Health and Human Services,
Assistant Secretary for Preparedness and Response
Assessment of Mechanical Ventilators in US Acute Care Hospitals

JUSTIFICATION

1. Circumstances for Requesting Emergency Information Collection Approval

The Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR) is requesting Office of Management and Budget (OMB) emergency review and approval of this mission critical data collection effort to determine the quantities and types of mechanical ventilators in US acute care hospitals. Since its emergence in North America during early 2009, novel influenza A (H1N1) virus has spread among people worldwide to cause a pandemic. While most ill persons experience self-limited mild illness, approximately 20% of hospitalized patients with severe complications have required intensive care unit (ICU) admission. Most of the adult patients and many of the children requiring ICU care due to 2009-H1N1 have required mechanical ventilation for survival; despite being very ill, the majority of patients have survived. The severity of illness described within the current case-series descriptions of critically ill patients with 2009-H1N1 (albeit this scope and breadth of clinical ICU data to date has been quite limited) suggest that if these patients were not able to access resource-intensive ICU care including mechanical ventilation then the vast majority would have almost assuredly died. Therefore, one of the mission critical elements of 2009-H1N1 HHS planning and response is to support hospitals across the nation to have sufficient quantities of mechanical ventilators and ancillary respiratory equipment to care for their patients. The current quantity of full-feature mechanical ventilators in US hospitals is estimated to be between 50,000 and 105,000 devices. Several estimates have been determined in the past decade but all have employed methodologies with major limitations. Consequently, an accurate and precise estimate of device number remains elusive. In a number of influenza prediction models, if the lower number is correct, many patients may not have immediate access to mechanical ventilators without additional sources of devices being made available, while if the upper estimate is true, shortages may not be seen or may be immediately remedied. To support planning to make sure adequate numbers of mechanical ventilators and ancillary equipment are available for the influenza response, HHS, with ASPR's lead, is rapidly trying to determine quantities and types of mechanical ventilators in US hospitals to evaluate potential equipment quantity vulnerabilities and to mitigate equipment gaps (if shortages are uncovered). The goal is to ensure that all patients in the US with respiratory failure during the

pandemic have access to life-sustaining medical care such as mechanical ventilation.

In the U.S., patients with 2009-H1N1 associated critical illness continue to be admitted to ICUs and require mechanical ventilation. In the Southern Hemisphere, temperate climate countries such as Argentina, Chile, New Zealand, and Australia have experienced dramatic surges in critically ill patients in recent weeks during their typical wintertime influenza season. Argentina, whose total population number is equal to 13% of the US population, has reported nearly 80% as many pandemic influenza deaths as in the U.S. It is expected that pandemic influenza will have a major impact upon the US population this upcoming fall and winter, with many ICU admissions and increasing need for mechanical ventilation for 2009-H1N1 patients. As schools throughout the U.S. will be opening soon, outbreaks of 2009-H1N1 virus are expected to increase. Therefore, there is an urgent need to determine the quantities, types and geographical distribution of mechanical ventilators in the US.

A number of methodologies have been employed to estimate total US mechanical ventilators. Many of the sampling frames were convenience samples so the extrapolated predictions of total devices in the US had large confidence intervals. Also, not only is the number of devices important, but so are the categories of devices. Not all mechanical ventilators have the same features and functionality. Some mechanical ventilators cannot be used for children, especially sick small children. Others cannot run without a continuous source of high pressure air and oxygen. Still others were not intended to be used on anyone with severe respiratory failure (intended more for patients with chronic ventilator needs due to spinal cord injuries rather than acute lung disease). The majority of previous attempts to get at US ventilator numbers did not ascertain the types of ventilators so the total count provides little information on how many of the ventilators could be used for particular populations. Such granular information is crucial to ensure that available mechanical ventilators can meet patients' needs. Furthermore, the mechanical ventilator becomes useless without all of its consumable ancillary equipment such as the ventilator circuit which is the tubing which connects the ventilator to the patient. Much of the consumable equipment is meant for use in a single patient and then is disposed (due to infection risks). Much of this equipment are mechanical ventilator vendor- and model-specific, and generally hospitals may not have extensive reserve supplies of equipment on hand due to storage constraints. Previous HHS efforts have determined that there are limited ancillary equipment reserves at manufacturers and in the distributor supply chain; therefore, HHS needs to determine the most common devices in US hospitals in case

they must support national stockpiles of ancillary equipment. Data on types and quantities of mechanical ventilators in US hospitals would be crucial to make such efforts successful.

Pursuant to section 2811 of the PHS Act, the ASPR serves as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies. In addition to other tasks, the ASPR coordinates with State, local, and tribal public health officials and healthcare systems to ensure effective integration of Federal public health and medical assets during an emergency. US Health and Human Services (HHS) has identified an urgent and compelling need to determine quantities and types of mechanical ventilators in the US to better prepare for possible increased respiratory failure due to 2009-H1N1. ASPR has contracted with the American Association of Respiratory Care (AARC) to facilitate collection of a national inventory of mechanical ventilators in US acute care hospitals.

We are requesting OMB's emergency review and approval of this data collection effort.

2. Purpose and Use of Information Collection

The overarching purpose of this initiative is to determine the types and quantities of mechanical ventilators in US acute care hospitals so that patients with respiratory failure during the pandemic will have access to adequate mechanical ventilation and have an optimal chance of survival. This information will be used to populate baseline mechanical ventilation equipment assumptions in HHS 2009-H1N1 prediction models to predict possible resource vulnerabilities. This information will be used to assist policymakers and scientific advisors to determine if additional respiratory equipment needs to be made available to US hospitals through strategies such as enhancing the numbers of ventilators and ancillary respiratory equipment in the Strategic National Stockpile. Also, this information will be used to work with industry partners through the HHS/ASPR Critical Infrastructure Program to maximize supply chain support of mechanical ventilation.

3. Use of Improved Information Technology and Burden Reduction

Surveys were mailed to the managers of respiratory care departments at all US acute care hospitals and critical access hospitals (5678 sites were identified from the American Hospital Association database). Respondents will be encouraged to enter data directly into a data collection form on a secure web-based data entry system which will then directly populate data directly into a Sequel database hosted on an AARC server. The web-based forms were designed specifically to facilitate ease of data entry for the respondents. Most fields have drop-down boxes and no redundant information needs to be entered. The HHS office of Chief Information Officer and the Department of Homeland Security Protected Critical Infrastructure Information program have both

evaluated the electronic data collection mechanism. Also, respondents will be able to mail back a hard copy of the survey instrument to the AARC if they choose not to enter data directly into the website. The AARC will then manually enter any hard copies which are received. All AARC data collection effort will be performed under the DHS Protected Critical Infrastructure Program.

4. Efforts to Identify Duplication and Use of Similar Information

Dr. Rubinson from ASPR has been working on surge mechanical ventilation issues for nearly a decade and is considered one of the country's leading authorities on mechanical ventilation and pandemics. He has been involved with numerous HHS and outside efforts to identify any other activities or sources of data which can determine US mechanical ventilator numbers. To date, there are no other sufficiently accurate and precise determinations of US mechanical ventilator quantities and types. This is the first attempt to inventory device numbers for the entire country through contacting every US acute care hospital.

5. Impact on Small Businesses or Other Small Entities

This activity does not have a significant impact on small entities. Critical access hospitals (CAH) will be receiving the survey. They are likely to have at most several ventilators, therefore the impact on smaller entities (determination of device numbers to be able to report accurate data) is anticipated to be even less than for larger entities.

6. Consequences of Collecting the Information Less Frequent Collection

This is a one-time data collection.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This collection fully complies with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice/Outside Consultation

OMB waived the *Federal Register* requirement. The survey instrument was initially developed by two mechanical ventilator experts: Richard Branson, an Associate Professor of Surgery at the University of Cincinnati and Dr. Lewis Rubinson, who is currently a Senior Medical Advisor in the Emergency Care Coordination Center within ASPR. The instrument was developed prior to Dr. Rubinson being employed by HHS. It was initially distributed to New York City hospitals in 2005 and

then modified and used to collect information in Seattle-King County hospitals in 2006-2007. The tool has been validated in several Ohio and Florida hospitals, where on-site evaluations to quantity and categorize ventilators at hospitals were compared to respondent reports of devices. In addition this tool has been piloted multiple times over the past several years with a small subset of respiratory care therapists to ensure the questions were easy to understand and that the time to respond was as short as possible. Subsequently, Dr. Rubinson recently joined HHS and ASPR, and now this tool will be used to capture mechanical ventilator data from every US acute care hospital. A copy of the survey instrument is attached as APPENDIX 1.

9. Explanation of any Payment/Gift to Respondents

Neither payment nor gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Data will be associated with the individual health care facility and will be maintained on a secure server with password protection. There will be no patient data collected. Only data regarding the mechanical ventilators will be captured. Data will be treated in a confidential manner, unless otherwise compelled by law. The data is being collected under the protections of the Department of Homeland Security's Protected Critical Infrastructure Information (PCII) program. This Protected Critical Infrastructure Information (PCII) Program Procedures Manual (Manual) provides guidance governing PCII and the PCII Program as established by Section 214 of the Critical Infrastructure Information Act of 2002 (CII Act)*1* and Section 29.4(b)(4) of the implementing Regulation*2* (Regulation).

AARC has received approval from DHS's PCII program for this effort and all AARC and HHS staff who will have any contact with survey data will have completed PCII training. Statements regarding confidentiality in accordance with the PCII program (provides FOIA protection to this information) are included on the survey instrument. No institutional level data will be published. Aggregate data may be shared with local and state agencies to assist with their efforts; all aggregate reporting will be in accordance with PCII regulations.

11. Justification for Sensitive Questions

No sensitive information is being collected from individual persons.. Since this information may be deemed sensitive or proprietary by individual institutions, the effort is being undertaken under PCCI protections. This information is crucial for the nation's response to 2009-H1N1 and no alternative data can suffice to substitute for the current survey questions.

12. Estimates of Annualized Hour and Cost Burdens

Type of Respondent	Number of Respondents	Number of responses per respondent	Hours per Response	Total Hours Burden	Total Wage Rate	Total Cost Burden
Hospital staff (time to collect and input data)	5678	1	1.25	7,098	$30	$212,940

The burden was determined by piloting the current electronic and hardcopy versions of the survey instrument by several respiratory therapists. Also, many respiratory care departments have all of the information necessary to enter data immediately available to enter into the survey instrument. Some departments, though, will need to gather this data prior to survey response. In consultation with the AARC, an estimate of hour and costs burden to collect the requested data was selected through expert opinion to be consistent with the maximum average burden to be expected.

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There is no additional cost to respondents.

14. Annualized Cost to Federal Government

This is one-time collection with contracting costs totaling $100,000. Dr. Rubinson and ECCC will be assisting with analyses and program support. His effort is .2 FTE (.2 X $ 181,000) for 6 months for a cost of $36,200. The total cost to the government is $136,200.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will start as soon as clearance is granted. Data will be analyzed at an interim period by Dr. Rubinson (HHS) and Richard Branson (AARC). This interim analysis will be completed within several weeks of initial survey fielding. A second interim analysis will be performed within 4 weeks of survey fielding. After 8 weeks, the survey collection will be closed. Final analyses will be performed at that time and preparation to publish the information will be undertaken. All interim analyses will be shared with relevant government entities. The final publication will be prepared for public distribution and is planned for completion at the end of Fall or early Winter 2009.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not Applicable.

18. Certifications

There are no exceptions to the certification

B. Collection of Information Employing Statistical Methods If statistical methods will not be used to select respondents and item 17 on Form 83-I is checked "No" use this section to describe data collection procedures.

1. Respondent Universe and Sampling Methods

The entire universe of approximately 5678 hospitals will be asked to provide data. To obtain national situational awareness, data are need from all hospitals. The goal response rate is >90%. While traditional survey instruments have difficulty meeting this goal, the contract and all survey marketing have focused on how to maximize response rate. Much of the AARC contract support was to prepare their extensive network of members to report data as well as to assist with follow-up of non-respondents. Also, HHS has provided a letter of support from senior leadership which is included with all survey materials, is marketing the effort through its public information officers, is broadly notifying key partners through its Hospital Preparedness Program network of grantees and is mobilizing the ASPR Regional Emergency Coordinators to encourage all of their regional contacts to respond to the survey request.

2. Procedures for the Collection of Information

A hardcopy survey and cover letter will be mailed to 5678 hospitals identified as acute care hospitals within the American Hospital Association database. Respondents can manually write in data on the survey hardcopy and mail the instrument back to the AARC for data entry in to the study database. Alternatively, survey recipients are encouraged to enter data into a secure web-based data collection form which will directly populate the study database. Much of the electronic reporting form has been designed with drop-down menus (including to provide information regarding the responding hospital's name and zipcode) to minimize the time necessary for respondents to enter data. Every FDA approved ventilator is also available through drop down menus so minimal free-text reporting is required. As soon as the data is submitted electronically it will populate the database hosted on AARC secure servers. The HHS CIO has evaluated the security of the

web-based collection and database.

Once the data is collected, at periodic intervals the data will be exported into a flat file. The using STATA, frequency count descriptive statistics will be performed. Total numbers of devices and categories of devices will be determined by HHS region. Also, multivariable predictors of having particular categories of ventilators (using logistic regression analysis) will be determined. The independent variables will be various institutional demographic features (number of beds, etc) and geographical variables. The dependent variable will be whether or not they are likely to meet a categorical definition of having particular categorical ventilator capability. Also linear regression will be performed using numbers of mechanical ventilators as the dependent variable and similar independent predictors as the logistic regression.

The frequency counts will assist with device and ancillary equipment gap analyses. The multivariable models will assist to inform some of the solution strategies.

3. Methods to Maximize Response Rates and Deal with Nonresponse

The survey instrument was deliberately designed to be very short to encourage higher response rates. The goal response rate is >90%. While traditional survey instruments have difficulty meeting this goal, the contract and all survey marketing have focused on how to maximize response rate. Much of the AARC contract support was to prepare their extensive network of members to report data as well as to assist with follow-up of non-respondents. Also, HHS has provided a letter of support from senior leadership which is included with all survey materials, is marketing the effort through its public information officers, is broadly notifying key partners through its Hospital Preparedness Program network of grantees and is mobilizing the ASPR Regional Emergency Coordinators to encourage all of their regional contacts to respond to the survey request.

4. Tests of Procedures or Methods to be Undertaken

The survey instrument has been used for similar data collections in smaller sampling frames (New York City and Seattle-King County). Data was successfully collected with very high response rates. Also, survey instruments were sent out to several hospitals in Ohio and Florida in 2008 and then evaluators went on-site to count and type actual ventilators. The on-site evaluations were equivalent to the data provided by the respondents reporting through the survey instrument.

5. Individuals Consulted on Statistical Aspects and Individuals

Collecting and/or Analyzing Data

Data will be collected by the hospital staff and submitted to the AARC. The AARC is responsible for data management. Rich Branson, an AARC ventilator and research expert and Lewis Rubinson, MD, PhD from HHS/ASPR will be responsible for performing the analyses. Both have extensive experience with survey research and both have performed analyses of ventilator survey data from smaller sampling frames.

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