

# **AABB Interorganizational Task Force on Pandemic Influenza and the Blood Supply\***

## **PANDEMIC INFLUENZA PLANNING Efforts to Ensure a Safe, Available Blood Supply**

### **INTRODUCTION**

The blood community, under the auspices of AABB, has established the AABB Interorganizational Task Force on Pandemic Influenza and the Blood Supply (hereafter called the task force) to help identify the issues raised by, and planning options available to respond to, the threat of pandemic influenza. This document represents the initial work product of the task force. The first section of this document includes background regarding flu pandemics and the second explores possible effects a pandemic may have on the blood supply. The third section provides a summary of recent communications between the task force and the federal government regarding the critical role blood may play in a pandemic and warranted government actions. The fourth section gives an overview of many issues for which planning is needed. The outline that follows provides details on those issues and identifies options to address some of the complicated planning needs. In addition, a planning checklist in a format similar to those being distributed by the Department of Health and Human Services (HHS) to its many constituencies is provided to help collection facilities and transfusion services to organize their efforts.

AABB membership, although international in scope, closely reflects the decentralized character of the United States (US) health-care delivery system. The institutional membership for which these documents are being assembled ranges from enormous organizations of national and regional scope collecting, processing and delivering millions of components annually, to collection facilities and transfusion services responsible for collection and/or transfusion of only a few hundred components per year. These diverse organizations are geographically dispersed and in many, if not most, cases their coverage territories intersect with multiple local, regional and state public health authorities that will bear the bulk of pandemic planning and prioritization responsibilities. In light of this decentralization and diversity, these documents cannot provide a level of detail that would suffice as a facility's pandemic influenza plan. Individual organizations must develop their own plans and exercise them appropriately to ensure they are useful.

The task of preparing for an event as severe as the 1918 pandemic appears overwhelming, but the benefits will be manifold. The 1918 pandemic is a worst-case model for planning purposes, and the probability of a pandemic of this magnitude is thought to be low. Facilities may find that preparedness activities for disruption of this magnitude are a useful long-term goal. Less severe

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\*AABB serves as the designated coordinating entity for the Interorganizational Task Force on Pandemic Influenza and the Blood Supply. In addition to AABB, members include: America's Blood Centers, American Red Cross, Blood Centers of America, and AdvaMed. Representatives from the following government agencies also participate in Task Force discussions: Armed Services Blood Program, Centers for Disease Control and Prevention, Department of Health and Human Services, and Food and Drug Administration.

pandemics may not disrupt operations but the impact on the donor base still must be considered. Preparedness will save lives, including those of transfusion recipients who will have the blood they need during the pandemic, as well as the lives of blood donors and transfusion medicine professionals who will be at reduced risk of contracting influenza. Moreover, it is underappreciated that aggressive preparation for pandemic influenza will certainly increase the effectiveness of our response to annual flu epidemics. While these are not as dramatic as the severe pandemic scenarios being discussed internationally, they cause major morbidity, mortality and disruption.

There is an enormous knowledge deficit affecting key areas in the pandemic planning response. This situation has two implications for the blood community and the task force. First, the community needs to be frank in recognizing what it does not know and, second, the task force acknowledges that these will be living documents, changing with advancing knowledge.

The task force actively seeks the input of anyone who reads this information – email your comments/questions to [govt&legal@aabb.org](mailto:govt&legal@aabb.org).

## **GENERAL ASSUMPTIONS REGARDING INFLUENZA PANDEMICS**

Pandemic influenza occurred three times in the past century, in 1918, 1958 and 1968. Another influenza A pandemic is considered inevitable. The blood community will not be spared its impact.

*“My conclusions are that in an influenza pandemic, there will be a decrease in blood supply, a decrease in demand and blood drawing capacity, but no major impact on the safety of blood itself....”*

*“This is a disease that spreads rapidly across the country and the idea that you can take resources from one area that’s not affected and transfer to another just doesn’t work in a pandemic.”*

*Benjamin Schwartz, MD  
National Vaccine Program Office  
ACBSA May 16, 2005*

Dr. Schwartz captures a conventional wisdom many in the transfusion medicine community have accepted about the impact of pandemic influenza on the US blood supply. The first statement is almost certainly true, but cannot provide any sense of the net impact changes in donation and use will have on available supplies. There may not be a substantial decrease in demand for platelets, which may be needed at levels close to usual to support patients with hematologic malignancy and those undergoing stem cell transplantation or certain urgent surgical procedures that use substantial platelet support. The assumption that the requirement for Red Blood Cell (RBC) transfusion will decline as a result of delays in elective surgery imposed by hospitals struggling to provide surge capacity is probably correct. It does not, however, recognize the transfusion demands of ventilator-dependent flu victims in intensive care settings, where RBC use may be significant.

Flu has never been recognized as a transfusion-transmissible infection. However, asserting that influenza will not materially affect blood safety ignores the absence of systematic data establishing a lack of transfusion-transmission from asymptomatic blood donors incubating influenza, or during the recovery from active infection. It also does not recognize the implications of the precautionary approach to transfusion safety that has dominated the past 20+ years. Given significant concerns about the impact a pandemic may have on the availability of blood, the task force believes the Food and Drug Administration (FDA) should not impose donor restrictions without clear evidence of an interval of asymptomatic viremia and transfusion transmission.

The usual paradigm for response to local disasters -- interregional transfer of blood from unaffected to affected areas -- may not be available under worst-case pandemic scenarios where international and regional outbreaks can be essentially simultaneous and a pandemic wave may stretch across even three or four months. This demands careful advance planning for pandemic influenza, based on a *reasonable worst-case scenario*, updated as data emerge and exercised to highlight gaps and ensure effective implementation. It is arguable whether health care in general or the blood community in particular currently have all the tools needed to respond to a 1918-like event. However, the transfusion medicine community has many tools and many capable people who can develop plans that will mitigate the effects of a lesser epidemic, while building capacity toward more serious threats. Facilities need to identify all the partners upon whom they depend and who depend on them, and engage them if planning is to survive the stresses of an influenza pandemic.

The Centers for Disease Control and Prevention has adopted the current alert levels from the World Health Organization (WHO) global influenza preparedness plan. As reflected in Table 1 outlining the alert levels, the current status is alert level 3 – Pandemic Alert – because only limited human-to-human transmission of the virus has occurred.

**Table 1 WHO Pandemic Alert Levels**

<b>Agent Characteristic</b>	<b>Risk to Humans</b>	<b>Alert Level</b>
Inter-pandemic phase New virus in animals, no human cases	Low risk of human cases	1
	Higher risk of human cases	2
Pandemic alert  New virus causes human cases	No or very limited human-to-human transmission	3
	Evidence of increased human-to-human transmission	4
	Evidence of significant human-to-human transmission	5
Pandemic	Efficient and sustained human-to-human transmission	6

Media reports are dominated by the emergence of highly pathogenic avian H5N1 influenza A, but there is no adequate basis to predict what strain will emerge and cause the next pandemic, nor its timing. The following characteristics of pandemic influenza, avian or another strain, recognized by HHS in its 2005 Pandemic Influenza Plan, can inform the blood community's efforts:

- The virus will be able to spread rapidly worldwide.
- Infected people may be asymptomatic but infectious for a short period early in infection.
- Simultaneous or near-simultaneous outbreaks can occur in communities across large geographic areas with no respect for borders or geographic barriers, limiting the ability of any jurisdiction to provide support and assistance to other areas.
- Enormous demands on the health-care system will result.
- There will be delays and shortages in the availability of vaccines and antiviral drugs, (and almost everything else in the health-care supply chain).
- Disruptions of national and community infrastructures including transportation, supply chains, utilities and public safety may occur as a result of widespread illness, and there will be mortality and concern about ongoing exposure to the virus.

The HHS Secretary has emphasized that pandemic response in the US is primarily a local, regional and state responsibility. Thus, planning efforts in the US will be more complex than in many other countries in the developed world, where health-care and planning systems are more centralized.

**Table 2 Impact of Pandemics – Illness and Death**

Characteristic	Moderate Pandemic (1958/68-like)		Severe Pandemic (1918-like)	
Illness	90,000,000	30% of pop'n	90,000,000	30% of pop'n
Outpatient medical care	45,000,000	50% of ill	45,000,000	50% of ill
Hospitalization	865,000		9,900,000	
Intensive care unit stay	128,750		1,485,000	
Mechanical ventilation	64,875		742,500	
Total Deaths	209,000		1,903,000	

Credible estimates of the clinical attack rates, hospitalization and mortality rates during a pandemic are never available before the fact. Pandemic influenza will generally occur in a series of waves each lasting up to four months. It should be assumed that no vaccine will be available during the first wave, that antiviral medications will be in short supply and that the primary strategies for control will be containment using common sense infection control precautions and social distancing measures to slow and minimize transmission of the virus. The morbidity ranges based on the moderate Asian and Hong Kong outbreaks in the late 1950s and late 1960s, and the catastrophic 1918 pandemic in Table 2 should be useful for planning. HHS has included these estimates in its pandemic planning.

Facilities should assume that decisions addressing donor eligibility, infectious disease testing, component manufacturing and labeling in a crisis will continue to be the responsibility of FDA. During a pandemic that results in disruption of the blood supply, FDA will have a lead role in communicating acceptable variations from regulations, standards and standard operating procedures. The task force and individual blood organizations have the responsibility to maintain their current dialogue with FDA and prospectively define some of the limits within which to operate, realizing at all stages that an inadequate blood supply is an unsafe blood supply in its own right.

### **RISK MODELS AND PLANNING ASSUMPTIONS FOR THE BLOOD SUPPLY**

It is assumed that an influenza pandemic is “inevitable,” whether with the highly pathogenic H5N1 avian strain or an as-yet-unidentified strain. Current estimates of the impact of pandemic influenza on blood needs and blood availability are inadequate to allow precision in planning. In this environment, planning activities will, necessarily, be less focused than optimal. Still, there are many areas in which important preparatory activities are possible and advised.

**Blood Safety:** There is no historical evidence of transmission of influenza by transfusion, but there is an emerging consensus that scrutiny for flu transmission has been inadequate and that the lack of published reports is not compelling. A few small series and case reports suggest that influenza viremia in the day or two before onset of illness may occur. Case reports suggesting that some *severely ill* flu patients are viremic include recent case reports of fatal human infection with highly pathogenic H5N1 avian flu. Both governmental and private investigators have proposed studies of the potential significance of asymptomatic donor viremia for recipient safety. Asymptomatic viremia and the potential for transfusion transmission raises the issues of a donor

deferral for contact with influenza and the duration of a deferral following clinical influenza in a donor. To avoid compromising the adequacy of the blood supply during a severe pandemic, the task force believes donor deferral for contact with influenza, without clear evidence of asymptomatic viremia and transfusion transmission during the incubation period, is not appropriate. Further, the task force believes that a donor who has recovered from clinical influenza sufficiently to pass the donor screening process is an acceptable donor unless there is demonstration of transfusion transmission by asymptomatic viremia during the recovery period. These issues require support of appropriate research during the prepandemic period. Without clear data regarding any risk of transfusion transmission, it is unknown at this time whether FDA will consider new donor deferral policies related to influenza exposure and infection. The task force will continue to communicate with FDA regarding this important issue and will update facilities with any related developments.

Blood Supply: The most useful framework for planning would seem to be a pandemic approaching the magnitude of the 1918 pandemic with clinical attack rates in the 25% to 35% range during the initial wave and high mortality. An additional 10% loss of both donors and staff can be anticipated due to the need to care for ill family and children in the event of school closures, or fear of workplaces and public venues. Current estimates for the first pandemic wave range from 8 to 17 weeks, and center on 12 weeks; the duration of waves could be shorter in individual communities. It is anticipated that there will be up to three waves, each separated by 12 weeks or more.

It is reasonable to assume that elective surgical blood use will decline, as may traumatic injuries in the face of social distancing measures and concern about contagion. The degree to which this will be balanced by increased ICU admissions and ventilator care that will require some use of blood and components has not yet been modeled. Several US and international blood organizations are developing these models at the time of this writing.

During the January 2006 meeting of the HHS Advisory Committee on Blood Safety and Availability, alternative models for blood supply impact from the following organizations were discussed: HHS, The Blood Systems Research Institute and the American Red Cross. In addition, the Canadian Blood Services and the National Blood Service in the United Kingdom (UK) are working on their own models.

Few data are available on the demand side or the parameters within which demand can be reduced, although data from other sources provide points of departure and need to be collated. For example, during the 2003 epidemic of severe acute respiratory syndrome (SARS) in Toronto, Ontario, Canada, RBC demand at the several epicenter hospitals decreased 25%. Unpublished survey data from the UK and Australia suggest that clinicians and experts judge 20% to 40% of transfusions to be “lifesaving” (which may help to estimate the minimal demand level that must be met). If correct, these data may be helpful to transfusion services and clinicians developing policies relating to the triage of blood components. As described below, triage of blood, based on transfusion triggers, will likely be necessary in the event of significant shortages. In addition, models for the potential impact of a frozen RBC stockpile (now with a 14-day post-thaw expiration using licensed closed-system instrumentation) are needed.

All of the modeling efforts are in the earliest stages of development, with no useful output yet available. Once the results and interpretations of the models are available, they must be disseminated in a timely fashion for incorporation in, and revision of, local and regional plans to be used by collection facilities and transfusion services. The critical dependence of model output on assumptions that may or may not be borne out in a real pandemic must be recognized, so that undue reliance on specific conclusions of a given model does not limit the planning of any individual organization. The task force will share additional information regarding blood supply modeling with facilities as it becomes available.

## **TASK FORCE COMMUNICATIONS WITH THE FEDERAL GOVERNMENT**

The task force, in conjunction with the activities of the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism (Disasters Task Force), has been actively working with the government to help ensure that blood needs are adequately considered and planned for in the event of a pandemic. The critical role blood plays in health care is evidenced in the National Response Plan Emergency Support Function #8 ([http://www.dhs.gov/interweb/assetlibrary/NRP\\_FullText.pdf](http://www.dhs.gov/interweb/assetlibrary/NRP_FullText.pdf)), which outlines the role of both HHS and the Disasters Task Force in monitoring and working to meet blood needs in the event of a disaster. Representatives from the HHS, FDA, Centers for Disease Control and Prevention, and Armed Services Blood Program serve as liaisons to both of the interorganizational task forces. In addition, the Pandemic Influenza task force is advocating the following positions before the federal government:

- *The Federal Emergency Management Agency (FEMA) should recognize blood centers as “first responders” so that they can access transportation, fuel, communications support or other assistance needed to guarantee blood needs can be met in the event of a pandemic.* Most emergency response takes place at the state and local level, but without recognition by FEMA that blood centers are critical to health-care infrastructure, some blood centers have found it very difficult, or impossible, to access needed assistance during previous disasters. As a related matter and in response to concerns raised by the blood community, an influential House Appropriations Subcommittee recently directed the US Departments of Health and Human Services, Homeland Security and Transportation to work to ensure that blood centers have priority access to fuel, communications and transportation during disasters.
- *The federal government should designate essential blood center personnel for priority access to both vaccines and antiviral drugs as they become available during a pandemic.* In response to the task force’s request, the HHS pandemic planning document has identified essential blood center personnel as among the high-priority populations to receive vaccines. The task force continues to work with the federal government to ensure that blood center personnel are designated for similar priority access to antiviral drugs in any federal guidance documents. Transfusion service personnel are given high priority as health-care workers. However, ultimately it will be up to the states to determine who will be eligible to receive limited vaccine and antivirals. Therefore, collection facilities should actively communicate with their state and local public health and emergency

preparedness departments regarding the critical need to immunize and protect blood center personnel who are essential to maintaining a safe and adequate blood supply. The task force also continues to communicate with the government regarding which blood center personnel should be considered “essential” to maintain safe and adequate blood collections, and therefore eligible for priority status.

- *Committed platelet donors should be considered for priority access to vaccines and antiviral drugs, considering the critical, ongoing need for these lifesaving components.* Most recently, the task force has made this request to HHS and is awaiting a response. The task force will provide a working definition of “committed.”
- *Research is needed to better understand the risk of transfusion-transmitted influenza.* The task force has recommended to FDA and HHS that appropriate animal experiments should be conducted to expand our understanding of the rate and significance of asymptomatic influenza viremia. In the absence of more data than are currently available, new deferrals addressing this issue do not appear justified. Data obtained using currently circulating human influenza A strains, animal strains or recombinants may not be directly applicable to a new human pandemic virus, so development of investigational protocols to assess asymptomatic viremia should be considered for rapid activation when a pandemic is imminent or in progress.
- *Emergency regulatory policies may be needed to ensure an adequate blood supply during a pandemic.* The task force will continue to be in contact with FDA regarding myriad blood safety and availability issues affected by a pandemic, including donor deferral, donor qualifications, emergency donor criteria, how to manage postdonation information, infectious disease testing, reagent outdates, training and other current good manufacturing practice (cGMP) processes. The impact of any additional donor deferrals on the blood supply will need to be carefully considered before their implementation. When appropriate, the task force will share recommendations with FDA regarding such regulatory policies and will report on important developments to blood facilities. Collection facilities should closely follow the developments regarding donor deferral policies and prepare for deferrals related to exposure and potential infection. A potentially useful example of guidance FDA issued to address blood needs in emergency circumstances is the *FDA Policy Statement on Urgent Collection, Shipment and Use of Whole Blood and Blood Components Intended for Transfusion to Address Blood Supply Needs in the Current Disaster Situation* issued on September 11, 2001 (<http://www.fda.gov/cber/infosheets/dstrbld.htm>).
- *Blood drives should be recognized as an exception from designation as a public meeting or mass meeting if social distancing measures are implemented.* The task force is communicating with the federal government regarding the need to take this step and facilities are urged to share the same message with their state and local health departments.
- *Consistent messages about the effect of a pandemic on the blood supply should be provided to the public.* The task force will continue to work with HHS and other federal agencies to ensure that statements are consistent, whenever possible, and share them with blood facilities. Such statements necessarily will be revised as additional information about a pandemic and its impact on the blood supply becomes available.

## **OVERVIEW OF STEPS BLOOD CENTERS AND TRANSFUSION SERVICES SHOULD TAKE IN PREPARATION FOR A PANDEMIC**

Facilities may decide that planning for a 1918-like pandemic is impossible; however, they should work toward this goal. To assist in achieving this goal, this section provides a brief overview of topics that facilities should address. To further assist blood centers and transfusion services, the task force has also prepared a checklist for pandemic preparations and a corresponding, relatively detailed, issues outline. The checklist is designed to assist facilities in identifying areas in which they should be acting (eg, establishing procedures) to plan for a pandemic. The issues outline is meant to provide facilities with more detailed guidance regarding some of the possible options they have in preparing for and responding to a pandemic. Neither the checklist nor the outline is all-inclusive and undoubtedly will need to be revised as additional information becomes available. However, it is the task force's hope that facilities will find these tools helpful in implementing their own plans.

Planning scenarios suggest “absenteeism attributable to illness, the need to care for ill family members, and concern about infection may reach 40% during the peak weeks of community outbreak.” The blood community needs to extrapolate this estimate to donors, the vendors who supply just-in-time inventory needs and the very lean blood center and transfusion service staffs that maintain the highly regulated processes required for a safe and robust blood supply. Responding to this worst-case impact will require that facilities challenge and disrupt operational practices that have evolved over the last half-century.

Donor Issues: It is inevitable that donors will fail to make or keep appointments in numbers at least proportional to attack rates in individual communities and regions. This phenomenon will occur because of illness, need to care for ill and convalescing family members, and withdrawal from public venues as a result of concern or public health messages suggesting social distancing as an appropriate protective response. Social distancing is an important potential public health strategy for slowing and reducing the spread of pandemic influenza, the impact of which will need to be considered in facility communications with public health authorities and donors. Donors must feel comfortable that measures taken in collection facilities during a pandemic will provide them protection from unreasonable risks of infection in the donor room.

It would behoove collection facilities to consider apheresis platelet donors as distinct from whole blood or RBC donors. This is because of the limited shelf life of platelets compared to that of RBCs and the somewhat less elective nature of platelet use (eg, for support of patients with malignancy who cannot delay therapy) compared to use of RBCs (eg, for support of elective orthopedic surgical procedures that can be delayed during a pandemic).

Collection Facility or Transfusion Service Staff Issues: Absenteeism among collection facility and transfusion service staff will be at least proportional to local or regional attack rates. Again, the high absenteeism rate will be due to illness, care for ill family and concern or public health messages encouraging social distancing, but should be amenable to minimization by prospectively educating workers. Work rules need careful review to be certain facilities have

defined the circumstances of exposure, illness and recovery under which people will be required to remain out of, and allowed to return to, the workplace. For example, there are approaches to sick leave and paid time off that may encourage exposed and ill individuals to come to work, diametrically in opposition to what facilities will be trying to accomplish with mitigation efforts.

Staff must understand that basic hygienic measures, immunization and antiviral medications can reduce transmission of influenza, and facilities must consistently apply available measures. Annual vaccination of staff must be improved using innovative strategies like opt-out consent, more convenient vaccine delivery, and most critically, enthusiastic support of immunization by thought leaders.

Facilities need to evaluate to what degree employees can be cross-trained for critical tasks within the highly regulated environment.

Blood Safety and Availability: In the event of a pandemic, FDA and blood collection facilities may take emergency steps to limit blood shortages – eg, temporary changes to requirements relating to donor deferral, donor qualification, infectious disease testing, cGMP regulations, etc. Collection facilities should closely follow such developments and prepare for their implementation as much as possible.

In addition, blood centers and hospital transfusion facilities, together, should develop strategies for working with a potentially seriously limited blood supply, including the triage of components. In severe shortages, transfusion may be limited to lifesaving indications only. This message needs to be clearly communicated to transfusion services, transfusion physicians and hospital administrators well in advance of a pandemic so that operational and ethical dimensions can be explored. Sufficient data exist in the literature to allow transfusion services to establish transfusion triggers that are evidence-based and defensible. Hospital transfusion services should begin efforts now to establish such transfusion triggers in advance of a pandemic. It is likely that application of available evidence in this regard will provide as much protection for the adequacy of the blood supply as any other intervention. Blood centers should coordinate with their customers to establish, before a pandemic, the priorities of providing blood components if the supply becomes limited

Supply Chain Issues: The implications of pandemic influenza on the just-in-time supply chain for the collection, processing and distribution of blood and blood components are not completely understood. Facilities should assume that vendors will experience comparable attack rates and disruptions to those of blood centers. Stockpiling of supplies in anticipation of pandemic influenza represents a major adjustment of most common production business plans. Pandemic influenza has occurred only three times in the last century, and only once (1918) has the impact been catastrophic in the US. The willingness to adjust business models and the resources that will be committed to prepare for such “rare” if “inevitable” events may be highly variable among facilities. The capacity of supply chains to endure disruption, and the utility (and facilities’ ability) of stockpiling critical supplies in appropriate storage conditions must be assessed.

Local and State Public Health: The blood community needs to establish liaisons with and advocate before local/state public health emergency planning authorities to be sure its needs are

heard. Blood should be considered a critical element of the health-care infrastructure with a high priority for resources as triage decisions are considered. Updated information about influenza can be found at [www.pandemicflu.gov](http://www.pandemicflu.gov). In addition, facilities should be aware of their states' influenza surveillance systems, which are described in state pandemic plans (see: <http://www.cste.org/specialprojects/influenzaplans/statemap.asp>).

Communications Planning: Blood centers and transfusion services need to develop and implement strategies for communicating with their staff, donors, drive sponsors, suppliers and the public about pandemic-related issues. This includes prospective education about pandemic responses, redundant methods to reach these audiences during a pandemic, and appropriately designed messages. It is important that local crisis communication and disaster planning be inclusive of pandemic planning – ie, a pandemic plan alone is not enough. The Interorganizational Task Force on Domestic Disasters and Acts of Terrorism will manage national communications during a pandemic through its established mechanisms.