Addendum #2

January 30, 2008

Non-invasive ventilation

Non-invasive ventilation (NIV), ventilation via a nasal or face mask, is a standard of care for respiratory failure in the patient with chronic obstructive pulmonary disease (COPD). [1-4] However, the AARC guideline on ventilator acquisition for pandemic flu recommends that NIV not be used and that non-invasive ventilators are not recommended for stockpiling. [5] This addendum is intended to provide further clarification on these issues. The use of NIV in pandemic flu is not recommended for the following reasons

- Patients with respiratory failure from avian flu progress quickly to acute respiratory distress syndrome (ARDS)[6,7]
- The use of NIV for ARDS has been reported [8,9] but recent evidence cautions against this practice due to lack of efficacy and potential for complications [10,11]
- A recent survey of US hospitals suggest NIV is not commonly used for ARDS [12]
- The success of NIV is related to a significant time (1-2 hours) spent by the respiratory therapist at the bedside at initiation of NIV [13], an impracticality in a pandemic event
- Recognition of NIV failure and the requirement for emergency intubation is also more difficult in a scenario of too many patients and too few caregivers
- Some concern over NIV qualifying as an "aerosol producing procedure" possibly increasing the risk of caregiver exposure has be raised [14,15] although the evidence is weak and the experience from Southeast Asia does not support this theory [16,17]
- A leading physician from Hong Kong with significant experience in care of patients with severe acute respiratory syndrome (SARS) has also suggested the NIV not be used in febrile respiratory illness. [18]

Why not stockpile non-invasive ventilators?

Non-invasive ventilators tend to be cheaper and smaller than many conventional devices, but have limitations which preclude recommendation for stockpiling which include:

- No battery back-up
- Limited monitoring
- Limited alarms
- Inability to provide volume control (most devices provide pressure targeted ventilation) [19]

The main advantage of non-invasive ventilators is ability to function in the face of a leak (leak compensation). [20]

Current hospital inventory

Despite the limitations of non-invasive ventilators, many hospitals have these devices available. In a pandemic situation, we suggest the re-purposing of non-invasive ventilators for use as invasive ventilators. Some of the newer, more sophisticated NIV devices have built in alarms (e.g., Respironics Vision) and are more suitable than those without alarms. When simpler devices are used, the addition of pressure monitoring and low pressure/disconnect alarms is recommended. These devices should also only be used under the supervision of respiratory therapists.

Note: Re-purposing of non-invasive ventilators should only be done under the supervision of respiratory therapists. The traditional single limb circuits with a fixed leak used with a face mask can lead to carbon dioxide re-breathing during ventilation via an endotracheal tube. Use of circuits with an exhalation valve at the airway would be preferred in this instance

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人工呼吸器の調達ガイドライン
インフルエンザの流行や集団外傷の必要に備えるために

米国呼吸療法学会
2006 年 5 月 25 日

はじめに

2001 年 9 月 11 日の悲劇や同年の炭素菌テロ事件を契機として、アメリカ医学会は大量の患者が人工呼吸を必要とするような事態が起こった場合に備える取り組みを開始しました。人的災害だけでなく、鳥インフルエンザ（H5N1）という自然の脅威によっても、インフルエンザの世界的流行への備えを早めるよう求められています。数千人単位で人工呼吸が必要な患者が発生すると予想されるからです。

現在のところ、H5N1 はヒトからヒトに感染することがほとんどない状態にとどまっていますが、ウィルスが変異すると事態は急速に変わるでしょう。東南アジアからの報告では、H5N1 に感染すると重篤な急性呼吸不全（ARF）となることが示されています。

合衆国では ARF の治療にあたって酸素補給と人工呼吸を実施します。したがって H5N1 が大流行すると、人工呼吸器の需要が急増すると思われます。

H5N1 のような高病原性ウィルス株によるインフルエンザの大流行では、設備の不足のせいで回復の見込みのある患者が死亡することも予測されます。そのため、ARF の患者の人工呼吸に使用できる人工呼吸器をより多く備える必要があります。

合衆国における人工呼吸

合衆国では、集中治療室で呼吸療法士が医師の指示に従って人工呼吸の実施、管理を行うのが一般的です。ARF は深刻な病態ですが、回復する患者は少なくありません。しかし、重篤な ARF となると、即効性の解毒剤で対処できる場合（麻薬の過剰摂取にたいするナロキシンなど）を除くと、多くの患者が死亡します。

通常の場合であれば、合衆国内の病院には人工呼吸器、周辺機器、及び消耗品が通常の必要を満たす十分な数量で備えられています。しかし、需要がピークに達するとき（インフルエンザ流行時など）は、病院は人工呼吸器をレンタルして補充しなければならないこと

がよくあります。つまり、合衆国の病院には予備の人工呼吸器は備えられていない状態で、災害又は流行病の発生時に対処することは困難であるといえるのです。

集中治療に使用する人工呼吸器は、マイクロプロセッサで駆動する複雑な装置で、さまざまな病態、重篤度、呼吸モード、呼吸回数、圧力設定に対応できるように設計されています。高価で維持費のかかるこのタイプの人工呼吸器を備蓄の対象とするのは、費用の面を考慮すると現実的ではありません。

人工呼吸器の設定のちょっとした誤りでも患者の傷害や死亡につながる可能性があります。このタイプの人工呼吸器を安全、かつ効果的に使用するには、広範囲の訓練や資格要件が必要です。そのため、万一病気の大流行、あるいは集団外傷が発生したとき、呼吸療法士を補助する要員を、必要に応じて招集して使用するという方法は困難なのです。

米国呼吸療法学会は、病気の大流行（H5N1）、及び集団外傷の集団外傷（疾病）にどのように備え、対処すべきか、その対策について以下を提案します。

特に重要なことですが、集団外傷（疾病）対策として人工呼吸器の総数を増加させると、人工呼吸を必要とする患者の治療にあたる医師や呼吸療法士を補助する人的資源も増加させなければなりません。人的資源の問題は人工呼吸器の選択を左右する主要因であり、その重要性は人工呼吸器と同じです。

合衆国戦略的国家備蓄（SNS）追加の提案

合衆国疾病対策予防センタの戦略的国家備蓄（SNS）プログラムですでに約 6000 台の人工呼吸器を準備し、集団外傷（疾病）が発生した州に配備できるようにされています。しかし、深刻なインフルエンザの大流行が発生した場合には、この SNS の備蓄台数では不足すると思われます。

現在の SNS の備蓄台数を増やすことを提案します。

- 現在 SNS が備蓄している人工呼吸器の同等品（タイダルボリューム及び流量の制御、PEEP が可能でアラームシステムを搭載）を最低 5000 から 10000 台調達する。
- うち 1500 台は、ICU で使用する集中医療用の人工呼吸器と同等の機能と性能であること。1500 台のうち、1000 台は大人用、500 台は小児用とする。この構成にした場合、H5N1 の重篤な患者、特に合併症のある患者の臨床上の必要性に対応できる多用途の人工呼吸器が数多く必要になったとしても対応可能となる。

確実なトリアージをかかすことができません。台数の多い簡易型の人工呼吸器では対応できない患者を特定し、生存のために必要な適切な人工呼吸を確実に受けさせなければならないからです。

そのため地方計画が不可欠です。

地方計画策定にあたって考慮する重点項目

人的資源の問題

- 通常の状態でも集中医療専門家は不足しています。トリアージシステムによって医療サービスを必要不可欠なレベルの患者に限定しなければ、機器と要員をある程度確保することも困難になります。
- 人手の限界を超えるほど多くの人工呼吸が必要となった場合、集中医療以外の医療スタッフの応援を得て患者のケアにあたります。ただし、事前に呼吸療法士及び他の集中医療専門家による訓練を受けなければなりません。
- したがって、
    - ✓ 人工呼吸器は操作が容易であること。
    - ✓ 十分なアラームを備えていること。駆動源（ガス及び/または電気）、低圧、高圧、及び接続のアラームは必ず搭載すること。
    - ✓ 標準化した訓練プログラムを実施すること。はじめに訓練者のトレーニングを行うことでその後のトレーニングと介護士を増やして活用することが容易になる。
    - ✓ 人工呼吸は複雑であるのでこの訓練は呼吸療法士主導で実施すること。
    - ✓ 地域の災害管理チーム、集中医療の医師、及び呼吸療法士をまじえたチームで調達する装置の選定を行うこと。
    - ✓ 救急医療専門家が救急医療および搬送に使用する人工呼吸器では ARF 患者の長期人工呼吸に必要なパラメータ及び動作リミットは得られない。

ロジスティックサポート

- 気道クリアランスを確保し、酸素飽和度をモニタするため、十分な数量の呼吸回路、湿熱交換器、吸引装置、及びパルスオキシメータを確保すること。
- パンデミックの期間、人工呼吸器を次の患者に使用する場合は、患者と人工呼吸器をつなぐのに使用する呼吸回路（チューブ/バルブ）は、再使用可能であれば滅菌し、単回使用であれば交換すること。

- 自然災害では電気の供給が得られなくなるおそれがある。またパンデミックでは本来医療機器を設置すると意図していない施設で人工呼吸器を継続して使用する必要が生じる可能性がある。人工呼吸器はかならず圧縮ガス（空気）及び/または電気で駆動するので、複数の人工呼吸器を同時に駆動できる大容量のエアコンプレッサを追加駆動源として計画に含める必要がある。コンプレッサは清浄で除湿された空気を人工呼吸器製造業者が指定する圧で供給可能でなければならない。また、ガソリン、あるいはディーゼル駆動の発電機も必要である。
- インフラが破壊される事態（ハリケーン）や病院の供給ラインがなくなる事態（洪水、地震）では酸素の供給が制限されるおそれがある。
    - ✓ 酸素使用量の制限
    - ✓ 圧縮空気と数種類の電源の併用が望ましい。
- 幼児、小児を対象とすることも考慮して、人工呼吸器は小児にも使用可能であること。
- 感染性の呼吸器疾患の場合は、介護士は適切な防護手段をとること。
- 非侵襲性の人工呼吸（マスクによる人工呼吸）は行わないこと。感染の恐れがある。
- 介護士は必要な保護具を使用法を習得したうえで身につけ、除染に関する方法のトレーニングを受けること。
- 接触時間を最短にすること。

人工呼吸器の性能と能力

- H5N1 に罹患して ARF となっている患者を治療するのに必要な人工呼吸器の性能は以下の通りである：
    - ✓ 適用範囲が広いこと（小児から大人まで）
    - ✓ 操作が簡単で安全であること
    - ✓ 必要最小限のメンテナンス
    - ✓ 電気、ガスの供給がとまっても 4-6 時間は稼働できること。バッテリーは内部、外部のいずれでもよい。
    - ✓ 急性呼吸不全の人工呼吸で最低限必要とするのは、タイダルボリューム、呼吸数、吸気酸素濃度の制御、及び呼吸終末陽圧（PEEP）機能である。
    - ✓ 救急医療で使用する人工呼吸器は短時間（患者の搬送）動作用の設計である。インフルエンザの大流行や集団外傷の事態には適していない。

●人工呼吸器の総数の拡大

- ✓ ARF に対応可能な性能を搭載した人工呼吸器の備蓄が必要である。
- ✓ 人工呼吸器の駆動源及び前述の消耗品と周辺機器の備蓄が必要である。
- ✓ 調達に際して、定期的に備蓄品の在庫を確認して試験するシステムが必要である。

✓ 備蓄対象となっていない既存の人工呼吸器を効果的に使用すること。

- ✧ 不急の手術を取りやめることで麻酔用人工呼吸器を利用する。
- ✧ 都市、市、病院間で人工呼吸器を適切に配属する。
- ✧ 旧式であってもパンデミックや災害時に使用できる人工呼吸器があるか、またその状態はどうかを各病院に確認を依頼する。
- ✧ 地方で人工呼吸器を備蓄している場合、備蓄の配備手順を作成する。
- ✧ レンタル会社の事前手配により、確保できる人工呼吸器台数を確認する。
- ✧ SNS 備蓄へのアクセス方法を評価する。

要約

- 備蓄する人工呼吸器は、集団外傷及び/またはパンデミックの要求にかなう多用途のものであること。
- 計画にあたって、可能な限り人工呼吸器の標準化を考慮すること。標準化により、a)補助要員のトレーニング、b)消耗品等（回路その他）の在庫、c)使用場面の想定、が簡略化される。
- 購入にあたっては、操作が容易か、また、トレーニングが容易であるかを考慮する必要がある。
- 人工呼吸器の台数及び型式は、集団外傷への対応と H5N1 のようなパンデミックへの対応の違いを反映すること。
- しかし、人工呼吸器の備蓄は、集団外傷、パンデミックのいずれにも使用するものである。従ってパンデミックに必要とされる呼吸モードを搭載した人工呼吸器を増加させる必要が優先となる。
- 現在の人工呼吸器の備蓄台数を 5000 から 10000 台増加させること。この増加数のうち 1500 台（1000 台は大人用、500 台は小児用）は急性呼吸不全の患者に使用できる性能と能力が必要である。
- 人工呼吸器の備蓄は単に台数だけでなく臨床上の性能を考慮する必要があり、呼吸療法士は関係機関にそのアピールを行っている。
- 米国呼吸療法学会は、緊急準備機関が人工呼吸器の購入に関してさらに検討する際に援助する用意がある。また、人工呼吸器の調達にかかわる消耗品や輸送の問題についても助言する用意がある。

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Allocation of Ventilators in an Influenza Pandemic: Planning Document

NYS Workgroup on Ventilator Allocation in an Influenza Pandemic
NYS DOH/ NYS Task Force on Life & the Law

Executive Summary:

A powerful strain of avian influenza has generated concern about a possible pandemic, though scientists do not know with certainty whether or when a pandemic will occur. However, the better-prepared New York State is, the greater its chances of reducing morbidity, mortality and economic consequences. In a pandemic, many more patients could require the use of mechanical ventilators than can be accommodated with current supplies. A federal ventilator stockpile exists, and New York State plans to buy additional ventilators that would meet the needs of patients in a moderately severe pandemic. In a disaster on the scale of the 1918 influenza pandemic, however, stockpiles would not be sufficient to meet need. Even if the vast number of ventilators needed for a disaster of that scale were purchased, a sufficient number of trained staff would not be available to operate them. If the most severe forecast becomes a reality, New York State and the rest of the country will need to confront the rationing of ventilators.

An ethical framework must guide recommendations for allocating ventilators in a pandemic. Key ethical concepts are the duty to care for patients and the duty to use scarce resources wisely. Maintaining a balance between these two sometimes competing ethical obligations represents the core challenge in designing a just system for allocating ventilators.

The workgroup recommends an ethically and clinically sound system for allocating ventilators in a pandemic, containing the following elements:

1) Pre-triage requirements: Facilities must reduce the need for ventilators and expand resources before instituting ventilator triage procedures.
2) Patient categories for triage: All patients in acute care facilities will be equally subject to triage guidelines, regardless of their disease category or role in the community.
3) Implications of triage for facilities: State-wide consistency will prevent inequities; chronic care facilities will maintain different standards from acute care facilities.
4) Clinical evaluation: Clinicians will evaluate patients based on universally applied objective criteria, and offer time-based trials of ventilator support.
5) Triage decision-makers: Supervising physicians will take responsibility for triage decisions. Primary care clinicians will care for patients and will not determine ventilator allocation.
6) Palliative care: Palliative care will play a crucial role in providing comfort to patients, including those who do not receive ventilator treatment.
7) Appeals process: Physicians and patients require a means of requesting review for triage decisions; ethics committee members and others should be prepared to assist in the appeals process.
8) Communication about triage: Government and clinicians need to provide clear, accurate and consistent communication about triage guidelines. Data gathering and public comment can help improve the triage system.

The workgroup recommends that these guidelines be reviewed in public settings, including medical centers and community forums, with the explicit goals of encouraging education, comment and revision. After such public review, NYSDOH should incorporate improvements to these recommendations, and issue the revised document as a set of voluntary guidelines for acute care facilities.

NYSDOH is empowered to issue voluntary, non-binding guidelines for health care workers and facilities; such guidelines are readily implemented and would provide hospitals with an ethical and clinical framework for decision-making. The workgroup expects that compliance with voluntary guidelines would be extremely high. The complex legal issues raised by altered standards of care in a public health emergency create vulnerabilities for individual facilities as they draft policies. Facilities have requested

detailed procedural advice from the state, and do not seek wide latitude in devising their own policies.

NYSDOH is also empowered to issue binding regulations for hospitals that would apply to standards of care during a pandemic. However, these rationing recommendations remain untested in actual circumstances; issuing them as binding regulations may produce unforeseen consequences. A ventilator allocation system must be designed with sufficient flexibility to adjust to changing clinical information. The static nature of regulation could make it an awkward mode for clinically detailed recommendations.

Among the most challenging legal questions related to the pandemic is the issue of liability protection for clinicians and facilities that adhere to rationing criteria in a public health crisis. Voluntary guidelines issued by NYSDOH for ventilator allocation provide strong evidence for an acceptable standard of care during the dire circumstances of a pandemic. However, there is no guarantee that a court would accept adherence to the guidelines as a defense against liability should lawsuits arise.

Legislation is the only avenue certain to provide robust protection for providers who adhere to the guidelines. Such legislation could offer immunity to health care providers who follow guidelines for ventilator allocation, or alternatively, could guarantee defense and/or indemnification to providers. The combination of voluntary guidelines based on sound ethical and clinical principles, paired with legislation that protects providers who comply with the guidelines, offers the best possible balance of clarity, flexibility, and confidence in designing public health policy for allocating ventilators in a pandemic.

I. INTRODUCTION

The U.S. Department of Homeland Security "views pandemic influenza as both the most likely and most lethal of all threats facing the United States." [1] Scientists and policymakers cannot know with certainty whether an influenza pandemic will occur. However, the better-prepared New York State is, the greater its chances of reducing morbidity, mortality and economic consequences.

Both federal and state governments have drafted plans for a possible pandemic. The federal Department of Health and Human Services (DHHS) released a pandemic influenza plan that offers an assessment of public health and medical preparedness, and guidance to state and local health departments. The New York State Department of Health (NYSDOH) released its draft preparedness plan for pandemic influenza in February, 2006. The state plan includes a review of actions to be taken by health officials, emergency responders and care providers at different phases of the pandemic. The healthcare planning section deals with hospital surge capacity issues and addresses the roles of triage centers and home care. Finally, the communications section discusses effective strategies for conveying to the public risks and steps to cope with them.

In March 2006, the New York State Task Force on Life and the Law, at the request of NYSDOH, convened a workgroup to consider clinical and ethical issues in the allocation of mechanical ventilators in an influenza pandemic. The group brought together experts in law, medicine, policymaking and ethics with representatives from medical facilities and city, county, and state government to address necessary alterations in the standard of care in an emergency. The efforts of the workgroup will inform

NYSDOH plans for coping with the large number of critically ill patients thrust upon the medical care system during a pandemic. Pandemic planning must address potential shortfalls in many resources, including staff, protective equipment, and medications, including oxygen. The goal of the workgroup was to develop recommendations for healthcare institutions specifically for the allocation of ventilators in a public health emergency. The recommendations presented here are intended to guide health professionals and others to act in a manner consistent with ethical principles while preserving as many lives as possible. These guidelines should be publicly reviewed with the explicit goals of achieving publicity and transparency, inviting comment and ensuring that they reflect the values of New Yorkers. After such public review, NYSDOH should incorporate improvements to these recommendations, and issue the revised document as a set of voluntary guidelines for acute care facilities.

This document draws upon the expertise of the workgroup, literature review, and the incorporation of extensive commentary on earlier drafts. NYSDOH and the Task Force wish to thank the workgroup members for their exceptional efforts in helping develop the recommendations through their presentations, their comments, and the generous donation of their time and wisdom. A full list of workgroup members is in Appendix III.

II. BACKGROUND

Influenza viruses can be designated as A, B, or C, with influenza A viruses being the most dangerous. Because influenza A viruses mutate and spread rapidly, and can affect various species, they are often responsible for seasonal influenza epidemics and rarer pandemics.

Influenza

Seasonal Influenza: Despite the availability of vaccines and immunity present in the population, each year seasonal influenza kills 250,000-500,000 people worldwide. In the United States, seasonal influenza causes an annual average of 36,000 deaths, 200,000 hospitalizations and 37 billion dollars in economic costs. Peak influenza season runs from November through March. Pandemic influenza is not the same as seasonal influenza; depending on its virulence, pandemic influenza has the potential to kill far greater numbers of people across the world.

Pandemic Influenza: A pandemic is defined as an illness "occurring over a wide geographic area and affecting an exceptionally high proportion of the population." [2] According to the World Health Organization (WHO), there are three prerequisites for a pandemic: (1) emergence of a new virus to which there is little or no immunity, (2) virus replication that can cause serious illness in humans, and (3) efficient human-to-human transmission. [3] Because such a virus would be new and there would be no available vaccine, efficient transmission could have a devastating global impact.

There were three influenza pandemics during the 20th century. The 1918 influenza was the deadliest, killing an estimated 40–50 million people worldwide, when the world population was less than a third of today's population. [4] The influenza

pandemics of 1957 and 1968 were less severe, causing an estimated 2 million and 1 million deaths respectively. All three pandemics likely resulted from a mixture of genetic material from human and avian influenza viruses. [5]

Avian Influenza: Generally, influenza viruses are "highly species-specific, meaning that viruses that infect an individual species (humans, certain species of birds, pigs, horses, and seals) stay 'true' to that species, and only rarely spill over to cause infection in other species." [6] The highly pathogenic avian influenza (HPAI) subtype H5N1, which emerged in 1997 and has spread throughout the Eastern Hemisphere, is one of few HPAI viruses that has crossed the species barrier to infect humans.

H5N1 virus is highly contagious in wild waterfowl and can easily infect domestic poultry. The virus is also known to have infected other animals including mice, cats, and tigers. Bird-to-human transmission has occurred, mostly via direct human contact with the secretions and/or excretions of infected poultry. The effect on migratory birds is not fully established. Human-to-human transmission is inefficient and rare. Evidence suggests that spread beyond first generation close contacts occurred in Indonesia, though without significant viral mutations. [7]

Presently, there is no H5N1-specific vaccine licensed and available to the public. The vaccines produced to thwart yearly seasonal influenza outbreaks will be ineffective in the event of a human avian influenza pandemic.

Rapid onset, severe illness, and a high mortality rate characterize H5N1. Of the first 18 human cases that were reported in Hong Kong in 1997, six patients died. Since the second outbreak began in 2003, the WHO has confirmed 278 human cases resulting in 168 deaths (See Table 1).

Table 1: Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO as of March 12, 2007.

Country	2003		2004		2005		2006		2007		Total	
	cases	deaths	cases	deaths	cases	deaths	cases	deaths	cases	deaths	cases	deaths
Azerbaijan	0	0	0	0	0	0	8	5	0	0	8	5
Cambodia	0	0	0	0	4	4	2	2	0	0	6	6
China	1	1	0	0	8	5	13	8	1	0	23	14
Djibouti	0	0	0	0	0	0	1	0	0	0	1	0
Egypt	0	0	0	0	0	0	18	10	6	3	24	13
Indonesia	0	0	0	0	19	12	56	46	6	5	81	63
Iraq	0	0	0	0	0	0	3	2	0	0	3	2
Lao People's Democratic Republic	0	0	0	0	0	0	0	0	1	1	1	1
Nigeria	0	0	0	0	0	0	0	0	1	1	1	1
Thailand	0	0	17	12	5	2	3	3	0	0	25	17
Turkey	0	0	0	0	0	0	12	4	0	0	12	4
Viet Nam	3	3	29	20	61	19	0	0	0	0	93	42
Total	4	4	46	32	97	42	116	80	15	10	278	168

Total number of cases includes number of deaths. WHO reports only laboratory-confirmed cases. All dates refer to onset of illness.
(Source: The World Health Organization,
http://www.who.int/csr/disease/avian_influenza/country/cases_table_2007_03_12/en/index.html)

A true infection rate and death rate are impossible to determine because of the unknown number of people with less severe or subclinical illness who do not seek medical care. For this reason, although the measured death rate has been high (>60%), this is likely an overestimation.

The clinical course of H5N1 infection in humans is not fully understood, but is thought to be highly aggressive. In recent experience, onset of disease occurred within a median of 3-4 days post exposure; the time from disease onset to hospitalization was a median of 3-8 days, and the time from disease onset to death ranged from 4-30 days. [8]

Unlike seasonal influenza, H5N1 influenza disproportionately affects young, previously healthy children and adolescents. Most patients are critically ill, commonly presenting symptoms such as high fever, lower respiratory tract infection, abdominal pain, diarrhea, and vomiting. Pneumonia caused by secondary bacterial infection is a common complication of seasonal influenza. In H5N1 influenza patients, primary viral

pneumonia can occur without secondary bacterial infection; in seasonal influenza patients, primary viral pneumonia is relatively rare in adults.

Acute renal failure is estimated to occur in approximately 10-29% of avian influenza cases, with multi-organ failure occurring in almost all fatalities. To date, the majority of avian influenza patients have required a ventilator within 48 hours of hospitalization. [9] Acute respiratory distress syndrome (ARDS) occurs frequently, with respiratory failure expected in more than half of hospitalized patients.

Estimates of the Possible Impact of Pandemic Influenza in New York State

NYSDOH officials have used several outbreak scenarios to estimate the potential impact of pandemic influenza on New York. Officials relied upon the following baseline assumptions in crafting two possible scenarios:

> a specific H5N1 vaccine will not be available for at least 6 months, and will be in short supply thereafter; antiviral medications may be ineffective and in short supply
> the attack rate (percentage of people with pandemic flu out of the total population at risk) will vary, but may be as high as 35%
> the population of New York State is approximately 19 million,
> there are currently 3,981 adult and pediatric ICU beds staffed,
> 15% of the admitted patients with pandemic influenza will require intensive care,
> 7.5% of the admitted patients with pandemic influenza will require ventilators,
> there are currently 6,100 ventilators in acute care settings in New York State,
> at any given time, 85% of the ventilators in acute care settings are in use, and
> 70% of deaths related to pandemic influenza are projected to occur in a hospital.

The two outbreak scenarios are the DHHS moderate scenario, based on the 1957 and 1968 influenza pandemics, and the DHHS severe scenario, based on the 1918 influenza pandemic. The following estimates were calculated using the Centers for Disease Control and Prevention software programs FluAid2.0 and FluSurge2.0.

1. The DHHS moderate scenario with a 35% attack rate (percentage of population infected) and 6-week outbreak duration. Using New York State figures, there could be more than 93,753 total influenza-related hospital admissions with nearly 14,062 total influenza patients requiring intensive care unit (ICU) beds (See Table 2). More than 7,000 cumulative influenza patients would require ventilator support during at least part of the outbreak's duration, with over 2,171 patients needing them simultaneously during peak weeks. Those 2,171 ventilators represent 36% of the New York State capacity, which is critical considering the baseline assumption that 85% of the ventilators in acute care settings are in use during any given week. When this 85% normal utilization rate is considered, there is a projected shortfall of 1,256 ventilators. 18,650 total influenza-related deaths could be anticipated.

2. The DHHS severe scenario with a 35% attack rate during a 6-week outbreak. Though the attack rate is the same as the HHS moderate scenario, the impact will be far greater in this severe scenario; it assumes a more aggressive illness with a higher demand for intensive care and a much greater fatality rate. New York could expect over 770,000 hospital admissions with 115,500 influenza patients requiring ICU beds. During peak weeks, 35,000 patients—nearly 9 times current capacity—would require ICU care. Approximately 58,000 influenza patients would require ventilators during the 6-week outbreak, with 17,844 needing them in peak weeks. This is almost 3 times New York State's current ventilator capacity. The State could anticipate almost 153,000 total deaths over the duration of the outbreak; more than 107,000 deaths will occur in the hospital.

Table 2

	DHHS Moderate Scenario	DHHS Severe Scenario
Attack Rate	35%	35%
Total Admissions	93,753	770,640
Total Deaths	18,650	153,301

Deaths in Hospital	13,055	107,311
Total ICU Beds Needed	14,062	115,596
Peek Week Ventilator Need	2,171	17,844
Total Ventilators Needed	7,031	57,798
Ventilators Available (15%)	915	915
Projected Ventilator Shortfall	1,256	16,929
2006 NYS Ventilator Purchase	850	850
Amended Ventilator Availability	-406	-16,079

(Adapted from Bruce Fage, "Health Care Planning for New York State Pandemic Influenza," presentation at March 2, 2006 meeting)

NYSDOH pandemic planning includes careful consideration of the potential shortage of ventilators, based on the estimates discussed above and on federal plans. There is a federal government stockpile of ventilators, but its use is limited for any one locality; there are not enough ventilators to be distributed if many regions need them at once.

New York State plans to buy ventilators to help avoid rationing in the face of the DHHS moderate scenario; there are no current plans to buy enough ventilators for the most severe DHHS model. This plan balances the need to prepare for a potential pandemic against the need to maintain adequate funding for current and ongoing health care expenses. Moreover, severe staffing shortages are anticipated; purchasing additional ventilators beyond a certain level will not save additional lives, since there would not be sufficient personnel to operate them. In the event of an overwhelming burden on the healthcare system, New York will not have sufficient ventilators to meet critical care needs despite its emergency stockpile. If the most severe forecast becomes a reality, New York State, and the rest of the country, will need to confront the rationing of ventilators and other scarce resources.

A number of technical considerations will guide the purchase and use of these supplemental ventilators. Since a pandemic supposes excess numbers of patients requiring critical care, the extra ventilators should be portable so that they can be used