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Strategies for Providing Mechanical Ventilation in a Mass Casualty Incident: Distribution Versus Stockpiling

John Wilgis MBA RRT

Federal funding provides state public and private health care systems the ability to build and maintain a reserve supply of ventilators for emergency response to mass casualty incidents. Studying and planning the ventilator reserve capability requires subject-matter expertise, identification of best mechanical-ventilation practices and quality care standards, and contingency planning. Natural disasters such as pandemic influenza, or man-made disasters such as bioterrorism could necessitate field use of numerous mechanical ventilators. This paper discusses the pros and cons of stockpiling ventilators at one site (to be distributed as needed to disaster areas) versus increasing the number of ventilators at all hospitals. Respiratory-device corporations, respiratory professional associations, and respiratory therapists should be involved in the planning and development of respiratory mass casualty response systems. Key words: alternative care standards, caching, emergency management, Health Resources and Services Administration, mass casualty incident, mechanical ventilation, preparedness planning, public health, ventilator. [Respir Care 2008;53(1):96 –100. © 2008 Daedalus Enterprises]

Introduction

Throughout history, events have shaped the public and private health care system. Disease outbreaks, natural disasters, and warfare have forced changes to health care response capability for communities and society. Mass casualty incidents of any type alter health care response and necessitate that providers do the most good for the most people with the resources available. This premise is the foundation of emergency response in the United States, and many aspects of care delivery must be developed and coordinated for effectiveness, efficiency, and economic impact.

Recent events (eg, the attack on September 11, 2001, the anthrax attack in Washington DC, severe acute respiratory syndrome, and avian flu) have raised awareness among public and private health care officials of the need for planning, preparedness, and response capability. The 2 main public health issues that need to be addressed are: (1) a system for surge capacity and (2) a process to opti-

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mize patient outcomes in the face of health care needs that exceed available resources.[1] The largest component of a response effort for patient surge is the resources that enable successful reaction. Human resources, especially qualified medical professionals, are in short supply, and the same can be said for certain medical products and vital equipment such as ventilators.

Planning and Preparedness

Ventilators are at the center of the preparedness planning and emergency management debate. Man-made or natural disaster could create a large number of victims who require mechanical ventilation. Though goals for improving hospital surge capacity are addressed in the guidelines from the Joint Commission (formerly the Joint Commission on Accreditation of Health Care Organizations), the National Bioterrorism Hospital Preparedness Plan, the Centers for Disease Control and Prevention Public Health Emergency Preparedness Web site (http://www.bt.cdc.gov), the Urban Area Security Initiative, and the Metropolitan Medical Response System, specific target requirements differ.[2] Planning estimates and assumptions must consider several factors to enable states to properly care for people who need ventilator support.

At the top of the debate is the question of whether to stockpile ventilators in a strategic location and distribute them to disaster areas in the time of need, or instead to increase the number of ventilators at all hospitals and thus increase their response capability and avoid the distribution time in the stockpile strategy. Both plans are controversial, and each jurisdiction must weigh for itself the pros and cons of the 2 strategies. Plans that deal with the allocation of critical care resources present substantial challenges.[3] Public and private county, regional, and state health officials must cohesively determine the best approach to preparing for a disaster that would require numerous ventilators.

Partnership Engagement

Various stakeholders are involved in planning and building emergency ventilator reserve capacity. Government agencies, the private business sector, hospital associations and spokespeople, and others are involved in the process. Response capability and recovery are directly tied to these relationships, and team engagement improves the chance of developing functional, operable response plans. A formal system of group development and process defines how members will deal with key issues in developing and managing the ventilator emergency-response capability. Table 1 lists concerns that planners and stakeholders must consider.

Table 1. Issues in Creating a Strategic Cache of Mechanical Ventilators

Federal and state statutes that impact procurement and use
Available grant funding process
Partner and leadership roles
Technical equipment specifics
Supply and inventory specifics
Distribution factors
Communication abilities
Volunteer engagement
Security measures
Preventive maintenance
Financial impact

Table 2. Groups Involved in Planning for a Disaster That Would Require a Large Number of Mechanical Ventilators

Federal
Department of Homeland Security
Federal Emergency Management Agency
Department of Health and Human Services
Centers for Disease Control and Prevention
Environmental Protection Agency
State and Local
Local and state police
Department of health
Fire and rescue departments
Hospitals
Private
Professional associations
Industry representatives
Physician groups
Healthcare workforce

Creating a team and a system for ventilator reserve requires considering the various factors that affect ventilator storage and distribution across a county, region, or state. Public health and hospital representatives, teamed with ventilator physiologists, clinicians, and industry, must work cooperatively to determine the readiness standards, operational plans, inventory creation and management, acquisition standards, security measures, and distribution methods best suited to meet the target capability.

Planning and preparedness efforts extend beyond first responders and receivers. Many of these bring different perspectives and authority to the table. Table 2 shows some of the groups cooperatively engaged in planning, funding, and responding to the needs of state emergency management programs.

Federal funding provides the ability to improve disaster response capability. A rough estimate of the cost to double the number of ventilators in the United States, with safe but inexpensive equipment, is $1 billion.[4] Over the past 6 years, grants from the United States Department of Health

and Human Services Health Resources and Services Administration, which is administered through the Office of the Assistant Secretary of Preparedness and Response, have allotted specific dollar amounts to states to enhance the health care system response capability. Health care systems are all aspects of health response in a continuum of pre-hospital and hospital assets. Health Resources and Services Administration grants have made it possible for health care systems to improve mechanical ventilation capability, and care should be taken to consider cost disparity of caching systems versus direct distribution.

The respiratory care profession is in the middle of the planning and debate. Respiratory therapists are assisting agencies at all levels to assure that emergency ventilators are not measured by quantity alone, but also by clinical capabilities,[5] and the respiratory care profession as a whole is taking a leadership role in identifying the correct strategies for dealing with incidents that would create a large number of patients in need of mechanical ventilation and ensuring that the plans reflect current evidence-based mechanical ventilation practices.

Essential Education

Federal funding has provided state public health and health care systems the ability to build ventilator reserve capacity, but there is more at stake than just buying the equipment. All the stakeholders need education on mass casualty incident response that is as evidence-based as possible for situations in which health care needs exceed health care resources. The disaster-response system must incorporate staff, equipment, and supplies in a clearly structured, efficient system.[1] Leaders must be educated on the subject and the issues. First responders and receivers must have clinical core competencies in disaster response. Agency partners and public health officials need education on specific functions of hospital-based professionals. Industry partners should provide product-specific training materials specifically designed for disaster scenarios. And citizens need education on realistic expectations about what care to expect in a disaster and how they can (and can't) assist in the response.

Respiratory therapists must educate themselves on the standards and practices of public health agencies, government offices, other professions, and medical disaster response procedures. Respiratory therapists and their professional associations can help educate other stakeholders on important issues such as mechanical ventilation in a mass-casualty incident and the question of stockpiling versus distributing ventilators. Further education will also assist in identifying the support and logistical issues.[5] The education efforts should engage all stakeholders and work toward building consensus on approach, methods, and a course of action.

Necessary Equipment

Most hospitals cannot afford to purchase and maintain a large supply of sophisticated, full-feature ventilators to hold in reserve for mass casualty events.[6] Planning, decision making, and agreeing on an operational approach is difficult, and there are diverse strong opinions on the subject. Best practice and data should substantiate any negotiated settlement. The critical assessment should consider: single or multiple brands and models of ventilator equipment; required features; gas source; dependability and redundancy of power; infection-control factors; available ventilation modes; preventive maintenance requirements; ancillary equipment and supplies needed; equipment evaluation and performance measures; and cost comparison.

A state's effort to create a ventilator reserve capacity requires subject-matter expertise, identification of best practices and quality care standards, and contingency planning. Many states and countries (eg, Florida, New York, California, Ohio, Canada, and Israel) have examined the complexities of stockpiling ventilators for a mass casualty incident, and their findings can contribute to an informed debate.

To begin, a state needs to know how many ventilators currently exist and are in daily use within its borders. This information can be obtained from the state hospital association, under the auspices of the American Hospital Association.

Next, the following questions need to be addressed:

- Does the state augment ventilator resources during a time of need?
- If so, are the ventilators stockpiled or distributed to hospitals?
- How is this done? Federal funding? Other means?
- What is the process and who is involved?
- Who is making the decisions?
- Have they consulted with respiratory therapists in their state?
- What processes, specifications, and standards determine equipment selection?
- Are issues such as redundant power, gas source, infection control, and preventive maintenance addressed?
- Is a standardized piece of equipment being used?
- What about supplies such as tubing and circuits, suction catheters, and humidification devices?
- Is there consensus on when to use invasive versus non-invasive ventilation?
- Is the state's respiratory care profession engaged in the process?

Table 3. Pros and Cons of Stockpiling Ventilators in a Central Warehouse

Pros	Cons
Maintain accurate count of working and nonworking ventilators	Costs to: warehouse; maintain transportation modes to deliver ventilators at time of need; education of hospital personnel; replace unused disposal equipment; train biomedical technicians; maintain equipment; replace unused batteries or nonmaintained batteries
Large number of ventilators can be delivered to hospitals experiencing an isolated disaster	Clinicians do not develop trouble-shooting skills with the type of ventilators stockpiled because they do not regularly work with that type of ventilator
Ensure timely ventilator repairs	Takes time to deliver ventilators to hospitals
Ensure optimal distribution to hospitals during a pandemic	Need to develop a comprehensive plan for ventilator delivery
Decrease ventilator maintenance costs and ensure a maximum number of working ventilators	Hospitals depend on government for main service and repair during use
Reduce the need to train a large number of technicians to maintain ventilators	

Table 4. Pros and Cons of Distributing Ventilators to Hospitals

Pros	Cons
Hospital staff develop and maintain their expertise and trouble-shooting skills with the ventilators, which reduces government cost of clinician education	If the ventilators are regularly used for nondisaster patients (instead of kept in storage at the hospital), this increases wear and tear on the ventilators, which necessitates more frequent maintenance
Improve hospital staff's trouble-shooting skills	Difficult to deliver a large number of ventilators to an isolated disaster
Cost of disposable equipment becomes hospital's responsibility	Need guidelines for acquisition and return of ventilators
Asset to hospitals	Increases cost of training for biomedical technicians
No need to develop a comprehensive plan for ventilator delivery	More difficult to keep accurate count of working and nonworking ventilators
Increases willingness to participate in state-wide disaster plans	
Ventilators remain charged and ready	
Cost of training is hospital's responsibility	
Hospital staff can maintain current competence with new employees	

The answers to those questions help identify the strengths and opportunities for improvement.

Distribution Versus Stockpiling

Is it better to stockpile ventilators at one site and distribute them to disaster sites as needed (the stockpiling strategy), or instead to increase the number of ventilators at all hospitals (the distribution strategy)? The answer might not be the same for every jurisdiction. Many states have created work groups to address the question of distribution versus stockpiling, and respiratory therapists and their professional organizations are participating. Tables 3 and 4 list pros and cons of stockpiling versus distribution. States and their health care partners must determine what is best for their systems. Hospital preparedness grants from the Health Resources and Services Administration and the Department of Homeland Security are the primary resource for funding the acquisition of disaster-response ventilators.

Hospitals typically have enough ventilators to meet everyday demand, but not enough for demand peaks, at which time they rent additional ventilators.[6] The factors in the choice of distribution versus stockpiling include: equal distribution, standardized product selection, funding process and sustainment, education and training, preventive maintenance, hospital resistance and agreements, and distribution schedules. There are several challenging questions to address in planning for mechanical ventilation in a mass casualty scenario:

- If the ventilators are distributed to hospitals, will the ventilators be stored and not used except for a disaster?
- It is not likely that the model/brand of ventilator held in reserve for disaster will be same as the model(s)/brand(s) the hospital regularly uses, so if the ventilators are stored (instead of regularly used) at the hospital, will the hospital staff be familiar with the disaster ventilators and be expert in their use? This same question applies if the ventilators are stockpiled.
- If the disaster ventilators are regularly used (instead of stored) at the hospital, what percentage of them will be immediately ready for use in a disaster?
- If the ventilators are stockpiled, how long will it take to deliver them to the disaster area?

Some jurisdictions have chosen stockpiling. The stockpiling strategy requires working through regional differences, determining and managing the storage location, security measures, access, costs, oversight, accountability, and distribution and (post-disaster) retrieval of the equipment. Stockpiling is more expensive than distribution. Logistical considerations of stockpiling include maintaining the equipment, replacing equipment if it becomes obsolete, end-user training, and distribution/retrieval.[6] The most difficult management issues are preventive maintenance and costs. In some highly populated areas stockpiling might be cost-prohibitive.

The challenges are many and the debate is heated. Some states have made progress in working cooperatively with state and federal partners. What is important for everyone to remember is the emergency management imperative, Do the most good for the most people with the resources available. In an ideal world, there would be enough ventilators for everyone when needed, but reality forces us to determine contingency plans. The decisions may be unpopular with some, but we must determine the best course of action and remain consistent, which is not easy, and due diligence is imperative.

Decisions made by emergency management and public health planners impact the response capability and capacity of health care systems and facilities. Respiratory therapists should be involved in the planning. Many states have medical capability planning teams that receive help from the American Association for Respiratory Care and state professional societies. Continued professional emphasis and education are needed to expertly address the issue. Though the debate continues on alternative care standards, optimum ventilation modes, education, and resource management (both human and material), one thing is clear: current mechanical ventilation capacity is inadequate for many mass casualty incident scenarios, and it needs more development and strengthening.

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Summary

States must determine how they are going to manage health care surge in a mass casualty incident. Essential resources such as ventilators can be stockpiled or distributed, and there are pros and cons with each option. Understanding the various factors associated with stockpiling versus distribution establishes a foundation of preparedness to meet the perceived needs of a community. Ventilator reserves must be versatile enough to meet the ventilator demands of a mass casualty and/or pandemic event.[5] Federal funding has provided a means for hospitals to acquire ventilators, but there continues to be an insufficient number of ventilators available for a worst-case event.

Discussion

Muskat: John, thank you. That was excellent and thought-provoking. I have a couple of questions concerning the ventilator, concerning the option of choosing the hospital in-place storage versus the cache approach. Do we know the life expectancy of a ventilator that is going to be used on a daily basis? I'm not sure that the funding mandate that we've gotten since 9/11 is going to hold up forever. Are we using up these stockpile ventilators? Why wouldn't a private hospital, if they are given one of these ventilators by the state, just buy one less of their own, since they get to use it?

Wilgis: Excellent questions. I will start with your first one, and that's the life expectancy. We have not really looked at how well they're holding up. That is something that we try to get feedback about from our hospitals. I am fortunate in my role with Florida Hospital Association that I travel all over the state. My role is to work with hospitals on all of this stuff, so I do communicate very well with not-for-profits, for-profits, everyone. And I've had mixed reactions. There are some hospitals that have said, "We don't use them, we hold them in our own little cache room, and we bring them out from time to time." And I've had some hospitals say, "We are just using them for transport." I've had hospitals say they use them every day.

This is a concern to me because of the wear and tear on the units and the issue of its not being available when you would need it in a disaster. So I don't really have any concrete data on life expectancy. The Uni-Vent 754 has been battle-tested. I would ask you, what do you see in your experience in Iraq with the wear-and-tear issue? I mean, that's an extreme environment. At least in a hospital it's a little bit more controlled.

Muskat: In the extreme environment there is definitely wear and tear. The biggest problems have been dust getting into the ventilators and a declining battery half life. The life expectancy for a ventilator in Iraq is somewhere on the order of 2 years. Then it just simply gets turned into the warehouse and we never see it again. So that clearly is an issue, and I think that if you adopt the strategy of giving it to the hospitals, that's a question that not only needs to be investigated, but really giving a clearer set of understanding to the hospitals and say, look if we're going to give it to you, you need to set it aside but maintain it. I think if you don't, you're going to run the risk that when we really need it 5–10 years from now, it won't be available.

Wilgis: We have had hospitals come back to us and ask if they can spend their HRSA [Health Resources and Services Administration] funds on preventive maintenance and not ventilator purchase. One thing hospitals have had to replace is batteries. That has been a real issue for them. And your second question was. . . ?

Muskat: If the hospital is given one, why would they just not buy another one of their own, particularly if they are encouraged to use the gift ventilator. In a cost-conscious environment, hospitals are cutting corners wherever they can.

Wilgis: Again, hospitals are all over the board. We have some that do that and they're very grateful, especially some of our smaller, rural hospitals where they might have 5 ventilators in their whole fleet. Now we're giving them a couple to embellish their stockpile internally. We have other facilities that take their money and buy the top-of-the-line ICU [intensive care unit] ventilator, not thinking about a surge event. So, again, it comes down to the fact that we can only recommend what we think is appropriate. Hospitals can then choose what they want autonomously. It has been a challenge, and I think education about the process and planning essentials is key.

Rubinson: Do you have an ideal formula in Florida for distribution? Because I saw on your pros-and-cons slide you actually put delivery time is longer when you cache vents [ventilators] centrally. Obviously, if it's a spread-out event, then that may be true. But if they're regionally cached you don't have to go to each hospital and take ventilators away. So the other thing is the ratio; right now what I'm seeing is that if you bought 800 ventilators, while a big number, in total if they are all distributed evenly, that is less than 4 per hospital in Florida.

Wilgis: Let me start with your first question. We do have a mechanism for distribution. It started with one region that was caching. This was the northeast Florida region, and they were holding everything back. They had a pretty good formula of how they were going to send the units out to about 20 hospitals. The state department of health worked with individual counties to develop this process, and the counties controlled the distribution. A state-wide distribution plan or a formula is addressed through mutual aid and emergency management planning.

Florida statute describes the premise of how to respond and a sequence of events. The process begins with a declaration from the governor and goes from there. That's why I was interested in your comments yesterday about hospitals declaring disaster to their county EOCs [emergency operations centers] and going the other way. Your second question was. . . ?

Rubinson: Obviously, there are pros and cons, which you set out, but even if you bought 2,000 ventilators, if you distributed all of those out, that is still less than 10 per hospital.

Wilgis: Agreed. This is where it gets complex. Florida uses what they call Regional Health and Medical Co-Chairs. These are folks who work with the department of health. Three are physicians, one is a nurse, the others are county or county health department officials. These folks are charged with making decisions for their entire region. So, they select the hospitals that are funded. We know that we can't purchase enough ventilators for every hospital every year. The co-chairs herd the cats. Their role involves deciding which hospitals have the biggest gaps and which need the most support.

They started with our large trauma centers first and our large urban hospitals (where probably the most number of casualties would go to) and then they worked from there. Now we are looking at the gaps of other facilities, like our rural hospitals. The Regional Co-Chairs have a role in deciding how vents get distributed. Hospitals work with a Regional Hospital Coordinator who makes sure the process comes together and that hospitals live up to the language of the grant and all of that. It's really a complex system to learn to work within, and any of these roles can, and do, change.

Talmor: You mentioned sole-sourcing for ventilator purchasing. That is something that really concerns me and something that we've actually decided against in Massachusetts. It is worrying when a country the size of Canada decides on one ventilator, the Newport, which is essentially a ven-

tilator at the end of its development cycle. I see that happening in many places around the United States. Ventilators like the Uni-Vent 754, like the Newport, like the LTV 1200; all of these are 15-year-old ventilators that are being purchased in mass quantities. You open yourself up to problems; if there's a recall or if there are breakdowns, you are really losing capacity. For that reason, in Boston at least, or Massachusetts more correctly, we have decided to go with at least 2 ventilator types. I was wondering if you could comment further on that or if anybody else here could comment on that?

Branson: In Ohio the decision was made to go 50/50, so that if they did have one ventilator go down because of recalls, they would in fact not lose all of their capacity, and I think that's based on the CDC [Centers for Disease Control and Prevention] thinking as well—that if you have half and half, you won't all be wiped out by a single component failure or loss, although that adds to your education requirement because now you have to teach people how to use 2 ventilators, not just one. Every issue we bring up here has advantages and disadvantages as well. At present we are all speculating, because we have not tested the system.

Muskat: On the other hand, if you take a ventilator that's near the end of its development cycle, then you're going to get a ventilator that has been presumably tried and true for a number of years, so the likelihood of a recall is less likely. So, again, the trade off is that you have 2 ventilators that have 2 completely different systems, 2 circuit systems and so forth. The CDC's example with its 2 different ventilators, their different storage requirements and so forth, is a good example of what happens when you have 2 different items serving the same purpose.

The military made the choice to use the Uni-Vent 754 not only for the Air Force critical care teams but also did so for all of the field hospitals. Everybody used the same ventilators, so the transfer of patients became very seamless, so that you could literally change one circuit to the next and all you did was keep moving the ventilator back and forth. I would throw out that idea as a counter-argument to the idea of splitting.

Wilgis: I would just like to add some comments. In Florida we served as a group of subject-matter experts to the state. Uni-Vent 754 was already in the game. They had secured a contract for all ventilator purchase through HRSA funding for the state. At the time, Florida's funding went to purchase Uni-Vent 754s for hospitals. They were used widely in the military, they had air-worthiness through certification through DOD [Department of Defense[. We looked for standardization and an easy way to educate everyone. We worked very closely with that manufacturer and our state representatives to help achieve all of that. We developed a list of standards and specifications, starting with CDC criteria, and made the list very detailed. Some of the input influencing our decisions came from hospitals. Hospitals were saying, "We don't want that product, we want to look at something else," and that is why we opened up and went away from a sole provider.

Talmor: I would like to make a comment semi-related to this. While these transport type ventilators have been around for many years and are well-tested in the scenarios that they have been used in, the scenarios that they have been used in up to now aren't really avian influenza pandemics. They're being used as transport ventilators or for short-term ventilator management of young people with extremity injuries in Iraq.

So, again, we have a lot of unknowns as to the abilities of these ventilators to actually support patients who are sick with ARDS [acute respiratory distress syndrome]-like symptoms of avian influenza. There's been good work done by several people, some of them at this table, but I think we still have more unknowns than knowns on that.

Branson: I'm not in the military—but the injuries in Iraq from the improvised explosive devices are a combination of blast, massive blood loss, tissue destruction, reperfusion injury after massive transfusion, and with acute respiratory failure. These patients are on up to 20 cm H_2O PEEP [positive end-expiratory pressure] and are ventilated successfully from Balad to Landstuhl. You don't need a $30,000 ventilator for all these patients. It's just what we do because we have that luxury here in the United States. If you were stuck, you could go back and use an MA1 on lots of patients and be very successful. Just because we have this standard where we have to have the most expensive, most bells-and-whistles and most modes, none of which have any evidence that they are any better.

A host of portable ventilators usually thought of as transport, home-care, subacute-care ventilators could be successfully used to ventilate sick patients in the ICU. Just because we use them for only short periods of time, there is no evidence that suggests that they wouldn't continue to support oxygenation and ventilation for a longer period of time. I am not suggesting that these portable devices do not have limitations; clearly they do, but it seems that they provide the best alternative when you combine price, size, and performance.

Muskat: The Injury Severity Score for an injured soldier currently in Iraq is 25, which far exceeds any patient in our standard trauma centers today, which on average is around 15. Additionally, we provide care for a number of Iraqi patients

who remain in the field hospital for several days to a week or more on a Uni-Vent 754 ventilator. So I would argue that in the last 5 years we have really stressed the Uni-Vent 754 and figured out what it can and can't do. There are clearly pulmonary cripples that we have taken care of that exceed the capability of the ventilator; however, those numbers are fairly small. So I'm not putting a plug in for the Uni-Vent 754; I'm just saying that we need to pick a ventilator that is relatively cheap, small, and includes all of the things that we talked about yesterday.

Emergency hospital set up at Camp Funston, Kansas during the 1918 influenza epidemic
Courtesy National Museum of Health and Medicine
Armed Forces Institute of Pathology, Washington DC

The Pandemic Ventilator

Jeff Graansma

Background

When a new disease or virus spreads in a population that has never been exposed to that type before it is called a "pandemic". It can affect whole continents and spread worldwide. Many authorities are concerned that the H5N1 avian flu may cause a future pandemic. Some of the people affected by the avian flu will require short term assistance from a ventilator to survive. If an avian flu pandemic were to occur in Ontario, up to 118% of our hospital ventilators would be required just to assist pandemic victims.[1] This shortage of ventilators would force doctors to deny service to patients who need a ventilator, which would create an ethical dilemma. Some solutions have been proposed to this potential problem. Manual ventilators have been suggested, but putting a healthy person next to an infected person to assist their breathing could cause more infections in the healthy people. Splitting the air lines from one normal ventilator and putting two patients on one machine has also been suggested, but splitting the lines nullifies all the monitoring and alarm capabilities of a medical grade ventilator.

Purpose

The pandemic ventilator must be built using simple, reliable and readily available parts and materials. It has to be easy to build and maintain in the event of a flu pandemic so it could be used to supplement the existing supply of medical grade ventilators if a shortage occurs.

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[1] Ontario Ministry of Health and Long Term Care: Ontario Health Plan for an Influenza Pandemic. July 2007

Hypothesis

I will build a pandemic ventilator using the same material constraints that would apply during a pandemic to determine if it is feasible to build one with basic tools and experience. The unit will be tested to see if it can meet the specified requirements.

Procedure

The basic design is similar to the original concept published at the Pandemic Ventilator Project website. I think that the published design had some shortcomings that I thought could be improved on. Instead of the hinged based bellows system, I used a vertical sliding bellows system. I replaced the plastic bag with a stronger PVC bag. I also used an analog pressure transducer instead of the manometer. I replaced the magnetic switches with industry standard mechanical limit switches. I added a flow control valve to adjust the inspiratory to expiratory ratio. These changes were implemented to make the ventilator more reliable and install more features.

I constructed it using Bosch strut and plastic panels. I used an Allen Bradley Micrologix 1500 Programmable Logic Controller (PLC) to control the valves and relay information to the PC. The valves are standard direct acting solenoid valves. I used standard plumbing pipes and fittings to connect the elements together. I used a 5 volt low pressure transducer to monitor the patient inspiratory pressure. The PLC is programmed with basic ladder logic.

Once constructed, I used a Puritan-Bennett 0612 test lung to evaluate the ventilator and measure maximum pressure and airflow. I adjusted the weight on the bellows and the flow characteristics to make it operate within the normal pressure and flow limits of a regular ventilator.

Results

In order to get the ventilator to operate correctly, I needed to modify the original design, and do some troubleshooting to achieve reliable operation. A 4.5 kg weight was required on the bellows plate. This generated a maximum pressure equivalent to 22 cm of water and this is within a safe operating range. The tidal volume, which is the volume of air exchanged in each cycle, was about 0.4 liters. The minute volume, which is the total volume of air exchanged in one minute, was about 7 liters. These are within the normal therapeutic ranges for a ventilator. Maximum pressure can be adjusted by changing the bellows weight. Changing the setting of the limit switches and the flow controller can adjust volume. The ventilator has been operating reliably during the testing phase.

Testing

Functional testing was done on the ventilator in order to show that the design features would work and to see how accurately they were calibrated.

Test of minute volume and total volume monitor accuracy

The tidal volume was measured over a two minute interval using a Boeringer ventilator spirometer. The spirometer measured 10.6 liters of air volume. The ventilator recorded 10.7 liters of air volume. The calculated minute volume is 5.3 liters per minute. The ventilator displayed 5.0 liters per minute for minute volume.

Test of pressure monitor accuracy

The patient circuit pressure was measured using a Checkmate ventilator pressure monitor. The circuit was pressurized at different pressure intervals and the readings from the Checkmate and the ventilator were recorded.

Reading	Checkmate pressure cm H_2O	ventilator pressure cm H_2O
1	10	12
2	20	21
3	30	30
5	40	41
5	50	49

Test of high patient pressure alarm

The high patient pressure alarm limit was set on the ventilator. An alarm condition was created by pressing down on the lung simulator during the inhale portion of the ventilation cycle. The visual alarm on the monitor turned on.

Reading	high pressure patient alarm setpoint cm H_2O	alarm test Checkmate pressure reading cm H_2O
1	40	40
2	45	46
3	50	51

Test of patient line occlusion alarm

The patient line was occluded between the inhale valve and the patient connector. The alarm occurred within three seconds. The audible alarm sounded and the visual alarm indicator turned red which indicated a malfunction. The occlusion was removed, the alarm was then reset with the reset switch and the ventilator continued to run without error.

Test of loss of air pressure source alarm

The pump was unplugged to simulate a loss of air pressure. An alarm occurred within two seconds. The audible alarm sounded and the visual alarm indicator turned red which indicated a malfunction. The pump was reconnected, the alarm was then reset with the reset switch and the ventilator continued to run without error.

Test of respiratory rate monitor accuracy

The number of respiratory cycles was counted over a two minute interval. The number of cycles recorded was 27. The number of cycles displayed by the ventilator was 27.

Conclusions

I was able to achieve operations similar to a normal medical ventilator. Multiple copies of the ventilator would be very easy to build to meet the needs of a ventilator shortage during a pandemic. With more development time I can improve the monitoring, display and alarm systems.

Applications

An additional use of the pandemic ventilator design or something similar to it could be a sustainable solution for a ventilator for use in the third world. The design of this ventilator is simple enough that it could be built, maintained and used with minimal experience and training.

Acknowledgements

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Mass Casualty Respiratory Care: A Discussion of Issues of Interest

This Journal conference was the first to be held with a live audience. After the final faculty presentation, and in lieu of a conference summary from the guest editors, the conference faculty had a discussion session that addressed written questions from the audience. The moderators, Lewis Rubinson and Rich Branson, reviewed the questions and addressed them either to specific conference faculty or to the entire conference faculty group. There were too many questions to address in the allotted time, so the moderators selected the questions they thought either most pertinent or most likely to be answerable. Key words: disaster, mass casualty, mechanical ventilation, ventilator, oxygen, emergency preparedness, resource management, disaster medicine, personal protective equipment, information technology. [Respir Care 2008;53(2):239–248. © 2008 Daedalus Enterprises]

Rubinson: There are a lot of very thoughtful questions, which I think shows that this conference was very worthwhile. The first question is for Ray Ritz. It's from Harry Roman of the respiratory therapy school of the U.S. Army Medical Department, at Fort Sam Houston in San Antonio, Texas. He asks about the EDOC [Expeditionary Deployable Oxygen Concentrator] system, which is one of the oxygen-generation systems they're using for their combat support hospitals. His question is, would that ever be considered as an element of the Strategic National Stockpile [SNS]?

Ritz: Several different companies make such high-capacity O_2 concentrators. Their current focus of distribution is in places where they don't have liquid oxygen generating plants. They come in sizes from small to giant, and the giant ones can make something like 80,000 liters of oxygen an hour, I think. The smaller ones are more portable, and the larger ones are not portable. They might be a reasonable alternative for certain situations and conditions, with the recognized limitations of what they can produce, but they're moderately to very expensive, and some may not make 100% oxygen. That might be inconsequential if they may make 90% or greater oxygen. Some make close to 100% oxygen. I think the larger models need a compressor system that you supply, like your hospital's compressed air system. I think they aren't something you would deploy quickly, in the next 2 weeks. It requires a considerable amount of capital investment and a considerable amount of planning as to how the device would be deployed.

Malatino: Everything that goes into the SNS has to have a subject-matter expert behind it, and it's up to those experts whether an item will be included in the SNS. I think the current position is that these oxygen concentrators would not be added to the SNS. That doesn't mean the idea is off the table. Everything we put in the Stockpile has to have funding behind it, and you just mentioned the high cost. There is also the cost of storage. These oxygen concentrators would not go into the Push Packages, which we guarantee in 12 hours or less. They would go into Managed Inventory, which means anywhere from 24 to 48 hours, depending on how much it is and where it's going. So you have to wonder, how long would you want to wait to get something like this? Do you want to have it on hand or wait for it to arrive?

Ritz: If I was a state planning and developing a support infrastructure and I lived a long way from a liquid oxygen plant, I'd look into that kind of oxygen generator, because it could take a number of days for vendors to resupply your liquid oxygen system.

Rubinson: In Seattle, if an earthquake took down all of our manufacturing, the nearest places we can get liquid oxygen from are California and Salt Lake City. So having an oxygen generator would be ideal, but the question is, should we add concentrators for each vent [ventilator] at the expense of substantially reducing the number of vents. I think we all en-

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Richard D Branson MSc RRT FAARC has received honoraria and research support from Cardinal Health and Coviden; he has received honoraria and has consulted for INO Therapeutics; and he has received research support from Respironics. Steven B Nelson MSc RRT FAARC is an employee of Sun Microsystems, a company that provides goods and services that could be used in a mass casualty situation. The faculty report no other conflicts of interest.

Regarding the responses of faculty who are fully (Ms Malatino) or partially (Dr Rubinson) employed by the Centers for Disease Control and Prevention, their statements are their own and do not necessarily represent the views of the Centers for Disease Control and Prevention or of the Agency for Toxic Substances and Disease Registry.

dorsed a mechanism for a federal agency to be able to provide on-site oxygen, so I hope it continues to get pursued. My understanding is that FEMA [Federal Emergency Management Agency] has some oxygen-generation capability, but I think it's mostly portable devices that have relatively low capacity.

Moving on to the next question, this is for Mike Hanley. James Allen from Parkland Health and Hospital System in Dallas asks if you have an opinion on which would be a better option: individual hospitals having their own kind of Project XTREME groups or doing a regional Project XTREME group? He also asks, who would make the decision to activate it and what would be the criteria for activation?

Hanley: Disaster planning should be on a regional scale. Some of the ideas that you've heard about augmenting staff and other issues that we've discussed, they highlight the idea that you'll be relying on other resources within your community, and if you and another hospital are both planning on recruiting the same RT [respiratory therapist] from the same oxygen-supply company, you may find that you've lost out at the time that the disaster strikes. We should implement programs like Project XTREME regionally. Regarding who makes the decision, I think a training program like Project XTREME should only be used in an emergency officially declared by a representative of the state government, typically the governor. I'm not sure what the triggering criteria would be.

O'Laughlin: I concur that the effort, including planning and resource management, must be regional; that's necessary. If we try to all do it individually, we could waste a lot of time and money. Regarding the trigger, we do need a declared emergency, whether it's from the governor or the department of health as an agent of the governor. Generically speaking, resources would be depleted, and the information has traveled up the chain of command from the health-care-entity level up to health department officials and the request for a public health emergency declaration to authorize those measures if they're needed.

Rubinson: Though clearly there should be an obvious event and there should be some declaration, I'd be cautious about linking authority for health-system changes to a governmental declaration of emergency, especially at the state or federal level. Some declarations may be made with consideration of health-system issues, but health doesn't necessarily always drive the decision-making process.

O'Laughlin: I should clarify. In Minnesota I believe that the department of health can initiate certain activities to protect the public's health, to authorize certain things to be done. So I think you're right that it doesn't necessarily have to be a governor's declaration that's moving up to federal resources, but a governor's declaration for emergency powers would still need to be issued for certain protections to be instituted.

Rubinson: Agreed. This next question is for Rich Branson. It's from Lois Rowland of CJW [Chippenham Johnston Willis] Medical Center in Richmond, Virginia, and she asks if the Uni-Vent 754 ventilator is suited for infant ventilation with the supplied pediatric circuit? If the pediatric circuit is not acceptable for infant ventilation, can the user substitute an infant circuit?

Branson: You can ventilate a pediatric patient with the Uni-Vent 754, but of course we have to clearly state who is a pediatric patient. When you're using high-pressure air and high-pressure oxygen, the delivery of the tidal volume from 754 milliliters down to about 50 milliliters is very accurate. If you're using high-pressure oxygen and the internal compressor, the accuracy of the delivery at 50 milliliters is not as accurate. I think it's approved down to a patient size of 10 kilograms. But there are some setting changes that can help. If you hold down the manual breath and alarm silence buttons while turning the machine on, it allows you to change the trigger and the flow during the spontaneous breaths. Usually it's 60 liters a minute; you can turn it down to as low as 10 liters a minute if you're in IMV [intermittent mandatory ventilation] mode. That's one thing that I would do with pediatric patients. You can use the pressure plateau, which is really just like a mechanical pop-off [pressure-relief] valve, but then you won't have guaranteed tidal volume. I personally have never used it for infant ventilation, and I would be concerned about the dead space of the circuit with a small patient. I would have to defer to use according to its FDA [Food and Drug Administration] approval.

Branson: We have a related question from Dean Holland, also from Parkland in Dallas. He wants to know, what about using the old Bird IPPB [intermittent positive-pressure breathing] devices. If you have Mark 7s and Mark 14s and whatever else you might have around, can you adapt these and use them in the short term in a mass casualty event? And I think the answer clearly is—and this is where we want to make the distinction—there's a difference between a ventilator that you have that you would use and a ventilator that you would purchase to stockpile.

I would not stockpile Bird Mark-anythings. But if I happen to have some Bird Mark 14s and if it's those or nothing, obviously you would use them, but with the caveat that in a mass casualty situation where there are too many patients and too few caregivers, we shouldn't use ventilators that don't have the appropriate alarms: high-pressure, low-pressure, disconnect, apnea—those are all the things we need

to know if there's one RT running around trying to care for 20 patients with 3 Project XTREME extenders who are listening for alarms to come tell the RT that there's an alarm.

If you have these ventilators, you can use them, but I would not put those as my first priority or even in the top 10 probably for ventilators. Today's young RTs would look at a Bird Mark 14 and wonder where the button is for SIMV [synchronized intermittent mandatory ventilation]. If it doesn't have a button on it, they don't know how to use it. [Laughter] It's great for some of us old people who used to take those things apart and put them back together to talk about using them, but when you start bringing in all these young people who've never seen them, then I think that is potentially going to be a big problem.

Ritz: It's a marginal step up from manual ventilation.

Rubinson: This is a question for Mike, from William R Solly a Master's candidate in disaster medicine and management at the University of Pennsylvania Health System. Would it be feasible and perhaps safer for facilities to dedicate all of their RTs to vent management and to assign other traditional respiratory care roles such as nebulizer therapy, O_2 therapy, and other things they get on the general wards, to other health care providers rather than cross-training people to do the more complicated competencies?

Hanley: That certainly is one approach. You have to look at the Project XTREME training DVD [digital video disc] and our program and think about how it best applies to your hospital and clinical situation. In our training program we do not train the extenders in nebulized medication therapy, so you won't be able to use our program to do that, but it does emphasize the key idea that there are basic RT tasks that extenders could take over.

In my MICU [medical intensive care unit] at any one time there are 2 types of critically ill patients: stable and unstable. We had 3 patients in our ICU when I left on Friday who have been ventilated for 2 months, who have acute lung injury and are on 60 to 70% oxygen, and every few hours a therapist comes by and records the various settings and the results of patient monitoring. Once a day they assess the patient for weaning potential. You get the idea: a very stable patient. This patient is somebody that I think an extender could easily assist with the care of. They could obviously assist in the care of patients who are on the floor and free up your RTs to perform more sophisticated tasks.

So how you use the extenders is something that you have to decide about ahead of time. The question was about using nurses and other health care professionals to do these simpler tasks, but you have to consider where your resources are coming from and who might be available. If they're floor nurses they will already be busy. If you have extenders available, they may be able to do those tasks for you.

Branson: We teach parents to perform suctioning on pediatric home-care ventilated patients, so why can't we teach somebody to do it in the hospital? Well, clearly there is a difference between suctioning the home-care patient who's on room air and suctioning the patient with acute lung injury who's on 18 cm H_2O PEEP [positive end-expiratory pressure] and 80% oxygen with a closed-circuit system. You have to know how that system affects the ventilator performance, what alarms might go off, and how to examine the changes in hemodynamics.

People have criticized Project XTREME for that, but that's where we have to show leadership. The RT doesn't give the extender responsibility for suctioning that patient. You give them responsibilities with stable patients of the sort Mike described. Of course Project XTREME has lots of limitations, and I think Mike acknowledged all of them in his presentation. It's never been tested for a long period, and we don't know how long the training lasts. It's similar to what we've learned from CPR [cardiopulmonary resuscitation]. But we do know that there are some duties that can be performed, and it's our job to use extenders appropriately.

Rubinson: This question is for Ray. Sandra Barnes, from the Olive Harvey College Respiratory Care Program in Chicago, asks, are you aware of any grants that would cover acquisition of oxygen cylinders?

Ritz: In short, no. That idea was recently proposed to me by several vendors, who said, "You give me this amount of money and I will guarantee I will have available for you ventilators, or oxygen cylinders, or whatever." I am not aware of any grant money. I looked at this at the same that I looked at a vendor's proposal that I pay for a maintenance contract for my ventilators. In all likelihood the maintenance contract is going to cost me more money than just doing the repairs and required preventative maintenance. Those programs usually are more expensive than just taking care of the repairs as they come along. I don't think there is any grant money available for these types of programs.

Rubinson: Although they are different monies, in Seattle for public health we use about 5 different sources of money to pay for our preparedness effort, and they all have different restrictions. With certain money sources the equipment needs to be on the Department of Homeland Security list of equipment. With the ASPR [Assistant Secretary for Preparedness and Response] (which is the old HRSA [Health Resources and Services Administration]) noncompetitive grant money, you can use it for equipment procurement if it goes through the state

and the state passes it down to your region and your region decides that is a priority, and then the state approves that procurement. These grants are not specific for oxygen cylinders, but general equipment money is available. My guess is that the competitive grants would not award money just for buying oxygen cylinders. A proposal probably needs to be more comprehensive to win funding.

The next question is from Sunita Mehta, from Good Samaritan Hospital in San Jose, California, and she asks Eileen, is there any variation or difference in ventilator allocation going to a public versus a private hospital?

Malatino: The SNS does not have any responsibility for doing the allocations unless it happens to be pandemic flu or something where the problem is going to be nationwide. Then it might come from a higher authority such as Health and Human Services. Once we get the message that stuff has to go out, if it's a Push Package, it will go to a predetermined warehouse; that may be the same for Managed Inventory as well. There may be an instance with Managed Inventory, say with the ventilators, where they would arrive in an airport and then the state would pick them up, or the area of the region would pick them up and then they distribute them.

We do not decide where they go; that is a state or region or local decision. We do have consultants who work with the states, and they determine at what site they want something delivered if it's coming from Managed Inventory. Usually a Push Package goes to a predetermined facility, unless that facility is in a hot zone, or they've all been destroyed, and then there would be a decision at that time where they would be taken.

Rubinson: The next question is from Sharon at Mt Clemens Regional Medical Center, Mt Clemens, Michigan, who asks Lee Daugherty about fit-testing of N95 masks. She says that the Michigan OSHA [Occupational Safety and Health Administration] and, she thinks, the CDC [Centers for Disease Control and Prevention] require annual fit-testing for N95 masks, but she thinks that the semi-quantitative and the qualitative testing (the saccharine testing) is lame. Would there be any benefit to switching to a quantitative test? Would that be adequate for people who had changes such as weight gain, weight loss, facial, or oral changes? Does quantitative testing play any role, and for whom, and is it sufficient?

Daugherty: First, it is important to underscore the fact that although some states require quantitative testing, both qualitative and quantitative fit-testing meet OSHA standards. One concern in this debate is that with the qualitative test it is possible to "fake it," but quantitative testing allows objective fit confirmation. However, a major problem with quantitative testing is that the testing equipment is quite expensive and not always readily available. In a mass casualty situation, such as a pandemic, qualitative testing will be more practical and will still meet OSHA standards. Regarding re-testing, OSHA standards require re-testing annually, and changes in body weight, dental changes, and other changes can affect fit.

Malatino: We do have a medical surveillance program for our deployable people. The Technical Advisory Response Unit (TARU) goes out before the Push Package to receive it when it arrives. We also have full-time equivalents who are CDC employees, and we also have contractors. And we have occupational health at CDC, and we have a contract agency that does our contractors. They get fit-tested every year, and we are required by occupational health to do that.

Daugherty: Is that just within the Stockpile?

Malatino: Any deployable person from CDC who is required to have specialized equipment such as an N95 mask has to go through the same process.

Rubinson: This question is from George Steer at UTMB [University of Texas Medical Branch] in Galveston, and it is for Dan. Where do the NICU [neonatal intensive care unit] patients, especially those on ventilators, fit into the scheme of allocation of scarce resources?

O'Laughlin: There is a pediatrics subgroup in Minnesota that is working on that. Some of that equipment is so subspecialized that it doesn't apply to the rest of the pediatric population. Obviously, NICU patients are very sick. However, it also goes back to the question of the amount of resources allocated to a patient. Could those pediatric subspecialty NICU nursing staff, RTs, et cetera, be better utilized in another pediatric capacity? This issue comes up not infrequently about ECMO [extracorporeal membrane oxygenation]. How long is an infant going to be on ECMO? And are they to be taken off ECMO if somebody else who has a higher likelihood for survival comes in?[1] Usually these NICU locations are in pediatric specialty hospitals or large institutions, and those institutions will have to look at those policies and identify how high their resource ceiling is going to be for that patient population.

1. Truog RD, Triage in the ICU. Hastings Cent Rep 1992;22(3):13-17.

Talmor: The data are imperfect because we don't have a lot of experience with avian influenza, but until now the mortality in children with avian influenza has been close to 100%. As a triage factor we may find ourselves using age in the opposite direction of what we discussed earlier, so that is something for pediatric intensivists to think about.

Rubinson: When we've approached this with several groups, we've used PICU [pediatric intensive care unit] experts, but we haven't addressed the NICU. The question was basically set aside because it was too complex; it needs to be dealt with. When we originally started thinking about it, we thought the NICU would be less impacted, at least in terms of disease process, unless there is a lot of vertical disease transmission, because you don't see a whole bunch of neonates going out in the community at high risk. But if the equipment is the same, and some of it does overlap, I think it's a fair question and a subject that's right for our neonatal experts to try to give some guidance on.

The next question is from Gordy Gunderson from Sanford USD Medical Center in Sioux Falls, South Dakota. Are there any specific software tools, such as Emergency Preparedness Resource Inventory, that would help institutions track crucial resources during a mass casualty event?

Nelson: I don't know of any automated tools. Most of what's being done is on a contract basis, where some high-priced consultant writes you a report that tells you what you pretty much already knew and that's out of date by the time it's printed. I've worked with several different industries— education, state and local government, telecommunications, and health care, and they all fall under the same category. There just isn't a good product available, as far as I know.

O'Laughlin: There are some Web-based tools, but as far as looking at a specific facility and high-level detail, I cannot comment. When you look at broader regional application, there are some resources out there. New York uses HERDS [Health Emergency Response Data System] to track a lot of things, including some of their equipment.

In Minnesota we use a system that Seattle just picked up as well, designed by ImageTrend. It is a Web-based system that was initially designed for EMS [emergency medical services] diversion communication. The product is also being developed for us as an online command and control resource. That has not been fully released, so I can't provide any feedback yet.

Rubinson: The crucial element of regional collaboration is situation-awareness and knowing what's out there and getting the information in time and getting it to where it will be used. Though there are software systems that are clearly giving us a better picture than we had before, I am not aware of any one that does automated dumps of flat files or delimited files that speak with all the different data systems that it needs to. It needs to communicate with pharmacy and materials management and all these different groups that currently we request give us manual data.

Currently, without automated systems it's very hard to even get people to count once every 3 to 6 months, let alone to get information immediately. So there are mechanisms to have kind of a gestalt, but I'm not aware of anyone who is able to interface across all of the data systems to get a more detailed view.

Dan, you guys have just under 30 hospitals; we have 20-some hospitals, and we have all the ambulatory care community, and I don't know of anyone whose software is affordable for a region to be able to work across everyone's different data systems and that doesn't quadruple work at each of those institutions, because there is no money to support people's time at institutions to keep entering data.

O'Laughlin: How many people here could give an accurate count of the ventilators you have in your region? I see very few hands going up. And those that put your hands up have done a great deal of work and probably double- and triple-checked those numbers to see if they're accurate, and that was all by hand, I assume. So even with a number we should be able to gather easily, we have difficulty doing so. To ask us, with current technologies and systems, to get the finer numbers and quantities of multiple items across departments and facilities is, shall we say, challenging.

Rubinson: Keep in mind that if you do a lot of pushing region-purchased equipment out to institutions, rather than centrally stockpiling, you need to try to track where they are in the individual institutions so you can retrieve them quickly if necessary. This is an important logistical barrier to distributing equipment and expecting it to be returned and redistributed during disasters.

The next question is from Regina Reale from Multicare in Tacoma, Washington, who asks Eileen, have you spoken with the manufacturer of the Uni-Vent 754 to see if there is an easier way to recharge its batteries?

Malatino: It would mean retrofitting these cases and making the case a little bit bigger, so it would be an added expense. Our biomedical technicians, who open the cases and charge the batteries periodically, also rotate all the ventilators back through the manufacturer so they can take out the batteries and make sure they're still OK or replace them if necessary. They go through a process when they go back to the vendors as well. New ventilators that come into the Stockpile are going to be fitted so that we can just flip a switch, as opposed to having to take all of these out. But right now it would probably be more of an expense then it would be worth.

Rubinson: Regina also has a question for Mike, about getting the Project XTREME DVD. What is the Web address?