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分担研究報告書

非常時対応人工呼吸器の標準化に関する研究
米国における健康危機発生時のための人工呼吸器の備蓄の状況

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研究要旨

人工呼吸器の備蓄について、米国の Strategic National Stockpile (SNS)における状況を調査し、その備蓄人工呼吸器の仕様と維持管理のメカニズムを、我が国における準備のための基礎資料とした。パンデミック(H1N1)2009 は、幸運にも我が国の健康におけるインパクトは大きなものではなかったが、次シーズンにはどのようになるかは誰にもわからず、また発生が危惧されている鳥インフルエンザ A/H5N1 はもとより、今後の健康危機管理の観点から、今後人工呼吸器を含めた、国家備蓄を維持管理しておくべきである。

A. 研究目的

我が国では、新型インフルエンザへの事前準備として、新型インフルエンザ専門家会議を立ち上げ、主に A/H5N1 亜型の鳥インフルエンザウイルスに由来する高病原性を想定した準備が行われていた。このなかの医療対応として、重症者が多発した場合において人工呼吸器が不足するのではないかという議論は継続的に出ていたが、抗ウイルス薬の備蓄で精一杯の状況で、具体化されることはなかった。

このような状況下、2009 年 4 月にメキシコに端を発するパンデミックが勃発し、瞬く間に世界中に拡がり、WHO は 6 月 11 日、フェーズ6を宣言した。当初、メキシコにおいては重症例から発見されたため、死亡率が高いのではないかと危惧されたが、実際には大多数の軽症例が把握されていなかったための見かけ上のものであり、実際のパンデミックは、A/H1N1 亜型で、季節性の A/H1N1 亜型のウイルスと共通の抗原性があり、健常成人の多くは基礎免疫を持ち、一定の比率で重症例が存在したものの、多くの場合には軽症であった。

しかしながら、途中で病原性が変化する可能性は残され、また過去スペインフルにおいては、第二波において病原性が高まったということもあり、重症者が多発した場合に備えて、日本においても人工呼吸器を備蓄しておく必要性が議論された。どのような人工呼吸器を備蓄し、それらをどのように保管・管理し、維持していくべきかなど、多くの検討項目が挙げられた。

本分担研究では、すでに莫大な予算をもって、あらゆる医療資材を備蓄している米国にお

いて、人工呼吸器の備蓄の状況を調査し、もって、我が国における対応の資料とすることを目的とした。

B. 研究方法

米国疾病予防対策センター(Centers for Disease Control and Prevention: CDC)の戦略的国家備蓄部門(Division of Strategic National Stockpile)の対応チーム(Response Branch)の担当者に、他の用務で米国CDCを訪問した際に、聞き取り調査を行い、その後必要な情報については、電子メールにおいて問い合わせた。

(倫理面への配慮)

いわゆる、研究における倫理的な問題は発生しないが、人工呼吸器の備蓄は国家機密に属することであり、米国側の了解を取って、公開できない情報は研究班内部での共有として、報告書等には記載しないこととした。

C. 研究結果

米国では国家健康危機管理のために、元々はバイオテロに対応するために、1999 年に連邦政府の備蓄プログラムとして、戦略的国家備蓄(Strategic National Stockpile: 以下 SNS)が開始され、これまで総額 3,500,000,000USD 以上の抗微生物薬、医療資材、解毒薬、拮抗薬、抗ウイルス薬、ワクチンその他の医薬品が備蓄されている。備蓄場所については、セキュリティー上の理由から場所は公開されていないが、依頼があってから、国内どこの場所にも 12 時間以内に物品を届けられることを前提にシステムが構築されており、全国62カ所のプロジェクト・エリア内にちらばっている。

抗ウイルス薬の備蓄については、全国で 8100 万人分の備蓄を目標としており、このうち 3100 万人分が州の分担、5000 万人分が連邦政府の分担となっている。ただし、州分についても連邦からの 25%補助があり、後押しをしている。備蓄分から各州への分配は、人口比率によって行われるが、抗ウイルス薬以外に、1億個の N95 マスク、5000 万枚のサージカルマスク、抗生剤、人工呼吸器、シリンジ、針等を備蓄している。備蓄分の分配は、分配が決定されてから最初の 1 週間に 25%、次の 1 週間に 25%、残り 2 週間をかけて最後の 50%を分配する計画とされていた。

今回は 2009 年 4 月 26 日に備蓄の放出が決定され、1100 万人分の抗ウイルス薬、2500 万個の N95 マスク、1250 万枚のサージカルマスクが各州に人口比に応じて配分されたが、第二次以降の放出はされていない。ただし、各州でどの程度実際に使用されたのかを詳細に把握するシステムが存在していないことが課題であるが、9 月までには、放出分の補充が完了する見込み。備蓄タミフルについては、非常に厳密な環境下で保存されているため、力価を確認した上で、有効期限を延長する仕組みとしている(SLEP)。

人工呼吸器の備蓄については、最初に必要な仕様を決定し、1)電源要件、2)換気モード、3)設定方法、4)ガスフローのレンジ、5)PEEP の設定、6)酸素設定、7)測定系、8)持続使用時間、9)小児(体重 5kg)使用、10)アラーム系、11)物理的ショックや環境因子に対する耐久性について、詳細が定められている(非公開資料につき研究班内部のみで共有)。また、これらは第一線で働く呼吸器科専門医、あるいは人工呼吸に関する専門家の意見により、より理想的なものに改正する一方、コストとのバランスに基づいて仕様を決定している。

これらの基本仕様に基づき、数社から購入し、備蓄を行っている。これは当然のことながら、機器の進化と技術の進歩に併せて、購入年により異なるモデルが購入されている(実際の購入されて備蓄されているモデルについても国家の情報であり、また企業との関係から公開できない)。

メインテナンスについては、購入時に業者とメインテナンス契約を同時に結んでおり、SNSのロジスティックスタッフによりバッテリは定期的にチャージされている。また定期的に少なくとも三分の一の呼吸器はローテーションとして、業者に戻し、完全なメインテナンスと必要な場合の修理をして、またローテーションをするというサイクルにて行われている。放出された呼吸器は、使用後はそのまま業者に戻され、完全なメインテナンス後に備蓄に戻り、修理不能なものはそのまま廃棄となる。これらの補充は直ちに行われるのではなく、そのときの状況と予算に応じて補充は検討される。

D. 考察

パンデミック(H1N1)2009 は、幸運にもウイルス学的な病原性は高くなく、また多くの健常成人が基礎免疫を保有していたこともあって、感染者の多くは軽症であった。もちろん、小児と基礎疾患を持つ成人あるいは高齢者では重症化する例があるが、それらの総数は現状の日本の集中治療の Capacity を超えるものではなかったと考えられる。

厚生労働省の第四回新型インフルエンザ(A/H1N1)対策総括会議の資料によると、平成21年9月1日時点では、新型インフルエンザの入院診療を行う医療機関において、人工呼吸器の全保有台数は 32,179 台で、9 月 1～4 日の間に実際に使用されていたのは、16,100 台と報告され(1 県のみ調査中にてデータなし)、保有台数の約半数が占有状態にあったと考えられる。

一方、1997/98 シーズンに、A/H3N2 亜型の季節性インフルエンザウイルスに大幅な抗原変異がはいり、流行株がそれまでの Wuhan strain から Sydney strain に変わったときには、97/98 シーズンの流行は非常に大きかったものの、流行の中心が小児、学童であり、超過死亡は大幅に増加することはなかった。しかしながら、翌年 98/99 シーズンに同様のウイルスが流行した際には、罹患年齢層が、成人と高齢者にシフトしたため、過去 10 年間で最高の超過死亡を記録し、当時の新聞には、多くの病院で入院病床が不足し、廊下までベッドを並べ、人工呼吸器も払拭したことが報告されていた。

また、以前より危惧されている A/H5N1 亜型の鳥インフルエンザはインドネシア、ベトナム、エジプトなどでは依然として状況は変わらず、鳥からヒトへの感染は続いており、これがヒト世界に侵入する可能性は以前と変わっていない。

このように考えると、今回のパンデミックの人工呼吸器は保有台数の約半数が使用されていなかったが、もしも人工呼吸管理が必要な患者数が倍に増加すれば、その時点で人工呼吸器は不足するということになる。

当然のことながら、感染症はインフルエンザだけではなく、年々新興感染症が発生している状況と、炭疽などによるバイオテロの脅威を考えるに当たっては、危機管理の観点から、人工呼吸器を備蓄しておくと言うことは重要なことである。米国では、1999 年から人工呼吸器を含めた Strategic National Stockpile が維持されており、パンデミックと言っても、なんら慌て

ることなく、備蓄分は速やかに放出されている。

今後、本邦においても、国民の生命を守るという観点から、人工呼吸器を含めた、健康危機管理のための備蓄を平常時から維持しておくことはきわめて当然のことであると考える。

E. 結論

人工呼吸器の備蓄について、米国のStrategic National Stockpile(SNS)における状況を調査し、その備蓄人工呼吸器の仕様と維持管理のメカニズムを、我が国における準備のための基礎資料とした。パンデミック(H1N1)2009 は、幸運にも我が国の健康におけるインパクトは大きなものではなかったが、危機管理の視点から、今後人工呼吸器を含めた、国家備蓄を維持管理しておくべきである。

F. 健康危険情報

特記事項なし。

F. 研究発表

特記事項無し。

G. 知的財産権の出願・登録状況

特記事項無し

資料Ⅱ－1－①

米国 Strategic National Stockpile 資料

Ventilator Criteria	Mandatory Characteristics
Operating Characteristics	
1. Power source	a. AC with battery back-up and ability to run w/o gas source b. Battery duration should be at least 4 hours duration at: – Assist-volume control – 16 liters minute ventilation (corrected for compressible volume or measured at patient end of circuit) – 35 breaths per minute – 15 ml/ cm H2O compliance – 20 cm H2O/L/sec resistance – 10 cm H2O PEEP – low flow oxygen source at 4 lpm – **NOT** 50-55 psi oxygen source or medical air source – 1:2 I:E
2. Modes of ventilation	Volume control (assist/control and SIMV) for adults and pediatrics > 10kg (i.e. 50 cc VT) For infants 5-10 kg: Device must be able to provide volume control (assist control and SIMV) for a tidal volume as small as 25cc OR Device must be able to provide pressure control (assist control and SIMV; pressure limited, variable flow or constant flow, time-cycled mandatory breath) for 5 – 10 kg infants to achieve a targeted volume of 5-6 cc/kg
3 Control of settings (and range of settings when defined	o RESPIRATORY RATE – Lower limit < 8 bpm, Upper limit > 30 bpm o PEEP – Lower limit 0 – Upper limit > 15 cm H2O o TIDAL VOLUME (when in volume controlled mode) – Lower limit < 25 cc, (<50cc if meets pressure controlled option for 5 – 10 kg as defined in *Mandatory Operating Characteristics* 2. U – Upper limit > 1000 cc o FLOW OR INSPIRATORY:EXPIRATORY RATIO – Must allow for control of flow across mandatory range (using RR, VT, I:E,(and flow waveform if applicable) or direct setting of flow). See Mandatory *Operating Characteristics 4* o FiO2 (when operating with 50-55 PSI source O2) – Across the continuous range from room air to FiO2 1.0 For pressure controlled ventilation (if this is the mode which will be used for your device to reliably ventilate a 5-10 kg infant with a target tidal volume of 5-6 cc/kg) o INSPIRATORY PRESSURE LIMIT o RESPIRATORY RATE o PEEP o FiO2 (when operating with 50-55 PSI source O2) o FLOW OR INSPIRATORY:EXPIRATORY RATIO

4 Range of inspiratory gas flow	Minimum of < 10 L/min Upper limit >80 L/min Must be able to sustain upper limit of flow for a volume controlled breath, 0.75 sec inspiratory time, VT 1000 cc against: a). simulated 25 cm H2O mean airway pressure b). simulated 70 cm H2O peak inspiratory pressure
5 Positive End Expiratory Pressure (PEEP)	Device-controlled internal PEEP PEEP compensation for set PEEP level during spontaneous pressure triggered breaths (if applicable for mechanisms of trigger)
6 Operate w/o 50-55 psi oxygen source	Full device operational capability including provision of supplemental oxygen (except for fine control of oxygen across the continuous range from room air to FiO2 1.0) when connected to an oxygen concentrator, oxygen generator, or low flow compressed oxygen source in the absence of any 50-55 psi gas source (absence of both medical air and oxygen)
7. Measurements	Inspired tidal volume or Expired tidal volume Must be measured at patient end of ventilator circuit with a pneumotachometer. Volume determined by this method (either inspiratory or expiratory, must be displayed for each individual breath to the operator). Peak inspiratory pressure must be measured and displayed
Performance	
1. Sustained use	Ventilator model must have documented evidence of sustained performance for 2000 hour evaluation listed below: Documented evidence of sustained performance (F1100 standards) for: 1) 2000 hours 2) Assist-volume control or SIMV 3) 10 liters minute ventilation 4) 20 breaths per minute 5) compliance 50 ml/ cm H2O 6) Resistance 20 cm H2O/L/sec
2 Pediatric use	Ventilator has FDA approval for use in all of the following populations: adult, pediatric, and infant. The device must be approved specifically for use with infants weighing as little as 5 kg.
Safety	
1. Alarms	Audible and visible alarms -disconnect, apnea, high pressure, low source gas pressure Remote alarm interface
Stockpiling Issues	
1. Durability and versatility for different operating environments	1. Fluid spill resistance 2. Mechanical shock per IEC 60601-1 and IEC 60601-1-2 3. Mechanical vibration 4. EMC and electrical safety testing 5. Storage temperature range: -20 C to 60 C 6. Operating temperature range 5 C to 40 C

Guidelines for Acquisition of Ventilators to Meet Demands for Pandemic Flu and Mass Casualty Incidents

Including
Addendum #1 (June 5, 2006)
Addendum #2 (January 30, 2008)

American Association for Respiratory Care
May 25, 2006
AARC, 9425 N. MacArthur Blvd., Irving TX 75063
972-243-2272 * info@aarc.org

Introduction

Following the tragedy of September 11, 2001 and the anthrax mailings of the same year, the U.S. medical community has undertaken steps to deal with a potential event that could result in a large number of patients requiring mechanical ventilation. More recently, the threat from nature, in the form of the Avian Flu (H5N1), has accelerated preparations for a pandemic flu, which might result in thousands of patients requiring mechanical ventilation.

At present, the H5N1 flu remains difficult to transmit from person to person, but mutation of the virus could change this quickly. Reports from Southeast Asia suggest that the virulence of H5N1 results in severe acute respiratory failure (ARF).

In the United States, the treatment for ARF is supplemental oxygen and mechanical ventilation. Thus we can expect a surge in demand for ventilators if a pandemic of H5N1 were to occur.

In the wake of a pandemic flu with a virulent flu strain like H5N1, patients with survivable illness will die from lack of resources unless more ventilators that have the capabilities to provide ventilatory support for patients with ARF are readily available.

Mechanical Ventilation in the U.S.

Mechanical ventilation typically is implemented and managed by respiratory therapists, in intensive care units, under the direction of a physician. Despite the severity of ARF, most patients survive. However most patients with severe ARF, except when caused by conditions immediately correctable by antidotes, (e.g., naloxone for opiate overdose), are likely to die.

Typically U.S. hospitals maintain a sufficient numbers of ventilators, support equipment, and supplies to meet current health care demands. At times of peak demand (i.e., flu season), hospitals frequently are required to supplement their ventilator inventories, by renting additional ventilators. Thus, U. S. hospitals have virtually no reserve ventilators to respond to a disaster or pandemic.

Mechanical ventilators, used in critical care settings, are complex microprocessor-driven devices designed to support a wide range of medical conditions, acuities, ventilation modes, flow rates, and pressure settings. The high cost of purchasing and maintaining such critical care ventilators makes stockpiling these devices financially impractical.

A simple ventilator setting error can cause patient injury or death. The extensive training and competency requirements necessary to operate these ventilators safely and effectively impedes the use of support personnel who may be called upon to assist respiratory therapists if a pandemic or other mass casualty event hits the country.

The following represents the recommendations from the American Association for Respiratory Care to assist with decisions to plan and implement mass casualty response for both pandemics (H5N1) and other mass casualty disasters.

It must be emphasized that ramping up ventilator capacity, for any mass casualty response, will likewise require ramping up of human resources to assist respiratory therapists and physicians with treatment of patients requiring mechanical ventilation. This human resource issue is a key factor in ventilator selection, of no less importance than the ventilator itself.

Recommendations of Additions to the U.S. Strategic National Stockpile (SNS)

We understand that the U.S. Centers for Disease Control and Prevention's Strategic National Stockpile (SNS) program owns and maintains approximately 6,000 mechanical ventilators for distribution to states affected by mass casualty events. However, a serious influenza pandemic is likely to overwhelm even the SNS inventory.

Therefore, we recommend that the current SNS inventory be expanded.

- At least 5,000 to 10,000 ventilators that are similar to ventilators that are currently in the SNS, with the ability to control tidal volume, rate, and PEEP, as well as having an alarm system, should be acquired.
- These additional ventilators should include 1,500 critical care ventilators with the same features and capabilities as those currently in use in ICUs across the country. Of this 1,500, 1,000 should be adult and 500 should be pediatric ventilators. This added resource will help meet the anticipated surge in demand for the most clinically versatile ventilators that will support the clinical needs of the severe H5N1 patients, especially those who have co-morbidities.

A reliable triage system is absolutely necessary to identify the patients who cannot be managed with the more numerous but less complicated ventilators, and to assure that they receive the appropriate ventilator support necessary to sustain them throughout the incidence of H5N1.

As such, local planning will be essential.

Critical Points to Consider In Local Planning

Human Resources Issues

- Under normal conditions critical care professionals are in short supply. Using a triage system to reduce services to essential non-elective levels will free some personnel and equipment.
- If the need for mechanical ventilation overwhelms the staffing capacity, noncritical care professionals will be enlisted to assist in patient care, but only after undergoing some degree of training by respiratory therapists and other critical care specialists.
- Therefore:
  - ✓ Ventilators must be easy to use.
  - ✓ Ventilators must have adequate alarms to include loss of power source (gas and/or electricity), low pressure, high pressure, and disconnect.
  - ✓ Standardized training programs must be undertaken to first train the trainers, and then facilitate the training and use of additional caregivers.
  - ✓ The complexity of mechanical ventilation requires that respiratory therapists play the lead role in this educational effort.
  - ✓ The purchasing decision for these devices should include local disaster management teams, critical care physicians, and respiratory therapists.
  - ✓ Ventilators used by EMS professionals for emergency care and transport typically do not offer the parameters and operational limits needed for prolonged ventilation of the patient with ARF.

Logistical Support

- Adequate supplies of ventilator circuits, heat and moisture exchangers, suction equipment, and pulse oximeters must also be readily available in order to maintain airway clearance, and monitor oxygenation.
- Ventilator circuits (tubing/valves) used to connect the patient with the ventilator must be sterilized, if reusable, or replaced when ventilators are switched to different patients over the course of the pandemic.

- Natural disasters may eliminate electricity, or a pandemic may require continuing ventilator use in facilities not designed or configured for the wide array of medical technology devices. Since all mechanical ventilators are powered by compressed gas (air), and/or electricity, plans must include pre-identified additional sources for high capacity air compressors that can power several ventilators simultaneously. These compressors must be able to produce clean and dehumidified air at within a pressure range specified by the ventilator manufacturer. Gasoline- or diesel-powered generators should also be identified in the plan.

- Oxygen supply may be limited by events that destroy commercial infrastructure (hurricane) or hospital supplies (flood, earthquake.)

  ✓ Oxygen consumption of ventilators must be limited

  ✓ Ventilators capable of operating from compressed gas *and* a variety of electrical sources are preferred.

- Infants and children will also be victims, so ventilators should be capable of ventilating pediatric patients.

- In case of contagious respiratory disease caregivers should use appropriate protections.

  ✓ Non-invasive (mask) ventilation should be avoided due to risk of contamination.

  ✓ Caregivers must wear currently recommended personal protective equipment and receive appropriate training for its use and all procedures related to the decontamination process.

  ✓ Caregivers should minimize exposure time.

Ventilator Capabilities and Capacity

- The following ventilator capabilities are necessary to treat patients with H5N1 and the resultant ARF.

  ✓ Operate across a wide range of patient populations (infants to adults)

  ✓ Easy, safe operation.

✓ Minimal maintenance.

✓ Operate for 4-6 hours when electric and gas supplies are unavailable. This battery operation might include internal and external batteries.

✓ Ventilation of acute respiratory failure will require, at a minimum, the ability to control tidal volume, respiratory rate, inspired oxygen concentration, and positive end-expiratory pressure (PEEP).

✓ Note that devices used in EMS are designed for short-term use (transporting patients) and therefore may not have any value in a pandemic flu or mass casualty event.

- Increasing ventilator capacity

✓ Stockpiling of ventilators with the characteristics necessary to meet the challenges of ARF is recommended.

✓ Stockpiling ventilator power sources and the previously mentioned supplies and equipment is recommended.

✓ If not currently in place, a system to periodically inventory and test stockpile equipment must be instituted virtually at the time of acquisition,

✓ Efficient utilization of current, non-stockpiled ventilators must occur.

o Cancel elective surgery and utilize anesthesia ventilators.

o Allocate ventilators appropriately between hospitals, municipalities, and cities.

o Request all hospitals to determine the existence and condition of obsolete, yet functional, ventilators that could be used in the event of a pandemic or other disaster.

o Establish a procedure for appropriate distribution of local ventilator stockpiles, if they exist.

o Make advance arrangements with equipment rental companies to ascertain their ability to supply ventilators.

o Assess access to SNS reserves.

Summary

- Ventilator reserves must be versatile enough to meet the ventilator demands of a mass casualty and/or pandemic event.
- Planners should consider standardization of ventilators when practical, in order to simplify: a) training support staff, b) inventory of support resources (circuits, etc), and c) anticipated site of use.
- Ease of usage and ease in training must be considered at time of ventilator purchase.
- Numbers and types of ventilators should reflect the differences in need between disaster response with mass casualties and a pandemic such as H5N1.
- Ultimately, there will be just one reserve of ventilators to use in both disaster scenarios. As such the need to add ventilators that have ventilation mode capabilities to support pandemics is paramount.
- The current ventilator stockpile should be expanded by 5,000 to 10,000 ventilators. This should include approximately 1,500 ventilators (1,000 adult and 500 pediatric) with the features and capabilities that can support patients with Acute Respiratory Failure.
- Respiratory therapists can and are assisting agencies at all levels to assure that ventilator stockpiles are not measured by quantity alone, but also clinical capabilities.
- The American Association for Respiratory Care stands willing to assist all emergency preparedness agencies as they provide further consideration to the purchase of ventilators. It will also assist in identifying the support and logistical issues that manifest as part of this process.

Addendum #1

June 5, 2006

We have been notified by the CDC that there are actually about 4,000 ventilators in the CDC's Strategic National Stockpile. These include 2,000 IMPACT 754 and 2,100 LP10 ventilators. An additional 486 ventilators are on order but have not yet been received.

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