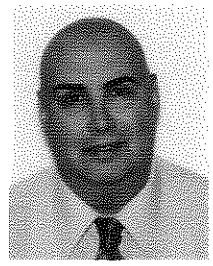
Automatic resuscitators can serve as effective "force multipliers" for emergency ventilatory support in mass casualty scenarios.

Frank G. Rando, P.A., RCP, CRT, CVT/CCP, EMT-P, CHMS Consultant/SME, Senior Faculty, Project Manager/Coordinator Nuclear-Radiological, Biological, Chemical Defense-Medical/Public Health Countermeasures Specialist, HAZMAT Specialist & DHS-Certified Weapons of Mass Destruction Instructor-SME US Department of Homeland Security National Emergency Training Center Emmitsburg, Maryland. Faculty/SME US Department of Homeland Security, Noble Training Center, Ft. McClellan/Anniston, Alabama, Faculty/SME.



Recently, I read with fervent interest, the article "Positive Pressure Ventilation Equipment for Mass Casualty Respiratory Failure" [1] written by Lewis Rubinson, M.D., PhD, Richard Branson, MS, RRT, et al. The authors raise the issue of planning for and providing mass casualty ventilatory support during large-scale, high impact and catastrophic incidents and events, and offer guidance in application and selection of ventilatory support equipment. As a clinician, emergency planner, instructor and consultant in the health care, emergency preparedness and emergency response fields for over 30 years, I have consistently voiced my concerns regarding inadequate disaster planning and weak emergency response capabilities, and have been very proactive in enhancing emergency preparedness and response capabilities on multiple fronts, including national and international arenas.

Among my main concerns over the years, have been health care/public health readiness and the development, availability and reliability of medical and public health countermeasures and assets, including the implementation of a strategic civilian health care system designed to meet the challenges of unconventional and asymmetric threats and catastrophic events. The inducement of mass Acute Respiratory Distress Syndrome (ARDS) and subsequent Acute Respiratory Failure (ARF) from a variety of etiologies, including pandemic health threats, is plausible and worrisome.

The health care, public health and emergency planning and response communities must utilize and adopt innovative concepts and medical devices to maximize the success of a major emergency response. While the stockpiling, deployment and application of full-feature and critical care ventilators may seem appropriate and optimal, the realities of mass casualty response and medical management dictate that the real-time activation, deployment, distribution and actual implementation of full-feature ventilators from the Strategic National Stockpile (SNS) will require substantial time, even if regional resources are tapped. Furthermore, key human assets, in the form of Disaster Medical Assistance Teams (DMATs), members of local Medical Reserve Corps and other HHS assets such as the proposed "rapid deployment force" of specially trained respiratory therapists designed to augment local medical response assets, will also require time before they are "boots on the ground".

In our business as health professionals, "time is tissue". The old and consistent emergency management adage, that initially, "all disasters are local events" must be remembered in our collective emergency planning efforts. What does the isolated, local health care system do for the first 72 hours of a critical incident or event?

While the selection and use of full-feature and critical care ventilators are the optimal choices, we must not discount the use of pneumatic driven automatic resuscitators/ventilators and other ancillary devices to provide EMERGENT and SHORT-TERM, interim ventilatory support in both pre-hospital and hospital environments, while awaiting the transition to more optimal, sophisticated ventilatory support equipment.

The authors advocate bag-valve mask ventilation (BVM) in lieu of Pneumatic,

[1] LEWIS RUBINSON, RICHARD D. BRANSON, NICKI PESIK, and DANIEL TALMOR, "POSITIVE PRESSURE VENTILATION EQUIPMENT FOR MASS CASUALTY RESPIRATORY FAILURE" in BIOSECURITY AND BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, AND SCIENCE Volume 4, Number 2, 2006.

automatic resuscitators/ventilators such as VORTRAN Automatic Resuscitator (a.k.a. SureVent) devices. As a mass casualty planner and clinician, I cannot envision providing MANUAL resuscitation and/or ventilatory support for a patient surge of 50-100 patients, simultaneously, and for an extended period during a critical incident or event, let alone where patient surges could easily exceed the thousands in large scale, high-impact events.

The following two case scenarios are submitted for the readers' consideration:

Case Scenario A-

A local industrial processing facility has an accidental release of a highly irritant gas in a highly concentrated area of an urbanized "mixed zoning area" during a heavy thermal inversion. The facility is located adjacent to a major elevated freeway, an inner city neighborhood, several schools and child care centers, and a major international airport. Three hospitals are located in the vicinity, and one is impinged and impacted by the plume. The release occurs on a Wednesday morning during a heavily congested and stalled freeway commute and hundreds of community residents, including school children are en route to work and school.

Case Scenario B –

On a busy subway platform, several passengers suddenly become unconscious, while others are actively seizing or vomiting. An incoming train arrives and hundreds are exposed to some airborne contaminant. Within seconds to minutes, others become violently ill, collapse and lose consciousness.

Not only are both scenarios plausible, they are real world case studies that have actually occurred and can occur again.

Scenario A is based on what has been described by the US Attorney's Office as "the most dangerous 2 miles in the US", along the Pulaski Skyway which is a major conduit from New York City to New Jersey and is dotted by gas and oil pipelines, petroleum storage facilities, chemical processing and manufacturing complexes, and major port areas. It is also based on major industrial releases, the most serious occurring In December of 1984 in Bhopal, India where a Union Carbide pesticide manufacturing plant released a large quantity of methyl isocyanate, a highly toxic irritant gas. This was a classic example of mass chemical exposure with ensuing ARDS/non-carcinogenic pulmonary edema and Acute Respiratory Failure, and has served as a frequent "lessons learned" model for emergency planners.

Scenario B is also based on the 1995 Aum Shinrikyo Sarin nerve agent attack on the Tokyo subway system. During the first hour of this terrorist act, 500 patients arrived at St. Lukes' Hospital Emergency Department. Within 24 hours, 5,500 patients were seen and treated at area hospitals.

For argument's sake let us model a scenario based on a mixed patient population of 100 actual/frank and impending cases of respiratory failure presenting at two separate emergency departments.

Is manual bag-valve mask ventilation for those requiring ventilatory assistance really a viable option given the above scenario? Many of these patients may also present with concomitant physical injuries and require other clinical interventions in addition to decontamination.

Is manual ventilation utilizing a BVM labor intensive? Is this really practical or "good practice" in a mass casualty event? Can we, as human operators, better overcome airway resistance utilizing a BVM, rather than an automatic resuscitator? Can we, and should we, really entrust manual ventilatory supports to non-medical augmentees, i.e. untrained individuals? If we do, we as clinicians MUST closely supervise them. Does this not detract clinicians from conducting critical functions such as triage/clinical decision-making and treatment?

Is clinical observation and patient monitoring also required during BVM use, as it is for the SureVent, for example? Are we, as clinicians really capable, and assured, of delivering a more "consistent" tidal volume using a BVM as opposed to an automatic resuscitator?

Are blood gas parameters, which indicate the efficacy/adequacy of ventilation and oxygenation, consistently better using BVMs over automatic resuscitators? How about overall clinical outcomes?

Automatic resuscitators as "force multipliers"

Can we treat the causes of airway resistance by utilizing pharmacotherapeutics such as aerosolized bronchodilators and adequate, rapid atropinization coupled with suctioning for nerve agent toxicity, for example, and still utilize an automatic resuscitator device?

Does utilizing a PEEP (Positive-End Expiratory Pressure) valve with a BVM actually provide a more consistent and optimal level of PEEP than using a PEEP valve with an automatic resuscitator?

The authors claiming that medical gas supplies are a precious and highly consumable commodity in mass casualty events is true, however, this can also be mitigated if clinicians take the time to be innovative and "think outside the box", which usually consists of the "controlled-chaos" of a sophisticated, state-of-the art Critical Care Unit or Emergency Department.

The SureVent/VAR automatic resuscitators, for example come, with a mass casualty "Event-Case" capable of providing ventilatory support to seven patients via a built-in manifold system. The manifold system can be connected to a single or multiple gas supply, such as a portable H-cylinder "oxygen farm", which in many municipalities has become part of a regional or municipal mass casualty cache, or even air compressors utilizing clean air or cylinders/wall sources with medical grade air. Three (3) of these systems, placed in a triage and treatment area of a hospital, for example, would be able to provide EMERGENT and SHORT-TERM ventilatory support to twenty-one (21) patients simultaneously.

Of course, clinical observation and patient monitoring must be provided by a properly trained clinician, however, in a triage and treatment area, the deployment of personnel in those critical areas are a matter of standard protocol. This also allows clinicians to maximize their clinical performance to possibly perform other therapeutic and diagnostic procedures, especially during critical personnel shortages, as may be expected during an initial medical response.

Also, the single patient use feature of the disposable VORTRAN Automatic Resuscitator (VAR™) eliminates any cross-infectivity, cross-contamination and equipment sterilization or decontamination issues. We must also remember that when these patients are eventually interfaced with full-feature and sophisticated critical care ventilators, the patient-ventilator interface must be closely and carefully monitored by a trained clinician, usually the respiratory therapist or critical care nurse.

The patient-ventilator interface is a complex, multifactorial clinical problem, and despite the sophistication of the mechanical ventilator. The responsible and conscientious clinician can NEVER really "walk away" from the intubated, critically ill or injured, ventilator dependent patient, despite all of the "bells and whistles". Even in the modern critical care unit, it is not uncommon for a respiratory therapist or critical care professional to conduct periodic "vent checks" and assessments of physiological and ventilator parameters and settings.

While the automatic resuscitators are NOT designed or intended for use as full-feature critical care ventilators or for long-term mechanical ventilatory support, they have been proven to be highly useful in a variety of clinical settings and under austere conditions.

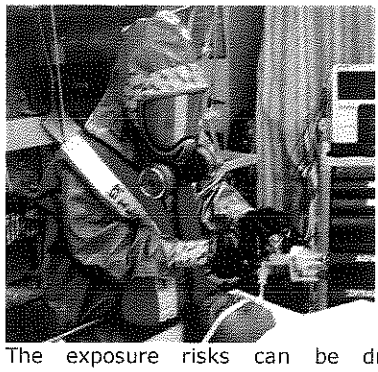
These devices do have limitations, such as pressure limits, making them an inappropriate choice for pathology associated with decreased chest wall or lung compliance. The authors also report operational failures from positional changes which can be compensated for when it occurs, and the manufacturers have been consistent in addressing this issue through training, publications and other means.

Also, automatic resuscitators, such as the VAR™ device are being re-engineered to provide more efficient gas consumption and a PEEP valve and intrinsic alarm system are also planned for incorporation into future models.

Clinical trials, and possibly animal models utilizing a lung injury/ARDS model, are being planned to fully evaluate the mechanics and efficacy of providing limited mechanical ventilatory support for ARDS. A pediatric model has been approved by the FDA, and has been on the market for at least two years.

The authors maintain that the close clinical observation required with the use of the automatic resuscitator will pose occupational exposure risks involving environmental or etiologic agents. This risk can be drastically minimized, if clinicians wear appropriate personal protective equipment and clothing

such as a full-facial air purifying respirator or powered air purifying respirator with the appropriate cartridges, P-100 filters, or HEPA filtration system, Ty-Vek clothing, boots and inner and outer gloves. This level of protection (Level C) is sufficient to protect against a variety of chemical, biological or radiological agents, bioaerosols and airborne transmissible viruses and other microorganisms. Also, for high-risk airborne biological hazards, such as bioaerosols the use of biocontainment such as negative-pressure rooms, is highly recommended.



The exposure risks can be drastically minimized, if clinicians wear appropriate personal protective equipment and clothing.

In a mass casualty event, compassionate, yet, realistic triage criteria and paradigms must also be in place, readily available and implemented as an integral and critical component of the health care facility's disaster plan. There should be a standardized and unwavering protocol for selective resource allocation and a diversion of critical resources, such as mechanical ventilators, from elective and clinically non-viable cases.

The deployment of mechanical ventilators for mass casualty management should utilize a tiered clinical decision-making system coupled with the strategic use of a "hybrid" system of ventilators which could be a mix of available critical care, transport and automatic resuscitator/ventilator types to augment and maximize the response and optimize clinical outcomes.

Automatic resuscitators can serve as effective "force multipliers" for emergent and short-term ventilatory support in mass casualty scenarios. Also, non-invasive ventilatory strategies should be considered in augmenting mechanical ventilator reserves that will be in high demand during large-scale, high impact, mass casualty events.

Nevertheless, providing austere care in overtaxed health care delivery systems will still require efficient triage systems, so that "the most good can be done for the most people".

Accurate triage reduces the acute burden on health care facilities and organizations. On average, only 10-15% of disaster casualties present in "serious" categories to warrant overnight hospitalization. This may change significantly for pandemic health threats, for example.

Therefore, effective triage cannot be overemphasized and is crucial in providing equitable and rational casualty distribution to receiving medical facilities and reducing health care facility overloads to manageable, even "pre-disaster" levels. For the "expectant", or dead and dying category, palliative care and comfort should be provided for dying patients or care should be provided on an "as-available basis" so that they do not consume scarce resources for those who have a chance of long-term survival. These victims would include 100% total body surface area burn (TBSA), lethal, and some sub-lethal radiation injury, overwhelming sepsis, disseminated intravascular coagulation (DIC), persistent vegetative states, chronic or end-stage renal failure, end-stage cardiopulmonary disease, etc.

All of these factors and components need to interplay for an effective national health care preparedness strategy and to optimize the delivery of emergent and critical care, including mass casualty mechanical ventilatory support. We are all medical foot soldiers serving on an unfamiliar and unconventional battlefield; therefore unconventional medical threats require unconventional medical approaches and unconventional thinking.

In closing, I respectfully address the pressing issues that my esteemed colleagues have raised with the hope that I may have amplified and clarified some critical principles and misconceptions, and contributed to the understanding of austere and catastrophic medical care.

Respectfully submitted,

Frank G. Rando, P.A., RCP, CRT, EMT-P

CONTACT INFO: hazemerg@hotmail.com