience with NIV on regular hospital wards. They applied NIV to 76 patients, 41% of whom had an underlying diagnosis of COPD. Fourteen of the 76 patients had DNI orders. Seven of those 14 survived hospitalization.

Fernandez et al retrospectively reviewed all 233 patients who were treated with NIV over a 2-year period. These patients represented 7.1% of the patients admitted to the center’s medical-surgical ICU. Thirty-four patients had DNI orders. The DNI patients were older and had cancer more frequently than the non-DNI patients, and 33% of the DNI patients had COPD. Hospital survival of the DNI patients was 26%, versus 74% in the non-DNI patients. Fernandez et al emphasized that mid-term and long-term survival of the DNI patients was poor.

Chu et al specifically focused on the long-term survival of COPD patients with and without DNI orders. They compared data from 37 patients with COPD and DNI status to 43 patients with COPD but without DNI status, all of whom received NIV. The patients with DNI status were older, had more severe dyspnea scores, poorer Katz Activities of Daily Living scores, poorer comorbidity scores, poorer Acute Physiology and Chronic Health Evaluation (APACHE) scores, lower hemoglobin, and a longer period of time spent in the hospital during the previous year than did the patients without DNI status. One-year survival of the DNI patients was 27%, compared to 65% in the non-DNI patients with COPD. The median time spent in the hospital during the follow-up year was 9% in the non-DNI group and 11% in the DNI group.

Two large prospective case series focused only on NIV in DNI patients were reported by Levy et al and Schettino et al. Levy et al conducted a 4-center prospective cohort study over a 9-month period. Of 1,211 screened patients, 114 patients with DNI status were enrolled, and 49 (43%) survived to hospital discharge. Survival was not affected by age, sex, location (university-affiliated vs community hospital), initial pH, or initial PaO2. However, a higher baseline PaCO2 was associated with better survival. In addition, underlying primary diagnosis was an important determinant of survival (Fig. 2). Patients with congestive heart failure had significantly better survival than any of the other groups.

Schettino et al prospectively studied 137 applications of NIV to 131 DNI patients during a 1-year period at one center. Diagnosis affected NIV outcome (Fig. 3). Overall hospital survival was 36%, but 63.5% of patients with COPD and 61% of patients with cardiogenic pulmonary edema survived, whereas only 13% of patients with hypoxemic respiratory failure survived. Forty percent of the patients had advanced cancer, which was associated with a higher risk of death (85% mortality). An outcome score based on APACHE score and serum albumin determined before the initiation of NIV predicted survival.

Cuomo et al used NIV as a palliative treatment for ARF in 23 patients with end-stage cancer. After 1 hour of NIV, the Borg score and the ratio of Pao2 to fraction of inspired oxygen significantly increased. Thirteen of the 23 patients met successful ventilation criteria and were discharged alive. Hospital survival was 48%, but 1-year survival was 13%. Although it may be argued that many of the patients in this case series were CMO, the high hospital survival was 48%.

Fig. 2. Survival to hospital discharge of do-not-intubate patients who received noninvasive ventilation, by diagnosis. COPD = chronic obstructive pulmonary disease. CHF = congestive heart failure. (From Reference 40, with permission.)
survival rate argues against that classification. No data specifically on this category of patients receiving NIV have been published, but Nava et al. indicate that they have underway a randomized controlled trial at 10 palliative-care centers to study NIV in patients with end-stage solid-organ cancer.

Clinicians’ Perspectives

Little information is available on clinicians’ perspectives on NIV in DNI and CMO patients. Sinuff et al surveyed pulmonologists, intensivists, and respiratory therapists (RTs), in 18 Canadian and 2 United States institutions, on the use of NIV in patients with ARF near the end of life. The survey asked about factors associated with the use of NIV in DNI and CMO patients. Overall, 104 (57%) of 183 physicians and 290 (61%) of 473 RTs responded. Sixty-two percent of the physicians indicated that they include NIV in DNI discussions at least part of the time. Eighty-seven percent of the RTs indicated that NIV should be included in these discussions (Fig. 4). Regarding CMO patients, fewer respondents thought NIV should be included in the discussion. Forty-nine of the physicians indicated that at least some of the time they include NIV in the discussion, whereas 41% of the RTs thought that NIV should be part of the discussion. The RTs indicated that they were asked to initiate NIV on DNI and CMO patients more frequently than the physicians indicated they ordered it (see Fig. 4).

Both physicians and RTs indicated they used NIV more frequently in DNI patients than in CMO patients. The physicians were more likely than the RTs to believe that NIV relieves dyspnea and facilitates communication in DNI and CMO patients. The RTs more commonly than physicians indicated that NIV was used so that the patient’s family had time to come to terms with their loved one’s death. Physicians more commonly than RTs indicated that NIV was used so that patients would have time to get their personal affairs in order. Both physicians and RTs indicated that NIV at end of life for either DNI or CMO was more likely in patients with COPD or congestive heart failure than in patients with end-stage cancer.

These data clearly indicate an inconsistency of practice between physicians and RTs with regard to NIV at the end of life. Additional study is needed on the use of NIV in DNI and CMO patients, and about those patients’ perspectives on NIV.

Location of Care

I think most would agree that, ideally, when used as life-support, NIV for ARF should be applied in the ICU. Curtis et al defined NIV as life-support when the patient is unable to sustain spontaneous breathing for at least an hour without NIV. However, DNI and CMO patients have been successfully sustained on NIV outside the ICU. Both Schettino et al and Farha et al sustained DNI and CMO patients on general medical/surgical units. A general medical/surgical unit’s staff must understand the risks and benefits of NIV, and patients must be appropriately monitored, including alarms for ventilator disconnect, pressure-loss, high airway pressure, pulse oximetry, and cardiovascular monitoring, which should all annunciate in the hall and nursing station to rapidly alert staff of changes in patient status or ventilator malfunction. Elliott et al found that all categories of patients who require NIV could be safely and effectively managed on general medical units, given proper staff training and patient monitoring.
Summary

NIV can benefit patients who have elected specific limits on life-support and treatments (eg, DNI) and patients who will receive comfort measures only. The critical ethical issue with regard to NIV for DNI and CMO patients is informed consent. Have the risks and potential benefits of NIV been clearly discussed, and has the patient agreed to accept the risks? Data from terminal cancer patients suggest that the patient-important factors are retaining control over end-of-life care decisions and having adequate time to prepare for death. If control over care decisions is assured, NIV may be able to reverse an ARF that is not necessarily a life-terminating event, or improve patient comfort, or sustain life until the patient can put his affairs in order.

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Discussion

Epstein: Could the ethical dilemma be tempered if we stopped reporting survival? With regard to palliative care that’s clearly not the proper outcome; that’s why it’s great to get Stefano’s [Nava] outcomes. With a DNI patient it would be better to look at quality of life. We should not be looking at survival. We’re not necessarily trying to prolong survival at that point.

Kacmarek: All the published studies have been case series that documented practice, without any specific protocol assigned to NIV application. We just did a survey of our daily experience with providing NIV. It’s difficult to get the kind of outcomes that you’re referring to from those data, because there was not a specific protocolized approach.

If I were a patient, I would want to know both: whether NIV would make me more comfortable, and if it might make me survive a hospitalization that might not end my life but is just a secondary complication that could be reversed. I agree that we need more than just survival data, because survival is not always the outcome we’re looking for, but survival may be important for a patient considering NIV.

Hill: There are 3 categories of patient. In category 1, which is our usual approach, survival is a key goal. I think we agreed yesterday that with patients with COPD in category 1 we don’t need any additional evidence that NIV improves survival. We need to focus on other outcomes, because there’s a lot that can be done to make NIV better, but survival is certainly a key outcome.

Category 2 is the patients who want to survive hospitalization even though they decline intubation, so survival is an appropriate outcome. Patients in category 2 with COPD or congestive heart failure have good survival, although ethics issues would make it extremely difficult to do a formal RCT [randomized controlled trial].

Category 3 is patients in whom survival is not the issue and not an appropriate outcome. We included those patients in our study,1 and their survival is poor, not surprisingly. That’s what Stefano’s [Nava] getting at, and I’m very interested to hear how he put his study together.

At the bedside we should ask, “Are we achieving our goals?” A lot of RTs face situations where they’re forced to put a mask on a patient who is clearly terminal and becomes more uncomfortable because of the mask. The RTs ask, “Why do I have to keep putting the mask back on when I’m just making this patient miserable during his last few hours on earth?” At the bedside we should be asking if we are enhancing or reducing comfort.


Kacmarek: Yesterday we briefly discussed how you could initiate NIV on a patient as a comfort measure but that if you have to restrain the patient you obviously have not achieved your goal. And of course the staff complain, “What are we doing to this poor person? Why are we continuing NIV when it is clearly not providing a better death, but a worse death?”

Epstein: Category 2 is patients who have placed limits on what they want you to do to them, and the goals with
those patients might be very different. Their goal might be, “Yes, I’d like to be well, but I also want to be comfortable and I don’t want to be short of breath.” We already have survival data from the primary trials. I’m not questioning whether that’s interesting information, and I’m not questioning that the patient would like to survive, but shouldn’t the focus be quality of life? Of course, with comfort-mesures-only patients we shouldn’t even look at survival; we should look at quality of death.

Keenan: I agree. It’s important that patients survive, but to truly inform patients we should provide not only an estimate of the likelihood of survival but also of the quality of that survival. The available studies give some idea of their likelihood of survival during hospitalization. Chu et al found relatively short survival over the subsequent year in these patients. Patients with COPD tend to have stepwise reductions in their level of functioning with each admission. When they’ve gotten to the point where they’ve elected not to be intubated and treated, they’re quite advanced.

We need studies of quality of life in patients with COPD who survive hospitalization, especially among those with more advanced disease who elect not to be intubated. Only then can we provide the information necessary for the patient to make a truly informed decision on using NIV but declining intubation. Some patients may elect not to use NIV if their quality of life will be worse than their pre-admission status.


Epstein: I imagine that patients understand that their longevity is compromised, so they’re looking for something different from NIV.

Nava: In many parts of the world the patients are marginally involved or not even asked about these end-of-life decisions. In Italy—you may say I live too close to the Vatican and that’s an issue, but also in England, for example, they do not have a formal DNI order. DNI is typical only in certain countries; some countries have a very paternalistic view.

Wildman et al found that anesthesiologists and intensivists did not admit a large proportion of COPD patients to the ICU because they thought that their survival chances were too low, but in fact their survival was pretty good, despite that they were not admitted to the ICU. This means that our predictions about patients’ survival are pretty bad.

The European Respiratory Society task force found that only 20% of on end-stage respiratory patients had a DNI order. Things are changing, however. For example, Spain is a typical Catholic-oriented country, but they recently introduced the possibility of advance directives. It was mainly related to political reasons; Zapatero took over from the previous prime minister, Aznar, who was very conservative.

Regarding what Nick asked about, of the 10 centers, 2 did not get ethics-committee approval, and 2 withdrew because their nurses did not want to be involved. So we ended up with 6 centers: 3 in Italy and 3 in Spain. It was an RCT with end-stage cancer patients. About 20 to 25% of the patients refused to enroll in the study after they got the explanation of how NIV works, and another 10% withdrew from NIV after they started. Only 60% of patients were eligible for NIV. Our primary outcomes were dyspnea, respiratory rate, morphine use, and a very simple quality-of-life questionnaire. In these patients quality of life is very difficult to measure, and since diseases progress, it is very difficult to accept change. Dyspnea and respiratory rate were reduced with both treatments. It’s surprising because there is nothing there concerning the use of oxygen therapy.

We always use oxygen in these patients, without clear scientific evidence. In our ongoing study we’re finding that oxygen alone reduces dyspnea, though NIV does so a little faster; in the first 2 or 3 hours you get a better decrease in dyspnea and respiratory rate with NIV. The most interesting finding is that they need less morphine with NIV; I expected that they’d need more opioids with NIV.

When I give a presentation about quality-of-life issues, I always start with 2 example patients. One says, “I want to survive for a while because I need to see the birth of my first nephew.” The other says, “I want to survive at least 2 more weeks because I need to see Inter Milan [an Italian football team] win the Italian league.”

We need to understand that the factors that determine quality of life can be quite different for different patients, and we might not agree with the desires that determine those decisions.


Kacmarek: Yes, the quality of life of someone who knows they’re going to die soon is difficult to assess, and their assessment can be different from
our assessment. Many patients with neuromuscular and neurologic diseases who elect continuous mechanical ventilation for years say their quality of life is great. I think I’d never want to live in that condition, but it is difficult to apply quality-of-life data from one person or one group to another, because it really is personal. The question is always what it means to me to continue to live—not what it means to another individual or group.

**Epstein:** We’re not talking about traditional quality of life when we look at people with chronic conditions, but something that’s actually laid out at the outset. We’re talking about goals such as reducing symptoms and having time to put your affairs in order, which are things you can study.

**Hill:** This is an extremely difficult topic to study. Stefano, some of the centers’ ethics committees wouldn’t even approve the study proposal, so those hospitals couldn’t participate. What to do with incompetent patients in studies like this is a conundrum. Do you exclude delirious patients?

**Nava:** Yes.

**Hill:** That narrows the study population quite a bit. Of course, the people we’d most like to hear from—the patients—aren’t around that long most of the time, and we can’t ask them afterwards how their experience was, so we’re very limited in tracking outcomes. But these are very important data you have. The data on oxygen alone are of great interest, though they’re going to apply to a relatively small proportion of the patients you see in this situation. Outcomes such as survival that were studied earlier don’t apply well, and you need new ones when you do these studies. Did you include families in your study?

**Nava:** Yes.

**Hill:** We should take caregivers’ perceptions into consideration too.

**Nava:** One problem was that, with the 20% survival rate we had—which was more than we expected when we designed the study—we faced the problem of whether to prescribe home mechanical ventilation.

**Kacmarek:** There’s nothing in the current data. There’s information on cancer patients’ perspectives on dying, but there’s nothing about the patient’s perspective on receiving NIV to manage a life-threatening episode of a terminal disease. The literature simply reports outcomes. We have an enormous need for information on this.

**Kallet:** I would like to see further study on the dynamic of how somebody starts NIV and can last a few hours before they say no, whereas some people go several days. It would be interesting to study hourly or daily changes in patients’ desires in end-of-life situations. That would be important information.

**Kacmarek:** That’d be tough data to get.

**Pierson:** Randy Curtis1 and others have made incredible strides in showing us that we can do objective research on these very awkward topics that previously were considered maybe inappropriate.


**Kacmarek:** Agreed. It’s just difficult.

**Mehta:** Bob, I wonder if there should be a fourth patient category: patients who are clearly at the end of their lives but are unaware of their diagnosis; they don’t know that they have cancer because the physician hasn’t discussed it with them. We all think it’s inappropriate to intubate, but to give them the time they need, perhaps we should offer them NIV. What do you think about that?

**Kacmarek:** You’re describing a patient who fits into one of these 3 categories, except nobody has told them their clinical situation? We need an ethicist to deal with this.

**Mehta:** They don’t fit into category 3, because they haven’t made the decision not to be intubated.

**Kacmarek:** And they don’t fit into category 2, because they have a terminal disease, but they don’t know about it, and they want to go back to their pre-admission status, so that puts them in category 1 at that point.

**Pierson:** I agree, I think they’re like the patient who completely denies the avalanche of evidence that they are terminal and dying. We’ve all seen these patients who say, “No, I want absolutely everything done; I know I’ve been admitted 6 times in the last 3 months, but I want everything.” That’s a category 1 patient, and if you’re going to respect patient autonomy, you have to agree—unless you’re going to throw autonomy out the window and be paternalistic, which in some areas of the world is acceptable. In the United States, though, it’s not acceptable not to try to do what the patient wants.

**Kacmarek:** That’s a different story; a patient who has been informed and has made a choice. What Geeta [Mehta] is describing is somebody who has not been informed of their medical condition: someone where we have made the choice for them. I don’t know where that fits. The big question is why hasn’t that patient been informed? All patients deserve to know about their condition, and why wouldn’t we tell the patient what’s going on?