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# Policy Recommendations for Mass Immunization Against Influenza in Connecticut Based on Comparisons of Influenza Vaccine Distribution Policy for Public Mass Vaccinations in Selected Areas of Connecticut, Massachusetts, and New York.

Thomas Roger Stansfield

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Policy Recommendations For Mass Immunization  
Against Influenza In Connecticut Based On  
Comparisons Of Influenza Vaccine Distribution  
Policy For Public Mass Vaccinations In Selected  
Areas Of Connecticut, Massachusetts, And New York

Thomas Roger Stansfield

B.S., University of Connecticut, 1987

A Thesis

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APPROVAL PAGE

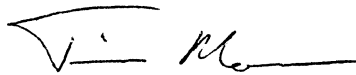
Master of Public Health Thesis

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Presented by

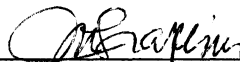
Thomas Roger Stansfield B.S.

Major Advisor



Dr. Timothy Morse

Associate Advisor



Dr. Marcia Trape-Cardoso

Associate Advisor



Donna DiMartino MPH

University of Connecticut

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## Introduction

Most of the scenarios begin the same, a plane lands or a cruise ship docks in the U.S. from an exotic country suffering at the outset of an epidemic of influenza. The passengers have been exposed but have no outward symptoms until the next day, two days or week later. By that time they have infected most of the people they have come in contact with and a vicious cycle of illness rapidly crosses the country. The Centers for Disease Control and Prevention have anticipated the occurrence of the particular strain of flu rampaging across the country, but the companies supplying the vaccine are having trouble replicating the virus in sufficient quantities and in a timely fashion. Faced with dramatic shortfalls in vaccine quantity and a near panicked public, local governments must decide who gets the limited vaccine available in order to maintain some semblance of order. Vaccine already shipped to unscrupulous "middleman" distributors leads to a dramatic rise in the price of the vaccine, and the manufacturers follow suit. "Black Market" vaccine sells without any control over whether the product is even genuine or unadulterated. Empty vaccine bottles are refilled with tap water and sold to high bidders and even health care facilities. A few states have control over vaccine distribution and a well thought out plan. Even so, only the most likely to suffer severe effects from the influenza and the direct caregivers themselves can be vaccinated. A vast number of the population is gravely sick and catastrophic numbers of lives are lost leaving the governmental

infrastructure withered. From the most mundane of activities such as garbage pick up to grave digging, the loss of manpower leaves cities crippled. Fires, looting and riots break out and a mass migration from cities to outlying areas in search of food, medical attention and safety leave whole areas of the country abandoned and in ruin.

This scenario has been played out in the past, though not to the modern extreme depicted above.

Influenza like disease has occurred throughout history, with as many as 31 possible pandemics.<sup>1</sup> A pandemic is defined as a worldwide occurrence of an illness clearly in excess of normal expectancy. This is an expansion of another epidemiological term, epidemic. An epidemic is an outbreak of illness in clear excess or normal expectancy in a region, community or group, smaller than a worldwide population<sup>2</sup>. The influenza (flu) pandemic of 1918 is estimated by the CDC to have killed 500,000 in a span of approximately eight months, in the United States alone. The particular strain of influenza virus was especially virulent. Adults who were otherwise healthy in the morning may have been dead by nighttime.<sup>3</sup> Another strain of flu in 1957, known as the Asian Flu, killed almost 70,000 of the more susceptible people in the population, the young and the elderly. The Asian flu was identified early and the population partially vaccinated against it.<sup>4</sup>

The 1968 Hong Kong Flu is rated as the “mildest” pandemic of this century. Antibiotics and the timing of the outbreak were credited with the

reduction in severity. "Only" 34,000 people died of this strain in the U.S.<sup>5</sup>. Other scares have come and gone in recent years. Rapid dissemination of "news" appears to have played a part in labeling outbreaks as potential pandemics. Thus far, another pandemic has not arisen.

Influenza is an acute upper respiratory infection that is largely self-limiting.<sup>6</sup> Flu is associated with causing complications in patients with underlying cardiac and pulmonary conditions, the very young, and those over 65 years of age, but the virus is such a potent threat to humans due to its ability to infect all age groups.<sup>7</sup>

It is also particularly virulent due to its own make up, its high degree of transmissibility and attack rate<sup>8</sup>, a reservoir of virus in aquatic bird species, and the viruses own ability to drift and mutate rapidly.<sup>9</sup> Influenza viruses naturally mutate themselves in two fashions; one is gradual evolution, known as drift, the other is rapid surface protein change known as antigenic shifts. It is these shifts which result in new subtypes of the virus.<sup>10</sup> Pandemics occur when there is an antigenic shift in the influenza A virus to a new subtype that the general public has not been exposed to, leaving them vulnerable to infection.<sup>11</sup>

Vaccination against influenza is available, in a typical year, to almost anyone in the U.S. interested in getting the injectable vaccine. It's cost effectiveness has been estimated as producing an annual savings of \$13.66 per person vaccinated.<sup>12</sup>

It is advised that anyone in one of the high risk groups, as outlined by the CDC, get the vaccine. In the 2000/2001 influenza season, risk categories were published as in chart 1.

CHART 1<sup>13</sup>

Category 1	<p>Groups at highest risk of influenza-related complications, including:</p> <ul style="list-style-type: none"> <li>• Persons 65 years of age or older</li> <li>• Residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions</li> <li>• Adults and children who have chronic disorders of the pulmonary system, e.g., emphysema, chronic bronchitis or asthma.</li> <li>• Adults and children who have chronic disorders of the cardiovascular systems, e.g., congestive heart failure</li> <li>• Adults and children who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes and mellitus), renal dysfunction, hemoglobinopathies, (e.g. sickle cell disease), or immunosuppression (e.g. caused by medications or HIV).</li> <li>• Children aged 6 months to 18 years who are receiving long-term aspirin therapy and therefore might be at risk for developing Reye syndrome after influenza injection</li> <li>• Women who will be in the second or third trimester of pregnancy during the influenza season.</li> </ul>
Category 2	<p>Persons who can transmit influenza virus to persons in category 1 because they provide direct care, including:</p> <ul style="list-style-type: none"> <li>• Physicians, nurses, nursing assistants, orderlies, pharmacists, public safety workers, emergency response workers, laboratory staff, health care students, housekeeping staff and other staff in hospital and outpatient settings who have direct patient contact.</li> <li>• Employees of nursing homes and chronic-care facilities who have direct contact with patients or residents.</li> <li>• Employees of assisted living and other residences for persons in high risk groups who provide direct care.</li> <li>• Providers of home care to people at high risk (e.g., visiting nurses and volunteer workers).</li> <li>• Household members (including children) of persons in high risk groups.</li> </ul>
Category 3	<p>Otherwise healthy persons aged 6 months and older who wish to reduce their likelihood of becoming ill with influenza, such as:</p> <ul style="list-style-type: none"> <li>• Students and other persons in institutional settings (e.g., college students in dormitories)</li> <li>• Employees of health care facilities who do not provide direct patient care.</li> <li>• Persons who provide essential community services</li> <li>• Work site clinics</li> <li>• Others.</li> </ul>

Influenza vaccine was developed more than 50 years ago and has been the primary flu prevention and control tool ever since.<sup>14</sup> Influenza strains are monitored by the World Health Organization (WHO) throughout the year and particular strains are chosen by the spring of that year. The three licensed manufacturers of vaccine produce 70-80 million doses per year.<sup>15</sup> Approximately 90% of the vaccine is administered through the private sector.<sup>16</sup>

Influenza vaccine is produced by growing viruses in embryonated chicken eggs. The virus is purified and inactivated and then the concentration adjusted against reference standards.<sup>17</sup> It can take up to 8 months to produce enough vaccine for the population.<sup>18</sup> In the event of a pandemic influenza crisis, severe shortages of vaccine are anticipated. Shortages may occur due to inefficacy of the vaccine developed, and / or the potentially sudden appearance of an unpredicted strain.<sup>19</sup>

Under-vaccination of the population would also create conditions ripe for an influenza epidemic. Enough of the population must be vaccinated to induce what is known as herd immunity. Herd immunity is roughly defined as that proportion of the population which must be immunized to reduce to a minimum the likelihood that a non-immunized person will encounter a source of infection<sup>2021</sup>. For influenza, that would be another non-immunized person. Vaccination does not protect, necessarily, the one who is immunized against influenza, as the vaccine is not 100% protective against influenza, but it

reduces to an acceptable probability an outbreak of influenza. Every disease has a different herd immunity threshold.<sup>22</sup> Measles for example has been estimated at 94% vaccination rate to effectively invoke herd immunity<sup>23</sup>. The Healthy Persons 2000 strategy noted in many journal articles suggests a minimum of 60% of the high risk population must be vaccinated against influenza for herd immunity to begin to be effective.<sup>24</sup>

Studies of those receiving the vaccine show disparities among races in the United States.<sup>25</sup> Reasons for the disparity appear to range amongst acculturation, lack of health insurance, poverty, lack of education and a lack of community support.<sup>26</sup> Based on the Medical Expenditure Panel Survey (MEPS) data from 1996 only 47% of blacks were vaccinated against influenza compared to about 68% of whites. The authors of the study hypothesized intervention aimed at all groups would benefit in greater vaccination rates<sup>27</sup>, thereby increasing the herd immunity within each group as it interacts within itself and other groups.

The 2000 – 2001 flu season began with discussion of it becoming a pandemic.<sup>28</sup> The hypothetical scenario at the start of this paper did not appear to be too far off with regards to the manufacturers having difficulty preparing sufficient quantity of vaccine. Two issues were identified in the shortages. The Food and Drug Administration had levied violations on two manufacturers and all the manufacturers had difficulties in developing enough vaccine. The difficulty experienced in the 2000-2001 flu season provided a

unique opportunity for public and private entities to focus attention on the problems with the national influenza vaccine manufacturing and delivery system.<sup>29</sup>

Influenza related deaths in a typical year average 10,000 to 40,000 persons. Hospitalizations average approximately 50,000 to 300,000 patients per year.<sup>30</sup> The Centers for Disease Control and Prevention (CDC) estimates that a pandemic of 1918 proportion would result in up to 300,000 dead from flu and as many as 100,000,000 clinically ill.<sup>31</sup>

The pandemic planning was revisited by the CDC and WHO in 1993 in an effort to revise a plan originally devised in 1978.<sup>32</sup> The panel, convened in the U.S., reasserted that "*State and local health jurisdictions will play critical roles implementing the national plan and should actively participate in the planning process.*"<sup>33</sup> Response to an influenza pandemic falls primarily on State and local authority. The CDC estimates that most jurisdictions do not yet have sufficient plans in place.<sup>34</sup>

As part of an on-going strategy for preparedness for the next pandemic, the CDC has identified a need for improving readiness and decreasing the time required to mount a response to a pandemic as well as developing flexible contingency plans for the distribution of vaccine.<sup>35</sup> The CDC urges that "*mechanisms must be in place far in advance of the pandemic... to reallocate and redistribute unused vaccine promptly and*

*efficiently*".<sup>36</sup> A crucial element to a pandemic plan is developing policies for the distribution of flu vaccine to the entire population in priority order.<sup>37</sup>

The WHO feels pandemic planning must accomplish two main objectives. One is effective risk assessment of the new virus. The second is risk management, not as it may refer to preventing a pandemic, but management of available resources in reducing the overall effects of a pandemic.<sup>38</sup> Pandemic response must be flexible enough to allow for rapid change, even in the target groups that are to receive the vaccine<sup>39</sup>

The WHO suggests a central clearinghouse where cooperating countries can pool vaccine purchases.<sup>40</sup> Each government and vaccine supplier will need to consider how much vaccine they will guarantee to purchase or sell in an emergency situation.<sup>41</sup> Without a "clearinghouse" to balance demand and supply, cost considerations rather than public health may drive vaccine distribution needs.<sup>42</sup> Security problems may develop during pandemic situations. Strict accountability on the part of the clearinghouse, the manufacturers, and the distributors must be enforced. This approach may be downsized to meet the needs of smaller governing bodies, such as States, Counties, or local health departments.<sup>43</sup>

## Statement of the problem

Mass immunization of the population against communicable disease is an obvious Public Health function. Mechanisms for obtaining the necessary doses and delivering them to the areas most in need during either an epidemic event or routine inoculation of the general public are in place throughout the United States. There is little government control over influenza vaccine manufacture and distribution. This is in stark contrast to most childhood vaccines which are distributed by governmental health agencies.<sup>44</sup>

Millions of U.S. citizens receive influenza vaccine each year. The beginning of the 2000-2001 influenza season tested many of the mechanisms in place in the tri-state region of Connecticut, New York, and Massachusetts. Protocols were altered by the CDC in response to the apparent shortages triggered by slow viral response to laboratory growth and actions taken against the drug companies by the FDA. The CDC posted its recommendations and expected them to be followed in an effort to vaccinate those most in need of protection first. This left much of the population, used to getting their annual vaccination, without a source of vaccine. Early in the so called crisis, stories circulated of large companies mass immunizing their staff, using up thousands of doses of scarce vaccine while nursing homes and the elderly remained unvaccinated.<sup>45</sup> The question arose, "how can they get vaccine when the department of public health has not even received theirs

yet?” Agencies began to look over their procurement policies, but orders had already been made months in advance. Some agencies ran out due to partial shipment of their ordered vaccine while others waited for weeks beyond their delivery date without any vaccine at all. Some agencies had just the opposite problem: they had received their allotted doses, ran their clinics but now had excess. This excess was not an uncommon occurrence, as it is better to be “safe than sorry”. Excess was always returnable up to 10% of the order in the past; however, this year the manufactures were not taking any vaccine back for credit. Excess vaccine was often discarded unused while the neighboring state or county went without.

As an example of the cost of vaccine and how it can spiral upwards even in a “non-pandemic” situation, in the 1999-2000 flu season vaccine cost \$25.00 per 10 dose vial. At the start of the 2000-2001 flu season, the same 10 dose vial cost \$50.00. The cost then jumped to \$140.00 per 10 dose vial at the peak of the 2000-2001 season.<sup>46</sup>

As noted earlier in this paper, pandemic planning is not new. Plans are still in the early stages of development or just newly completed but not fully disseminated or implemented. Without these plans in effect an influenza pandemic might be difficult to manage as efficiently as in a time when the plans were accepted and in effect. The 2000-2001 influenza season had all the makings of a young pandemic. Luckily, it never materialized. Public health officials were scrambling to adopt some sort of plan to immunize the

public. Protocols for who should be vaccinated had been set by the WHO and CDC. How the vaccine was to get to its intended targets was not clear.

This paper will attempt to analyze how selected areas in the tri-state region obtained their influenza vaccine for public mass immunizations, how those involved in procuring influenza vaccine felt about their current system, and if improvements could be made in an effort to avoid shortages and some of the confusion observed during the 2000-2001 influenza season. A refinement to the current system used in Connecticut will be proposed which may have implications beyond influenza vaccine.

September 11, 2001 saw the beginnings of a new era in pandemic planning. Although beyond the original scope of this paper, it is hoped that protocols suggested through the analysis of influenza vaccine distribution may have effects on how any vaccine intended for the general public may be disseminated and then redistributed to areas in need. Bioterrorism is not new to this world, but is only now being forced onto the American public. A deliberate epidemic will be combated with the same protocols as the perennial biologic threat, Influenza.

## Materials and Methods;

A questionnaire was developed for use via e-mail. The questionnaire is an interactive document meant to be filled out immediately while the document is still on the computer screen. It was thought this method would increase responses. About half of the respondents utilized this method, but an equal number filled out the questionnaire manually and faxed their responses back.

A total of eight drafts of the questionnaire were developed. Staff members of Sickness Prevention Achieved Through Regional Collaboration (SPARC) and the immunization program at the Torrington Area Health district reviewed the drafts of the questionnaire and suggested revisions. The first and longest draft consisted of 23 questions. The questions ranged from asking the source of vaccine to questions on who should be vaccinated. This shotgun approach was found to be awkward on test subjects and required too much "fill in the blanks" to be convenient.

Versions of the questionnaire were distributed to the SPARC and immunization program staff at the Torrington Area Health district and Dr. Timothy Morse PhD., the faculty advisor for this project. Also asked to participate in the review was one of the office assistants at the Torrington Area Health District. Her input was valuable because she was not part of the development of the questionnaire up to that point and therefore had insight which was overlooked by those of us dealing with the development.

By version three, the questions had been “boiled down” to ten on-target questions. It was felt that this number of questions was easier to complete and most involved simply circling a choice of answer. The questions now focused on where the respondent obtained their vaccine supply, how much they get, why they order the number of doses they do, and how they handle excess.

An important aspect of vaccine distribution was thought to be what becomes of excess vaccine? Re-distribution of available stock to areas which lack sufficient vaccine is a very important factor. Where vaccine overstock was shipped was noted.

By version eight, most of the fill in the blanks had been replaced by choices to be checked off in the appropriate box. The boxes became the on-line check boxes which standardized the manual form and the on-line version. Only one subjective question was left for the respondents. This question asked for comment on two previous questions, “do you feel the current method of procuring influenza vaccine is adequate?” and “how do you feel the current system worked for 2000 / 2001 flu season?” One answer blank was supplied for this two-part question.

The recipients were asked if vaccine was re-distributed to other facilities or returned to the manufacturer and if so, how the transfer was tracked. If the respondent checked “yes”, they were then asked to elaborate.

The completed form was informally field tested on the SPARC agency and the Torrington Area Health district personnel involved in influenza vaccine distribution. Each member of the test group felt the questionnaire flowed well and each completed the form and were thus the first respondents. See appendix "A" for the final draft of the questionnaire.

In an effort to contact people directly involved in the distribution of the influenza vaccine for use in public mass immunizations, a list of contacts was obtained from the regional office of the Assistant Director of SPARC, Donna DiMartino. The SPARC list was used to make telephone contacts and from these contacts, the list was expanded to others in the distribution network in the area of interest.

Distribution is defined as initiating orders or transfers of vaccine for use in public mass immunizations or the physical handling of vaccine for a specific group. (As the study progressed, it became clear that there was little transfer of vaccine taking place, but the remainder of the definition was adhered to.)

The list grew as each person on the SPARC list who was contacted by phone or e-mail gave another potential contact's name. Telephone interviews of local agency personnel also proved valuable. The number of people who handle influenza vaccine distribution in the study area was relatively low, although there are a tremendous number of volunteers and behind-the-scene people who coordinate clinics, set up clinics, and vaccinate the general public. When inadvertently contacted, the people who work the clinics would

invariably supply a name already on the recipient list. This information helped determine the study group had been found in its entirety.

## Results, Connecticut Study Area

Connecticut presented with a specific difficulty in obtaining subjects for the questionnaire. The questionnaire was limited to personnel thought to be in charge of the distribution of the vaccine to public mass immunization clinics within their specific group based on the information obtained from the contacts supplied by SPARC. Seven people were contacted in Connecticut as potential handlers of influenza vaccine within the study area. This number does not represent everyone who handles influenza vaccine in Litchfield County, there are dozens of people, especially in the private sector, in Connecticut who participate in the distribution of flu vaccine. Due to the current system of procurement, any properly licensed individual or agency wishing to vaccinate the public against flu can go directly to the manufacturer or any other distributor and purchase the vaccine. It has been estimated that 90% of adult flu immunizations in Connecticut are given through the private sector.<sup>47</sup>

Of the seven Litchfield County contacts, two (29%) were recipients of original drafts of the questionnaire. Due to the small number of contacts within each region, the survey created its own "case definition" of a contact as well as those who might have turned out to be exclusions from the study. By not responding, the person was excluded from the study. Respondents self-describing themselves as not involved in the process of distributing influenza vaccine would not included either. In Connecticut, three of the seven

respondents (43%) did not participate in vaccine distribution, but they were responsible for either tracking vaccine throughout the area or were part of the Connecticut Department of Health responsible for initiating the state contract with the manufacturer.

The seven initial Litchfield County contacts were each told by telephone or e-mail about this project and asked to fill out a questionnaire. All seven expressed an interest in the project and were given a form to fill out. Six responses were received, an 86% response rate. Of the six, four were determined to be "distributors of vaccine" based on the definition (66% of final recipients in the study area).

Influenza vaccine in the Connecticut study area is obtained from many different sources. Of the check boxes available, manufacturer direct, wholesale suppliers, local health departments, VNA, and hospital pharmacy were all noted as sources. "Other" was checked by the questionnaire author in one case because the respondent filled in the "other" narrative space but did not check any boxes (graph 1). It is important to note that a contact was allowed to check more than one source of vaccine. Unfortunately, no method of distinguishing what percentage of the vaccine obtained from each source by each contact was devised. The check boxes were distributed equally amongst the responses, each of the five choices noted above being checked once, with one of the four qualifying contacts checking two separate boxes.

The Connecticut Department of Public Health does not purchase nor distribute vaccine<sup>48</sup>. The State contracts with the manufacturers as an intermediary so local health departments and VNA can get discounts on their orders. The health departments that offer vaccine and other agencies such as the VNA must order directly from the manufacturer contracted with by the State in order to get the discount or, alternately, are free to order from other sources such as pharmaceutical vendors and wholesalers. Private physicians must order from whatever private source they deem best for them, since the State contract is not available for their use.

The amount of vaccine ordered is up to the person ordering. Past trends, current predictions, and current case loads all dictate how much vaccine a particular administrator in Connecticut will have on hand (graph 2).

When vaccine overstock is encountered in an agency the overstock is handled in many different ways. Five choices were given on the questionnaire (see appendix A). Three choices dominated the responses in the Connecticut study area. "Return to manufacturer/ wholesaler", "sell to a third party", and "discard" were the only choices indicated in the responses. The choices "never had excess" and "call state authority" were not chosen by the study group in Connecticut (graph 3). In 2000 the manufacturers refused returned vaccine for credit, whereas in the past, up to 10% could be returned for refund. It would appear from the responses that each agency has had

excesses in the past. This may be true because it has been far easier in the past to return excess than to attempt ordering more vaccine.

Many health administrators appear to have a fear of running low on vaccine. The clinic or agency which runs out of vaccine is at the mercy of the manufacturer with regards to formulation of additional vaccine and the price. Many respondents mentioned the price fluctuation later in the influenza season. At any given time, the price could be up or down from contracted prices by as much as 50%, according to some respondents.

All the Connecticut respondents thought the current method of vaccine procurement was adequate (graph 4). Of the four respondents answering how they felt the system worked for them in the 2000/2001 flu season, most (75%) felt it was "satisfactory", while the remaining 25% felt it worked "poorly". No one felt it worked "very well" (graph 5).

Open comments were received regarding the distribution of influenza vaccine. A respondent suggested greater organization was needed while another, along the same theme, suggested centralizing the vaccine distribution either at the state level or regionally.

Prioritizing the recipients of the vaccine was also suggested. It was felt that the general public is offered the influenza vaccine too early, and that the high-risk recipients should be nearly completely immunized before the lower risk recipients. It was pointed out that private physicians, nursing homes and the like did not receive their vaccine orders until late in the flu season. These

locations represent places where the high risk recipients are accessed and therefore should be receiving their vaccine first. Private physicians do not typically run clinics in Connecticut and therefore their orders are smaller than the VNA or local health departments.

Redistribution of vaccine was included in the open response portion of the form. Suggestions included returning unused vaccine to a centralized location for redistribution to clinics in need. The American Lung Association of Connecticut maintained a list of all the Influenza vaccination clinics. As calls from clinics running low on vaccine began to come in, the ALA contacted clinics that had completed their schedules and inquired about excess vaccine. This informal method was credited with supplying those in need of vaccine with enough to complete their schedules as well.

Lack of communication amongst those in need with those with excess was mentioned several times as a shortcoming of the current system. All track transfer of vaccine as required by law, and the issue was not the transfers themselves, but to whom they should transfer vaccine. Without knowing who was in short supply, a clinic with an excess may discard unused vaccine not knowing shortages even exist.

## Results, Massachusetts Study Area

Nine people in the Massachusetts area were deemed appropriate to be contacted. Of the nine, five verbally felt they had the time or inclination to fill out a form for the study. Three completed forms were returned, for a 33% response rate. Follow up by phone of those who did not return forms proved unsuccessful.

Public clinics in Massachusetts (those sponsored by local boards of health or a Visiting Nurse Association) are able to obtain influenza vaccine from a stockpile maintained by the Massachusetts Department of Public Health. An allotment from the Massachusetts Department of Health determines the number of doses delivered locally. The allotted doses are based on the number of doses ordered by that health department or agency the previous season. These doses can only be administered to category 1 recipients from the CDC protocols (see Chart). Clinics wishing to vaccinate the general public or augment the supply issued them by the State, must purchase the vaccine themselves. Of the clinics offering vaccine to the general public which responded to the survey, most get theirs directly from the manufacturer (graph 1). The State of Massachusetts has ordered 740,000 doses of vaccine for the 2001-2002 flu season.<sup>49</sup>

Any influenza vaccine left over from the scheduled clinics appears to be discarded. In past years, excess vaccine was returned to the manufacturer. In the 2000-2001 influenza season, this practice was discontinued by the

manufacturers. Clinics were forced to either discard unused doses or contact the State for instructions. Some were able to sell unused vaccine to other clinics in need (graph 3).

All the respondents in the public sector felt the system for obtaining vaccine was inadequate and that the system functioned poorly for the 2000-2001 influenza season. Cited as reasons for the inadequacy was the feeling that if shortfalls in vaccine occurred during the clinics, ordering more vaccine from the State was difficult. Some clinicians were told that prior to augmenting their vaccine supply during the season, a demonstrated need had to be established, defined as less than 100 doses left on hand. To wait until that low a number of doses is in reserve may have meant that some clinics would open and then be shut down after only 100 doses were administered. This would most likely incite some ill feelings toward the clinicians from the public.

Those in the private sector had the opposite response as those in the public sector, they felt the system was adequate and that it worked very well (graphs 4 and 5). It was reported that the private sector receives their vaccine earlier because they paid more than the public sector. If the vaccine was in fact delivered earlier to the private sector, that group would have good reason to feel the system worked well. In fact, both a hospital administrator and the public clinic operators voiced a need for their facility to be put at the top of the distribution list.

## Results, New York Study Area

Eight people were contacted in New York. Of the eight, only three met the study definition. All three returned forms with valuable information, a 37% response rate. Although low in actual number, the response appeared to include the key personnel involved in vaccine distribution for the New York study area.

Most often, administrators of influenza vaccine at public clinics in New York State purchase their vaccine directly from the manufacturer (graph 1) through a State contract with the New York Department of Health. Like Massachusetts, the vaccine is earmarked for the category 1 groups only, as outlined by the CDC. The number of doses ordered is based almost exclusively on past trends and current projections of potential disease (graph 2).

When overstock occurs, all of the respondents checked that they discarded excess vaccine. One respondent also indicated that vaccine is returned or sold to a third party (graph 3). All of the respondents felt the method of obtaining influenza vaccine was adequate (graph 4). Two of the three respondents felt the system functioned satisfactorily for the 2000-2001 influenza season, although one respondent voted "poorly" with no explanation put forward (graph 5).

Respondents in New York felt that the system could be improved by pooling the vaccine. Although this comment appeared with little further explanation or methodology, their reasoning appeared to be so no particular group went without vaccine. Splitting the order between more than one manufacturer was suggested as a means of obtaining at least part of an order. This would eliminate relying on only one manufacturer as the contract dictates and having drastic shortfalls in supply due to manufacturing difficulties as seen in the 2000-2001 influenza season.

It was also suggested that the restrictions on who gets the vaccine be lifted. Limiting the recipients to the CDC priority list was restrictive to some administrators. This suggestion was made by a group which apparently had no shortages in supply, as did many of the other vaccine administrators.

## Summary

There are three manufacturers of influenza vaccine: Aventis Pasteur Maerieux, Wyeth Ayerest Lederle. These are for-profit pharmaceutical companies who make a product which is in seasonal demand and sell it to anyone wishing to pay their prices. Because there are three of them, there is a certain amount of competition amongst them. Because they are for-profit businesses, they are also the targets for criticism. They have been accused by the responders in this survey of selling to the highest bidder and delivering earlier to areas of larger orders for the greatest profit.

Each state handles ordering influenza vaccine pretty much the same. Each state attempts to get the best price for the vaccine from any of the companies. Once a contract is settled, the states then either take delivery of the vaccine itself, or makes the contract available to agencies within the state so each agency can then order what it needs. The agencies are on their own to either supplement the state allocation, or, in the case of shortages, augment their supply through contracts of their own.

Connecticut agencies in charge of vaccinating the public against influenza are on their own to get the supplies necessary. The State provides a contract number on which the various agencies can order vaccine from a single manufacturer only. It does not supply the vaccine itself. The contract allows for a "price break"<sup>50</sup>. An agency can supplement shortages or simply

handle the ordering on their own by buying direct from the manufacturer or through private wholesalers.

Connecticut is different from the other two states surveyed in that it does not have a strong county system. Litchfield County, the area from which respondents were surveyed, has a fairly strong regional collaboration made up of the regionalized health department, the Torrington Area Health District, which covers eighteen communities in Litchfield County and SPARC.

It was interesting to note that the three respondents answering the question if “they felt that the current system of vaccine procurement was adequate”, said yes and yet one still felt the system “worked” poorly. Most of the respondents (75%) selecting an option on how they felt the system in Connecticut worked selected “satisfactorily”, however.

Massachusetts contracts with a manufacturer in a similar fashion to Connecticut. The differences lie in what happens next. The Massachusetts Department of Health bases the contracted number of doses on past trends. It only orders the number necessary to vaccinate the category 1 groups as outlined by the CDC. The Department of Health then distributes the vaccine to the various county or regional distribution centers.

The local Boards of Health at the town level and other health agencies like the VNA, receive from the distribution center that number of doses allotted to them based on the previous years usage. This number is only to

include the category 1 groups, the vaccine is not to be used for vaccination of the general public.

A local board of health that wants to run a clinic open to the general population with no restrictions must purchase vaccine on their own.

Vaccination of the general public often involves payment to the agency for the shot, which has been pointed out as a source of friction between care givers and receivers. Many feel that public agencies are obligated to provide vaccine via taxes, but in fact most local governments can not afford to purchase vaccine without reimbursement of some kind.

The New York Department of Health also contracts with one of the manufacturers and has allotments sent to the various county health departments. The county health departments tend to vaccinate only the high-risk population. The general population must go to a private physician or public clinic.

The vaccine shortage scare of the 2000-2001 influenza season is long since over and vaccination rates are now available from the CDC. The target vaccination rate for high risk individuals noted in the Healthy Persons 2000 strategy of 60%<sup>51</sup> was in fact exceeded on average in the U.S. for the 2000-2001 influenza season. Based on data collected and released for the period January through June, for persons aged 65 years and over, the estimate of influenza vaccinations was about 64.3% in 2001.<sup>52</sup> In this respect the system ultimately succeeded although the recommended schedule of vaccination for a

typical year was delayed.

## Conclusions:

In a post 9/11 time of heightened homeland security, the potential inadequate supply and distribution of vaccine needed due to possible terrorist activity dictates tighter control and accountability to ensure the public is protected. Shifting control from the strict capitalist system to a more centralized federal, state or regional distribution network would ensure that all the population is equally served.

Vaccine manufacturers should be increased to minimize the potential for shortages due to closure, for whatever reason, of one of the factories. Increasing the number of manufacturers would also help with the economics of vaccine production. With a number of producers to choose from, pricing would be expected to come down. Perhaps an incentive program to those companies capable of producing both high quality and high quantity of vaccine could be set up. The government is not currently set up to deal with manufacturing itself and a consideration of that possibility is beyond the scope of this thesis.

The economics of vaccine production were never intended to be studied as part of this project. It is certain that there are aspects of production and distribution which have not been addressed. The study vehicle developed was intended to study how vaccine reaches its intended target population and attempt to develop an improved methodology. Further study of the possibility of increasing production, the government's involvement

in production, and the entire economics of vaccine distribution is certainly warranted.

Flu vaccine reaching the target population is at the core of this study. The comparison of the three state systems, Connecticut, New York, and Massachusetts allowed for three distinct systems of distribution to be compared by those using the systems. The following is a protocol for influenza and, potentially, other vaccines and prophylactic agents such as Potassium Iodide. The premise of the protocol is to remove individual agencies from procuring vaccines and agents but maintaining their roles in final distribution to the public.

Central clearinghouses for vaccine distribution have been suggested by the WHO and CDC. An accounting system for allocation of vaccine could be developed such as exists in the State of Massachusetts. Resolutions put before the American Medical Association in December of 2000 moved to place the onus of control of distribution of influenza vaccine on government agencies. The resolution requested that the central government *"...develop a mechanism to assure appropriate distribution of influenza vaccine initially to those providers, public and private, who will immunize the highest risk individuals first, and then use the remainder to protect other members of the public..."*<sup>53</sup>

Creation of a clearinghouse for vaccine would only be effective if the clearinghouse were able to order and take delivery of all the vaccine produced

by all the manufacturers and pool the entire lot. An oversight committee at the federal level could review allocation of vaccine to each state. As each state submits to the clearinghouse for its allotment, it will be given what it needs for tier 1 recipients only, based on statistics already compiled from past influenza seasons.

The clearinghouse system would function best if there were a mirror clearinghouse in each state wishing to receive federal vaccine. The state clearinghouse would function much the same as the federal one. State clearinghouses would receive orders from regional distribution centers, such as health districts or individual health departments. Those wishing to vaccinate people would apply to the regional office for an allotment based on past tier 1 vaccinations. Since the state office has received their allotment based on the same numbers given to the federal clearinghouse, there should be enough to go around. Excess vaccine is returned to the clearinghouse immediately after the clinic and redistributed to any areas which saw an increased need for vaccine.

Excess vaccine at the state level is returned to the federal clearinghouse as needed to fill deficiencies throughout the nation. Once the federal clearinghouse is satisfied the priority population has been vaccinated, shipping of the remainder of the vaccine can commence. The federal clearinghouse would allocate to the states, based on past need, their required doses. The states would ship to any regional distribution clearinghouse that

has expressed a desire to vaccinate the general public. This need is compiled from requests from individual clinics and practitioners wishing to vaccinate the general public.

Where vaccine is located at any one time is crucial. Tracking of available vaccine could take place via Internet or other real-time electronic means. Each recipient of vaccine would log in the amount of vaccine on hand and keep a running tally of the amount used. The tracking would not only enhance accountability, but may enhance the distribution of available vaccine. As one district completes its immunizations, its surpluses would immediately be known and a transfer order can be issued to send that surplus directly to another district in need. This works both ways, as the district uses up its allotment, that shortage would be immediately noted and the surplus from another district transferred directly instead of going back to the clearinghouse. The clearinghouse would manage all transfers and maintain the accounting.

In summary, individual clinics and practitioners would apply twice to their regional clearinghouse. Once for their priority recipients, and again for the remainder of the population. The state clearinghouse would then apply to the federal clearinghouse for each of the two categories. The federal clearinghouse ships to the state facility which then ships to the clinics. Excess vaccine follows a reverse path until the country has vaccinated all their priority patients. Shipping then proceeds for the remainder of the population to the

states, which ship to the clinics. Excess is again returned to the state for reallocation within the state, then back to the federal clearinghouse.

Smaller versions of this system could be implemented starting at the state level. No single state should rely wholly on any single manufacturer. The state could pool the vaccine and be the primary clearinghouse for its regional districts. No longer would large privately owned facilities be able to order vaccine for its employees while nearby elderly housing goes unvaccinated. Private facilities wishing to vaccinate would apply to the state just the same as a clinic or private practitioner. The private facility would receive its allocation when the priority population has been vaccinated. The remainder of the population would have to wait until the second round of distribution.

Parallels have been suggested between the influenza distribution plan suggested in this paper and the current methodology of distribution of tuberculosis (TB) medications in the State of Connecticut. TB is an infectious pulmonary disease which if left untreated has a 50% fatality rate. As with influenza, it is inhaled by the patient and can be spread from person to person especially in crowded conditions such as overcrowded urban settings and prison populations.<sup>54</sup> HIV is often associated closely with TB.<sup>55</sup>

In Connecticut, the State funds and provides the anti-tuberculosis medications to hundreds of medical clinicians. It also provides for diagnostic treatment and prevention services and case management and screening to local health departments, prisons, convalescent and nursing homes, schools, universities and hospitals.<sup>56</sup>

The similarities between the programs include the State having total control over the distribution of the TB medications. TB cases are vigorously tracked through the current program and needs are therefore predictable. The methodology has proven very effective in the fight against TB. From 1986 to 1996 TB incidence decreased in Connecticut on average 2% per year.<sup>57</sup>

A state run program of distribution of TB medications is a small-scale example of how effective the suggested protocol for Influenza vaccine can be. The applicability of the protocol to other infectious disease medications during epidemic situations, naturally occurring or as a result of accidental or malicious release of disease organisms should be closely studied.

## APPENDIX 1

### Final version of influenza vaccine distribution questionnaire

#### INFLUENZA VACCINE QUESTIONNAIRE PART OF AN M.P.H. THESIS PROJECT ON IMPROVING VACCINE DISTRIBUTION DURING INFLUENZA PANDEMICS AND VACCINE SHORTAGES

PLEASE COMPLETE AND RETURN TO:  
TOM STANSFIELD R.S.  
TORRINGTON AREA HEALTH DISTRICT  
350 MAIN STREET  
SUITE A

TORRINGTON, CT. 06790 ph. 860-489-0436 email [tstansfield@tahd.org](mailto:tstansfield@tahd.org)

Responder's Name \_\_\_\_\_ Position Title \_\_\_\_\_

Address \_\_\_\_\_

Phone and/or email \_\_\_\_\_

Name and title of person responsible for ordering influenza vaccine (if different)

\_\_\_\_\_  
\_\_\_\_\_

1. Please describe your role in vaccine distribution

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2. Where / how do you get your vaccine?

☐ Manufacturer Direct

☐ Local Pharmacist

☐ State Health Department

☐ VNA or similar

☐ Local Health Department

☐ Hospital Pharmacy

☐ Wholesale Supplier

Other \_\_\_\_\_

3. How much bulk vaccine do you get each year? Avg. # of Doses \_\_\_\_\_

4. What factors determine the quantity of vaccine you order? (check all that apply)

☐ Past trends

☐ Current data / projections

☐ Current case load of patients

☐ Other \_\_\_\_\_

5. How do you handle excess vaccine? (check all that apply)

☐ Return to manufacturer / wholesaler ☐ Call State authority

☐ Sell to third party (hosp.

M.D. etc)

☐ Discard

☐ Never had excess

6. Do you track vaccine transfers? ☐ Yes ☐ No If so, how?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

7. Do you feel the your current method of procuring influenza vaccine is adequate? ☐ Yes ☐ No

8. How do you feel the your current system worked for 2000 / 2001 flu season? (check one)

☐ Poorly  
Very Well

☐ Satisfactory

☐

9. Comment on questions 7 and / or 8 AND what do you think could be done to improve the distribution of influenza vaccine

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10. Do you know to whom else I should speak?

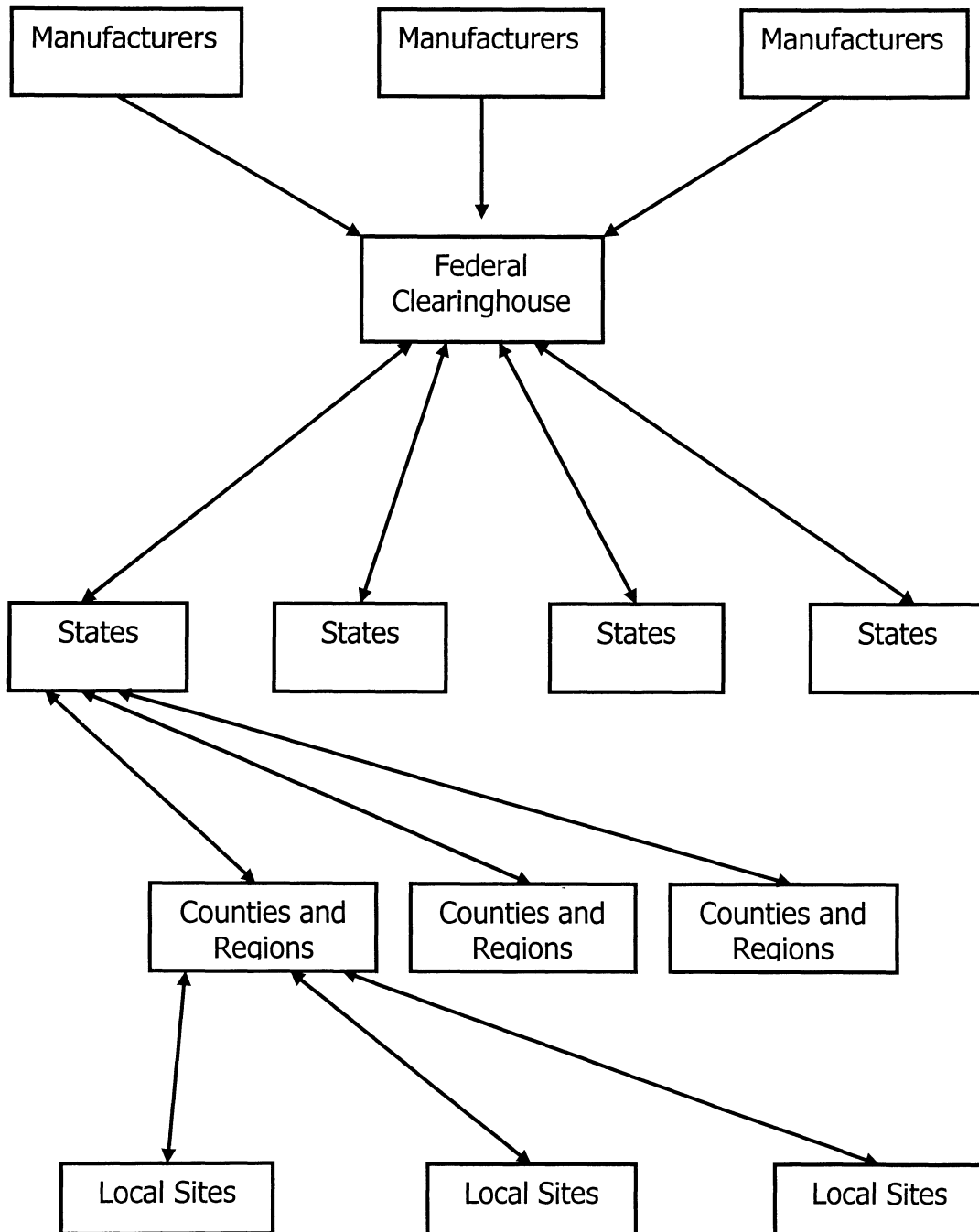
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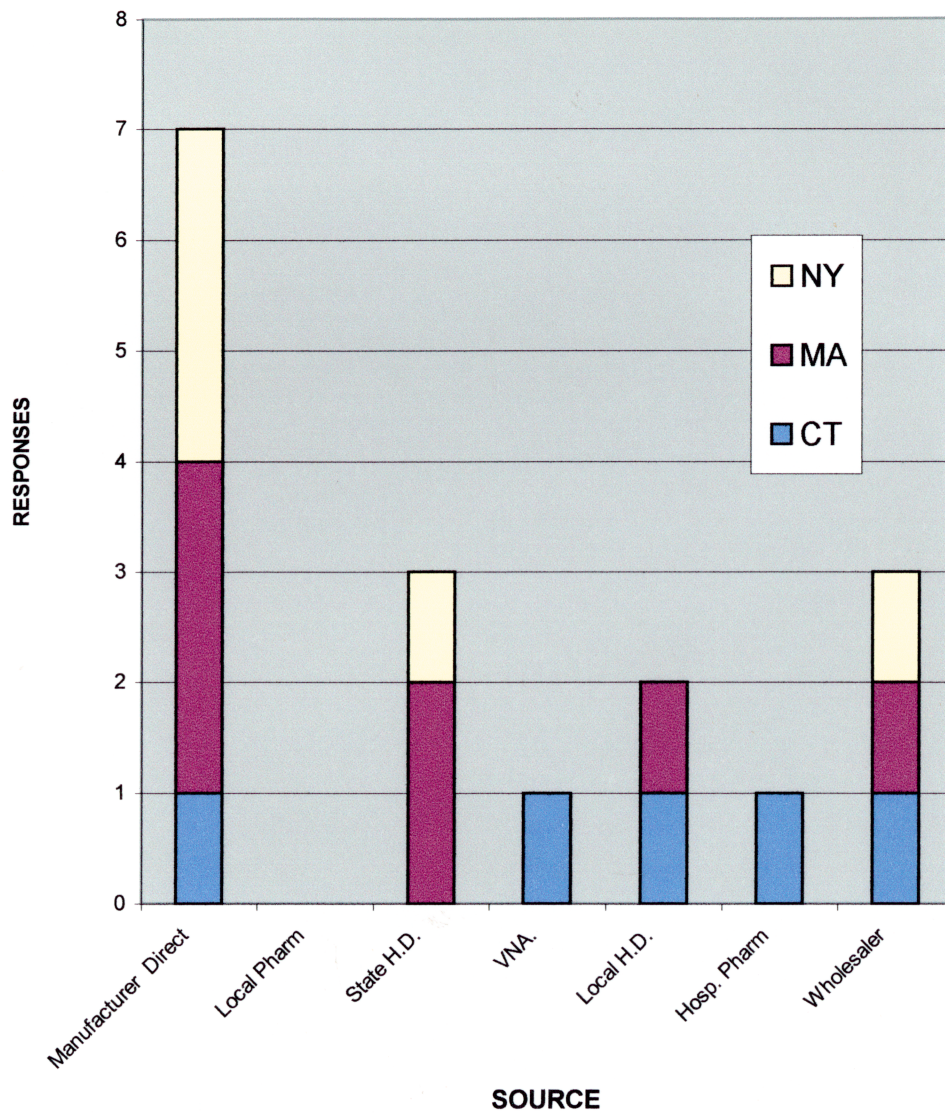
Thank you very much for your time and cooperation. Any Further comments, suggestions etc. are always welcome.

Appendix 2  
Flow Chart of Distribution



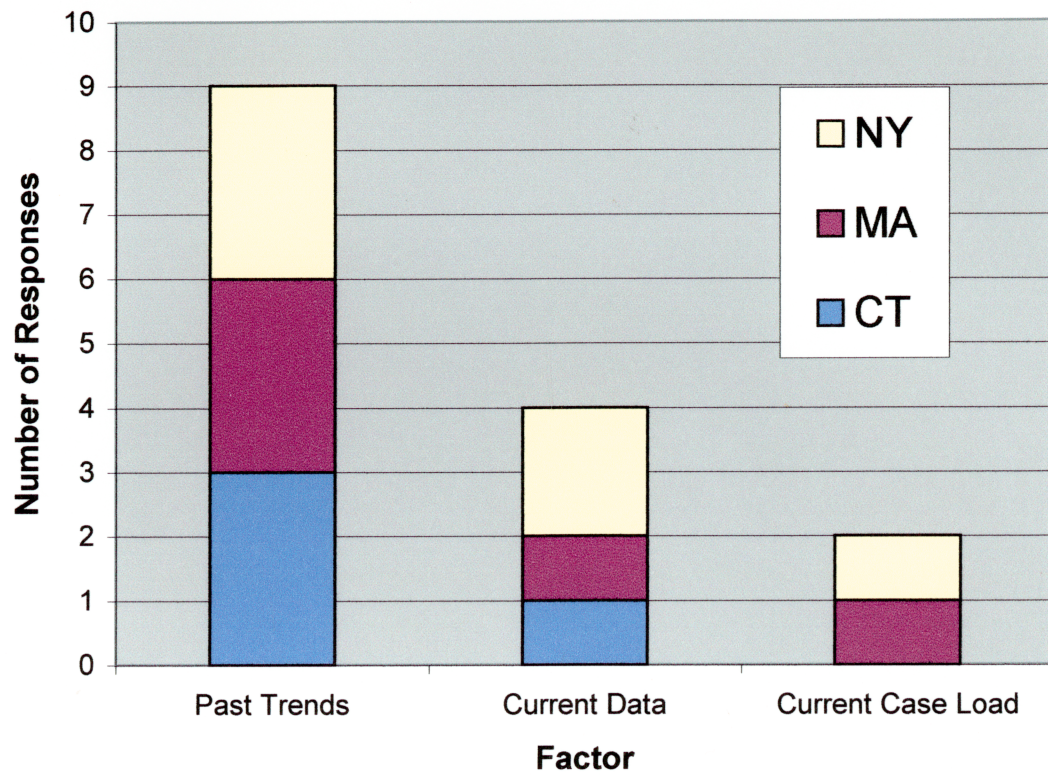
Graph 1

**Question #2**  
**SOURCE OF VACCINE**



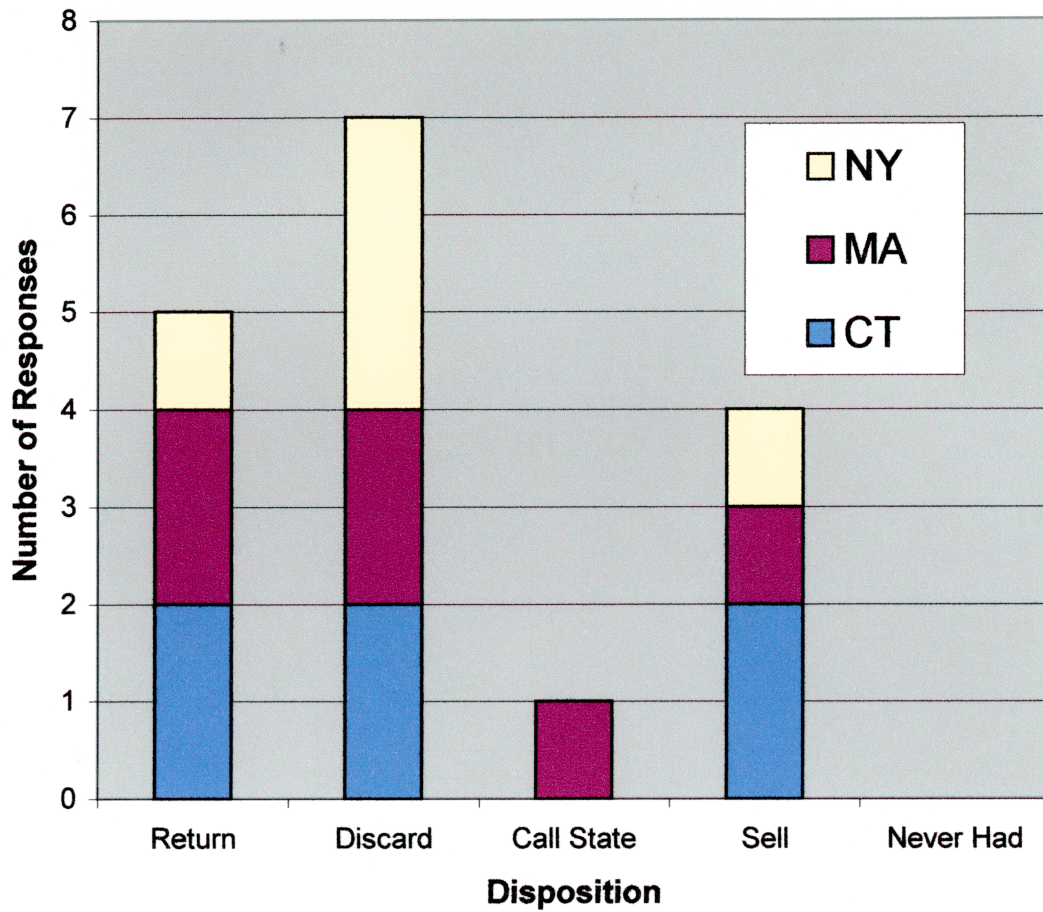
Graph 2

**Question #4, What factors determine the quantity of Vaccine ordered?**



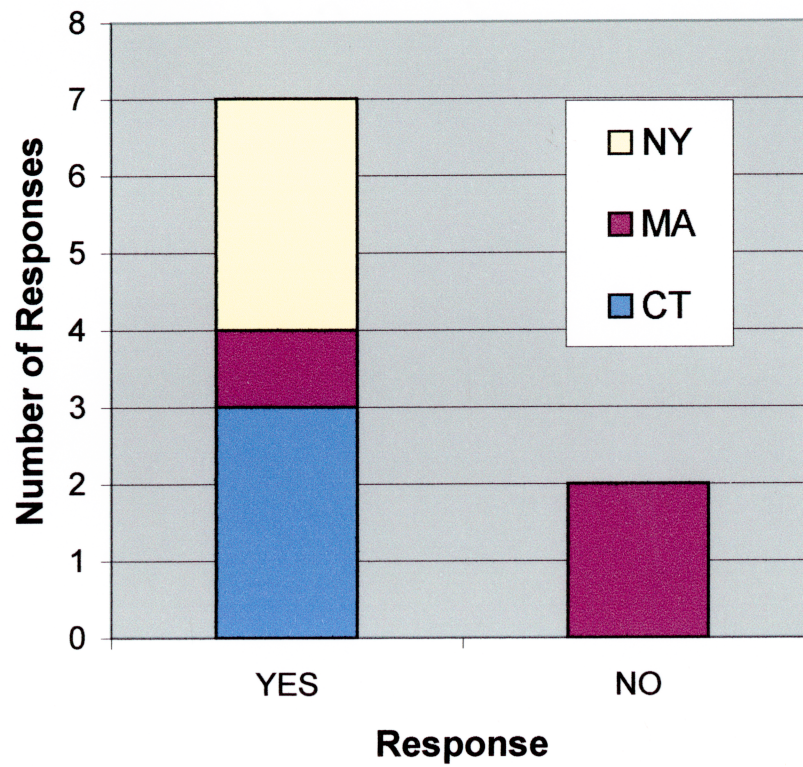
Graph 3

**Question #5, How is Excess Vaccine Handled?**



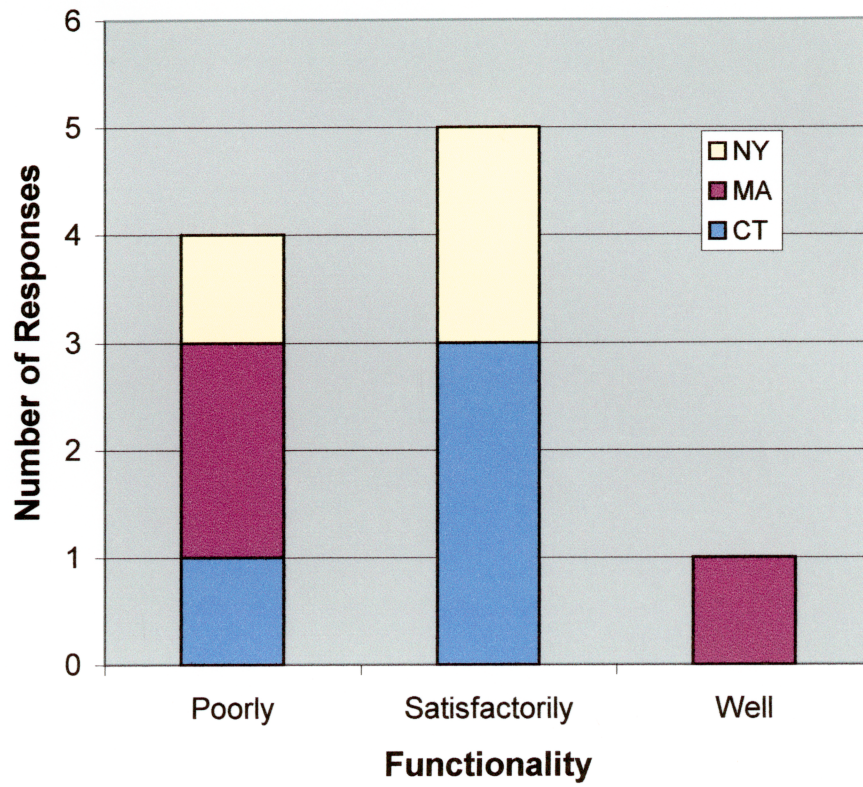
Graph 4

**Question #7, Is the current system of vaccine procurement adequate?**



Graph 5

**Question #8, How well does the current system  
Function?**



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