machines be excluded from surge-capacity stockpiles, and that BiPAP machines already on hand should be re-purposed for invasive ventilation in the event of a large-scale epidemic. I would like to challenge that position and instead argue that we should plan to use NIV as much as possible during an epidemic.

Branson et al¹ acknowledge that under normal circumstances NIV is the standard of care for patients with chronic obstructive pulmonary disease in respiratory failure. Then they tell us that, "The literature that details the success of NIV in chronic obstructive pulmonary disease clearly demonstrates a substantial time commitment (1–2 h) spent by the RT at the bedside at initiation, which is an impracticality in mass-casualty respiratory failure." The evidence they cite to justify that statement is in an article from 1995.

With so many dedicated BiPAP machines in use, 1 haven't we come a long way with NIV since 1995? In my experience, patients who are dyspneic often express relief within a minute of having the mask applied, and if BiPAP is not working for the patient, then it becomes apparent in much less time than an hour. If we take the suggestion of Branson et al and abandon NIV during an epidemic, and intubate these patients instead, then why would we expect that this practice would reduce our time commitment to them?

The next pandemic could be much worse than the Spanish flu of 1918, which killed 50 million mostly young, healthy people.2 Or it may be a disease like severe acute respiratory syndrome (SARS), that puts older adults with pre-existing illnesses at most risk of dying.3 We don't know the nature of the next epidemic, but if it is on a scale for which our best-laid plans could remain feasible, then most of its victims would not develop full-blown acute respiratory distress syndrome (ARDS). There would be a spectrum of severity and a mix of complaints. While Branson et al are correct in saying that NIV would not help patients with severe ARDS, we are now seeing evidence that the early application of NIV can be used to support patients with less severe hypoxic illness,4,5 so some of those who are infected could probably get by with BiPAP.

Branson et al suggest that BiPAP machines be re-purposed for invasive ventilation, to address a concern that NIV is a high-risk "aerosol producing procedure." It is surprising that they even raise this as an

issue, since they concede that evidence for the "high-risk" theory is weak and unsupported by the Asian experience. They even cite articles that describe how NIV was used safely and effectively with SARS patients in China. Why then would a concern about occupational risk, which is overblown according to empirical evidence, justify intubating a patient when that is not in the patient's best interest?

There is a great deal of evidence that hospitalization time and mortality are reduced whenever patients can be ventilated noninvasively rather than intubated.⁶ During a mass-casualty event we would still aim to give each patient his best chance of recovery, so how could we subject anyone to the risks associated with being intubated in a case where intubation could be avoided?

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The authors respond:

We appreciate John McCracken's assessment of our paper. First, we want to clarify

that we never intended to promulgate our recommendations as gospel. Currently, there is insufficient direct evidence to conclusively determine optimal strategies for oxygenation and ventilation during a massrespiratory-failure surge event. We believe, though, that the various available positivepressure ventilation (PPV) strategies will not all be equally effective for such events, and strong indirect evidence even suggests that some PPV strategies may be nearly useless (eg, automatic resuscitator to ventilate a patient with severe respiratory failure over numerous days). McCracken argues that "we should plan to use noninvasive ventilation (NIV) as much as possible during an epidemic." We respectfully disagree. For an event when the number of patients with severe respiratory failure will far exceed the usual capability of appropriate staff and PPV equipment, we strongly recommend against planning for widespread use of NIV when considering (1) optimal use of existing PPV devices, and (2) stockpiling additional PPV equipment.

The United States Department of Homeland Security National Planning Guidelines are intended to coordinate and prioritize emergency preparedness efforts at all response levels. Those guidelines contain 15 National Planning Scenarios, and at least two thirds of those may include catastrophic numbers of patients in acute respiratory failure.2 A successful PPV strategy for such a catastrophe must be grounded in accurate predictions of patients' needs and healthcare systems' and communities' capabilities for these events. There is wide variability in the predicted distribution of types and severity of respiratory failure and the characteristics of the affected populations (eg underlying chronic obstructive pulmonary disease [COPD] or previously healthy). This is where the direct evidence base is thin-

When an event occurs, the newly available data may suggest a better PPV strategy than ours for that event. Unfortunately, waiting for the disaster to occur to develop the evidence-based strategy "just-in-time" will probably prove to be "just too late," and many patients may not have access to a life-sustaining intervention. Our surge-event PPV recommendations were developed to apply across the broad range of mass-respiratory-failure scenarios. The extensive investment for equipment procurement and maintenance, logistics planning, and enduser training requires surge PPV concepts

to be sufficient across the range of plausible scenarios, rather than having different solutions for different hazards. Surge PPV equipment must therefore be sufficient for "airway protection"/neuromuscular ventilatory failure (botulism and trauma), air-flow obstruction (inhalation exposure in patients with underlying airways disease or nerveagent exposure), and, most importantly, hypoxemic respiratory failure due to pneumonia, large hemorrhagic effusions (eg, anthrax), or acute lung injury (ALI) and acute respiratory distress syndrome (ARDS) (eg, plague, influenza, non-water-soluble chemical inhalation, trauma, neutropenic sepsis during acute radiation syndrome, and possibly anthrax).

In the setting of insufficient direct evidence, optimal surge PPV planning has been compiled from numerous related fields and extrapolated to disaster scenarios to develop defensible strategies. Because data must be assembled from divergent fields (eg, critical care, disaster medicine, virology, public health), national and international panels with broad ranges of expertise have been convened to develop PPV surge guidance. Their recommendations have been derived from published literature (when available). opinions of experts in disaster management, and experience of caregivers who have participated in care of patients with severe febrile respiratory illness. The groups consistently caution against deliberate liberal use or stockpiling of NIV PPV equipment. These recommendations have been vetted through medical societies3,4 and published in peerreviewed journals.⁵⁻⁷ The recommendations in our paper were crafted from the iterative efforts of those groups.

The most recent reviews of NIV support its everyday use for acute respiratory failure in hemodynamically stable patients without ongoing cardiac ischemia due to COPD exacerbation, cardiogenic pulmonary edema, or ALI/ARDS in immunocompromised patients. 8-10 NIV probably also has a role in postoperative respiratory failure and deliberately bridging selected patients after extubation. 11 However, most mass-respiratory-failure events will have predominantly hypoxemic respiratory failure, and data that conclusively support use of NIV for that indication remain elusive.

McCracken suggests that, "most... victims would not develop full-blown ARDS. There would be a spectrum of severity and a mix of complaints." We agree there may be a spectrum of disease severity and pa-

tient outcome. Many patients will have persistent P_{aO₂}/F_{IO₂} (ratio of P_{aO₂} to fraction of inspired oxygen) > 300 mm Hg, and, without other indications for intubation or mechanical ventilation, will not require PPV. They were not intended to be considered for surge PPV. For those who require PPV due to hypoxemia, the spectrum of disease is unlikely to be well-defined by the level of respiratory failure (eg, presence or absence of ARDS). Discriminating between patients with and without ALI/ARDS is not very reliable, 12 and the mortality is similar. 12,13 This is not surprising, because the majority of patients with ALI also meet ARDS criteria. Most of these patients meet both criteria the same day that ALI criteria are first met.13

Even in a group of patients with ARDS (mean P_{aO_2}/F_{IO_2} 128.6 \pm 33.3 mm Hg at day 0), outcomes are highly variable.14 In that study, the temporal changes in P_{aO₂}/ F_{1O2} suggested that initially patients are quite ill and then some start to resolve their lung injury. This disease course suggests that an up-front strategy of a less-supportive PPV device may be imprudent. Most patients with ARDS die of multi-organ dysfunction, not refractory hypoxemia.15 Hence, the spectrum of disease severity in mass-respiratory-failure events will probably vary by number of non-pulmonary-organ dysfunction and presence of hemodynamic instability. ARDS alone is not the worst-case scenario and does not describe a futile response situation. We therefore believe that surge PPV equipment must be able to successfully manage patients with ARDS.

In 1999 Confalonieri et al found a lower intubation rate (21% vs 50%, n = 56, p = 0.03) in patients with acute respiratory failure due to community-acquired pneumonia during a randomized controlled trial of NIV versus standard treatment. 16 More than 40% of the patients had COPD, and those patients had a lower intubation rate, shorter intensive-care-unit (ICU) and hospital stay, and lower 2-month mortality. Among the patients without COPD there was no statistical difference in intubation rate, and a nonstatistically-significant point estimate increase in hospital mortality and 2-month mortality. Ferrer et al studied NIV in patients with acute hypoxemic respiratory failure without both underlying severe chronic respiratory comorbidities and hypercapnia.17 Intubation rate, incidence of septic shock, and ICU mortality were all lower in the group that received NIV. These results are compelling, but they may not be generalizable to all patients with respiratory failure, since 64 of 172 eligible patients (hypoxemia on 50% oxygen via air-entrainment facemask) were excluded. Some were unable to cooperate with NIV due to agitation (n = 45), had severely depressed consciousness (n = 5), hemodynamic instability (n = 4), or required immediate intubation (n = 10). Also, the intubation and mortality rates were not better with NIV than with the standard treatment in the approximately 15% of patients with ARDS. In contrast to the Ferrer et al study, which found benefit from NIV in selected patients with pneumonia, Honrubia et al found no apparent benefit from NIV in patients with pneumonia. 18 As in the other studies, a substantial proportion of patients with respiratory failure were unable to be randomized.

The above-described studies may be optimistically interpreted as indicating that NIV has a role in selected patients with hypoxemic respiratory failure, but NIV's utility in all patients with respiratory failure due to pneumonia and ARDS remains suspect. Of course, the use of NIV in hemodynamically unstable patients is even more uncertain. For a 20-day period in 2002, in 70 ICUs in France, 1,076 of 1,943 (55%) patients required PPV. 74.9% were intubated prior to or at ICU admission. 55.8% of those who received NIV (12.9% of all who required PPV) were able to forestall intubation. Patients with de novo respiratory failure who had a respiratory rate > 35 breaths/ min and $P_{aO_7}/F_{IO_7} < 200$ mm Hg were more likely to fail NIV.19 Again, NIV may have benefited a small subset of patients in this study of everyday practice, but, overall, NIV was not an appropriate option for the overwhelming majority of patients. This is probably in part because patients with conditions less likely to respond to NIV (eg, de novo respiratory failure [42%]) were more common than patients with acute-onchronic respiratory failure (16%).

Another explanation could be that the limited overall benefit of NIV was due to missed opportunities caused by underutilization of NIV in France. But that explanation is not supported by recent reports from ICUs that have extensive experience with NIV. In those ICUs the overall percentage of patients with ARDS and acute hypoxemic respiratory failure who can remain unintubated is relatively small. Antonelli et al had a 50% success rate with NIV, after excluding patients with hypotension, excess secretions,

more than one organ failure, bleeding, and neurologic disturbances.²⁰ Close inspection of the data reveals that, of the 479 patients who met the ARDS criteria, 322 (69%) were already intubated, due to altered mental status, inability to manage secretions, hemodynamic or electrocardiographic instability, severe trauma, and/or more than 2 organ failures. The remaining 147 patients (30.6%) were then studied, and in fact only half of those selected patients with ARDS (15%) were successfully ventilated with NIV.

The experience that a high proportion of patients with hypoxemic respiratory failure cannot be successfully managed with NIV was also reported from a large academic center in the United States.²¹ Those authors and other recognized ventilator experts have therefore cautioned against liberal application of NIV to patients with ALI and ARDS.

Since we anticipate that most victims will have pneumonia, ALI, or ARDS during most mass-respiratory-failure events, we caution against stockpiling PPV equipment specifically designed for NIV and not intended for invasive ventilation. In addition, the majority of devices designed for NIV are not capable of volume ventilation. Volume ventilation is the only breath type that has been demonstrated to have a mortality benefit in ARDS.²² Caution must even be applied when considering NIV devices that have a volume-control ventilation mode, because these devices are likely to perform less well than devices designed for invasive mechanical ventilation, when used for invasively ventilating patients with severe respiratory failure. Hence, we advise against stockpiling NIV ventilators, but we encourage re-purposing NIV ventilators already on hand for invasive ventilation, if no other option exists. That is, though NIV ventilators should not be stockpiled, NIV ventilators already present and that are capable of ventilating through an endotracheal or cuffed tracheostomy tube should be re-purposed during a disaster. We do not believe that we or most other clinicians are able to immediately discriminate between all patients who will tolerate NIV and those who will fail NIV and require emergency intubation. Already a large proportion will bypass NIV because most clinicians will not attempt to use NIV on hemodynamically unstable patients and those with multi-organ-dysfunction syndrome. Several studies have shown that, in patients with hypoxemic respiratory failure, a low PaO2/FIO2 after 1 or 2-hours, and a high Simplified Acute Physiology

Score II score portend the need for intubation.^{23,24} The Simplified Acute Physiology Score requires several laboratory studies, and ideally is scored with the worst variables over 24 hours. Time and laboratory capacity may not be abundant resources during a mass-respiratory-failure event. Also, experienced staff are likely to be in short supply, and patients who fail NIV may not be identified at the 1 hour or 2 hour mark. We disagree with McCracken that early watching of patients is no longer resourceintensive. The data indicate that the first 2 hours of NIV is very important for getting the patient to tolerate NIV and to identify NIV failure.21 Even after the first day, intense observation is necessary. Schettino et al reported that 38% of NIV failures in hypoxemic respiratory failure occurred after 24 hours,²¹ and Antonelli et al reported that 30% of failures occurred after 48 hours.²³ A high proportion of these patients required intubation, and their mortality rate was high.

Even if NIV equipment and adequate numbers of appropriately trained staff are available, we would still caution against planning to use NIV to ventilate patients with respiratory failure, including those who have conditions that are more likely to respond to NIV (COPD exacerbation due to viral respiratory infection). McCracken appropriately highlighted the uncertainty regarding NIV and secondary transmission of respiratory infection.^{25,26} Some facilities successfully used NIV during the severe acute respiratory syndrome (SARS) epidemic, albeit with many modifications (expiratory filters in rooms with negative pressure, > 8 air exchanges per hour, and powered air-purifying respirators), others restricted use, and some reported a possible mode of transmission.^{27,28} If the pandemic strain of influenza is able to bind to receptors on the proximal respiratory epithelium, then perhaps transmission can occur via NIV. Also, if we apply McCracken's methodology to all personal protective equipment, we could argue that the lack of secondary transmission of SARS in the United States, despite inadequate use of personal protective equipment, indicates that even basic personal protective equipment is not needed.29

Paramedics are not obligated to rescue a person in an unsafe building (eg, fully involved with fire or structurally unsound), even if the victim would clearly benefit from assistance. Similarly, clinicians should wear personal protective equipment when providing respiratory care for patients with contagious diseases for which effective prophylaxis is not available and that can cause severe disease. The data are limited and inconclusive on the risk of SARS transmission via NIV, and we do not know if NIV will be implicated in transmission of other pathogens. We therefore stand by our recommendation not to plan for widespread use of NIV, even with existing equipment, when a contagious pathogen is suspected.

We find no data in the literature to change our stance regarding NIV. The basis of our recommendations includes provision of best care for the patient and safety for the caregivers.

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Blow-By Revisited

Respiratory care has changed substantially since I began my career as an "inhalation therapist." Intermittent positive-pressure breathing with a handful of medications was the predominant treatment. Today, respiratory therapists (RTs) utilize a wide range of drugs and aerosol devices supported

by evidence-based research. What has not changed is our primary choice of interfaces: mouthpiece or mask. Disposables aside, there is little difference between a 1970 and 2008 era mouthpiece or mask.

One "interface" between the nebulizer and the patient has undergone dramatic changes: the RT. RT education has transitioned from "on-the-job oxygen orderlies" to associate and bachelor of science degree programs, with a few graduate-level schools. For my purpose, it is the RT who chooses the appropriate interface for an infant. Unfortunately, infants are not familiar with the current literature, they don't know that a mouthpiece is the best interface, nor do they care that a "well fitting" mask is the next best. Infants come with a wide variety of temperaments; a few, with a modicum of care, will let you put a mask on their face and will even tolerate it for the time it takes to deliver the medication. However, for a variety of reasons, a substantial number will not tolerate a mask on their face. Some will let you hold it 2 cm from their face but will not let you put it on their face.1 Fortunately, RTs are familiar with the literature that supports an alternative delivery method: blow-by.2-8

The delivery and measurement of drug deposition in an infant lung model or in vivo is as much art as science, as reflected by the wide range of results in the literature. Estimates for blow-by range from negligible to greater than 100% of a mask-delivered dose,⁵ the wide range due to differences in nebulizers, blow-by technique, distance from the patient, and measurement methods. The results of the research support the use of blow-by via T-piece or corrugated tubing held half an inch (1.27 cm) or less from the face, as a technique in those infants for whom a mask is not practical.^{2-5,7}

Delivery of aerosolized medication to pediatric patients will continue to be a challenge that requires further research into the best techniques, interfaces, and the variables that the RT can control at the bedside. It is critical that RTs and physicians maintain familiarity with the current literature on treatment techniques and medications. However, for a specific patient, research can only provide guidance as to the appropriate technique. It is the role of the RT to evaluate the efficacy of the treatment regimen: Is the patient's work of breathing reduced? Are there fewer retractions? Is the respiratory rate lower? Are breath sounds improved? It is the RT at the bedside making a post-