AABB Interorganizational Task Force on Pandemic Influenza and the Blood Supply

PANDEMIC INFLUENZA ISSUES OUTLINE

The following outline provides blood collection facilities and transfusion services with suggestions for possible steps they can take to prepare for an influenza pandemic. This list is not all-inclusive and may necessarily change as more information becomes available.

Donor Issues

- *Donor Appointments* – Develop strategies to encourage well donors to make and keep appointments during a pandemic. Strategies may include some or all of the following:
  - Donor education by collection facilities about standard precautions for prevention of exposure and infection.
  - Coordination with public health officials to be certain that blood donation is appropriately and explicitly excluded from social distancing messages. This will require that public health officials are comfortable with the infection control procedures used by collection facilities.
  - Explicit donor reassurance that precautions, especially including respiratory and cough etiquette, are diligently observed by appropriately trained collection facility staff to prevent transmission of influenza in the collection setting and to address fears about presenting for donation.
  - Efforts to "recruit the recovered" into the donor base. This recognizes the unique benefit of those potential donors who have recovered from infection with the pandemic strain.
- *Reduced Blood Drives* – It should be assumed that some sponsors of blood drives, especially employers and schools, will begin to cancel drives during a pandemic as their potential donors become ill or need to be absent to care for loved ones.
  - Collection facilities should plan with key blood drive sponsors in advance of a pandemic to blunt the impact of absenteeism on their willingness to sponsor and support donation.
- *Collection Strategies*
  - A range of options for support of plateletpheresis collections should be developed. Possible strategies include the following:
    - Careful prospective education of current committed donors about their importance in this and other emergencies.
    - Strategies to increase plateletpheresis collections, eg, if the Food and Drug Administration (FDA) allows for more permissive emergency collection

frequency limits or a similar variance from established requirements.

- Planning to increase production of whole-blood-derived platelets.

- A range of options to support continued Red Blood Cell (RBC) collections should be developed.
  - Careful prospective education of current committed donors about their importance in this and other emergencies.
  - The working assumption is that demand for blood, particularly RBC, will decrease significantly in the face of an accelerating pandemic. This is due to a) inundation of hospitals with influenza cases; b) inundation of hospitals with "worried well;" and c) cancellation of elective surgery. Demand for blood may decrease by 10-40% based on unpublished estimates of the variability of RBC use for elective vs. urgent or emergent transfusion. Most of these studies are non-US so applicability to US hospitals is not clear. In order to anticipate what actions, if any, a blood center should take, blood centers will need to be in close contact with hospital transfusion services to get a real-time view of inventory demand.
  - Strategies to increase collections, eg, proposals for reduced interdonation intervals and emergency relaxation of current hemoglobin/hematocrit requirements have been presented to FDA.
- Possible stockpiling of Fresh Frozen Plasma (FFP). In order for this to be possible, FDA will have to allow the stockpiled units to be converted to Recovered Plasma as the units approach expiration. A similar measure was taken during West Nile virus (WNV) outbreaks.
- Recruitment of donors who have recovered from clinical influenza will be important in efforts to maintain the blood supply.
- The AABB Interorganizational Task Force on Disasters and Acts of Terrorism will take the lead in coordinating recognition and communication of shortages, movement of components and public messages about the blood supply consistent with the direction expressed by the Secretary of Health and Human Services (HHS) when pandemic flu appears.
- Collection centers should consider the need to increase donations in the event of a potential surge in demand for blood after the pandemic is over and delayed surgeries and medical procedures are rescheduled.

- *Facility Infection Control for Donors*
  - Plan for enhanced emphasis and monitoring of hand hygiene by staff and donors to increase donor confidence in facility safety and prevent spread of infection from very recently infected but asymptomatic individuals at donation venues. This activity should be implemented before a pandemic, so that it becomes habitual.
  - Evaluate the current disinfection process for all horizontal surfaces and determine if additional precautions need to be instituted. This activity should be implemented before a pandemic, so it becomes habitual.

  - Plan for facility entry checkpoints to screen donors and staff for signs and symptoms of influenza aimed at exclusion of ill persons to protect other donors and staff.
    - Facilities should consider whether personal protective equipment (PPE) may be needed despite efforts being made to exclude ill donors and staff.
  - On July 23, 2009, CDC's Healthcare Infection Control Advisory Committee adopted the recommendations of the Influenza A (H1N1) Working Group regarding infection control for care of ill patients with confirmed or suspected novel H1N1 infection in a healthcare setting. These recommendations included: healthcare personnel should wear a ***surgical mask*** when caring for patients with suspected or confirmed cases; and an N95 respirator was recommended for select high-risk procedures that are potentially aerolsol-generating. The relevance of healthcare responses to the donor room or mobile blood drive setting is limited if appropriate measures are taken to exclude the ill, and the main reason for the use of PPE may be to accommodate those donors who request these measures. For a discussion of appropriate PPE should a decision be made for its use, see the June 10, 2009 position statement of the Society for Healthcare Epidemiology of America, entitled "Interim Guidance on Infection Control Precautions for Novel Swine-Origin Influenza A H1N1 in Healthcare Facilities." http://www.shea-online.org/news/shea_news_index.cfv?id=1016. The Institute of Medicine has also released a related report, titled "Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A" (http://www.nap.edu/catalog.php?record_id=12748). In determining whether and which PPE to use, facilities should also coordinate with state and local public health officials.

- Plan for appropriate setup of collection areas (eg, maximum feasible separation of donors, ideally >3 feet)
- *Influenza Immunization* – Educate and encourage donors now and on a continuing basis to avail themselves of annual influenza immunization.
  - Collection facilities may provide general immunization education (flu and pneumococcal) to donors who present during prepandemic donation appointments. .
- *Vaccine Access and Availability* – Blood centers should consider taking steps to facilitate committed donor access to pandemic influenza vaccine.
  - In general, it is anticipated that pandemic flu vaccines will be in short supply and will not be available at all in the early weeks of a pandemic. The task force has advocated at the national level for inclusion of committed platelet and RBC donors in high-priority groups for pandemic vaccination. However, to date, the federal government has not yet included such donors in its list of populations prioritized for early vaccination. Individual collection facilities will likely need to establish this priority at a state and/or local level.
  - Should donors be designated as high priority for vaccine, given the likely delayed availability of pandemic vaccine, collection facilities may have to triage vaccine or vaccine access.
    - All presenting donors cannot be offered vaccine, to avoid inappropriate incentives

for donation, and a "run" on facilities offering vaccines. Facilities will need to establish a definition of a committed donor who would be eligible for immunization provided by the collection facility. For example, a committed plateletpheresis donor might be defined as a donor presenting for platelet collection four times annually during the two years before a pandemic. A committed whole blood donor might similarly be considered a donor presenting four times annually during the two years before a pandemic. Whole blood donors might be further stratified by blood group with special consideration given to group O donors, for example.

- Priorities for different types of donors may be required for triage. For example, committed plateletpheresis donors might be given vaccine first. Consider identification of high-priority donors for whom the facility may facilitate access to preventive services such as immunizations and antiviral drugs.
- Facilities considering providing immunizations on site should consult with legal counsel about relevant liability issues. Influenza immunization is now covered under the no-fault National Vaccine Injury Compensation Program (see http://www.hrsa.gov/vaccinecompensation).
- The novel H1N1 monovalent vaccine is being regulated in the US as a strain change as are routine adjustments in the composition of seasonal flu vaccines. There is no deferral for the latter and no need to consider deferral for the former at this time.

- *Antiviral Drugs* – Facilitate committed donor access to prophylactic antiviral drugs.
  - The primary strategy at the national level for use of antivirals drugs during pandemic influenza has been, and remains, for treatment. The efficacy of prophylactic antiviral drugs is speculative for a pandemic strain, and preventive therapy consumes more medication. The availability of antivirals during a pandemic is problematic, but collection facilities may consider facilitating access by committed donors to prophylactic drugs during a pandemic should such a strategy be endorsed in the public health community and adequate supplies become available.
    - The task force is advocating at the national level for inclusion of committed donors in high-priority groups for limited supplies of prophylactic antiviral drugs should they be available for preventive therapy. Facilities should voice similar messages to state and local groups who will be making triage decisions based on nationally articulated strategies and availability.
    - Donors affected would need to be appropriately counseled regarding medication use in this circumstance.
    - Facilities considering providing antiviral drugs to donors should consult with legal counsel about relevant liability issues.
- *Postdonation Information* – Collection facilities should develop processes for managing the collection and use of postdonation flu-related information, and be aware of the potential need to collect blood samples from these donors for further investigations of the potential for transfusion transmission of influenza.

- During pandemic waves, a substantial amount of postdonation information will be received by collection facilities, as donors who were well on the day of donation later report symptoms and/or signs compatible with influenza.
- There needs to be prospective consideration of a structured response to this information, with particular emphasis on whether there is a need for quarantine and recall of the affected components and notification of consignees. Although transfusion-transmitted influenza A is never recognized to have occurred, some may consider it prudent to withdraw products collected within the usual incubation period of the pandemic strain. The usual incubation of influenza A is two to three days, and the novel H1N1 appears to be similar in this regard. Decisions to withdraw otherwise acceptable components on the basis of receipt of postdonation information should balance theoretical safety concerns and real time adequacy (inventory) data.

Collection Facility or Transfusion Service Staff Issues

- *Work Rules and Staffing Concerns* – Blood centers and transfusion services should establish (and frequently review and revise, as needed) work rules to account for (and prevent, when possible) high staff absentee rates during a pandemic. Strategies may include the following:
  - Survey staff early in the planning process to assess their attitudes toward their roles as critical workers during a pandemic and their ability, willingness and under what circumstances they will "go the extra mile" to preserve the blood supply in this sort of emergency.
  - Prospectively define exposure to influenza, in the event that exposure will be considered a criterion for furlough.
  - Establish criteria for exclusion from and return to work.
  - Optimize staffing by using those who have "recovered" from influenza and are presumed to be immune.
  - Consider the feasibility of recruiting extra staff from among retired or former employees.
  - Consider prospectively strategies to cope with staff burnout due to their need to work excessive overtime, and the overall physical and psychological burdens of a catastrophic pandemic.
  - Consider the impact on staff of a potential demand surge for blood after the pandemic as delayed medical care is rescheduled.
  - Consult with labor unions as appropriate.
- *Facility Infection Control for Staff*
  - Review guidance on the Centers for Disease Control and Prevention (CDC) Web site *www.bt.cdc.gov/planning.*
  - Educate staff about standard precautions for prevention of exposure and infection and systems to ensure accountability for these precautions.

- Plan for facility entry checkpoints to screen employees daily for signs and symptoms of influenza aimed at exclusion of ill employees to protect donors and other staff.
- Plan for enhanced emphasis and monitoring of hand hygiene by staff and donors to increase confidence in facility safety and prevent spread of asymptomatic infection at donation venues. This activity should be implemented before a pandemic, so that it becomes a habit.
- Plan for appropriate setup of collection areas and availability of personal protective equipment to conform to droplet and contact precautions to protect staff and donors if required. Employment of droplet precautions may not be entirely evidence-based in the setting of well donors and staff, but it may be expected by the public (eg, although the use of masks among well staff and donors may be of minimal effectiveness in preventing spread of influenza, their use may be demanded by enough of the public to support their availability).

    - The OSHA document *Guidance on Preparing Workplaces for an Influenza Pandemic* can provide guidance on these issues. Access it at **http://www.osha.gov/Publications/influenza_pandemic.html#introduction** This guidance is cited using the explicit assumption that blood collection facilities are not healthcare providers in the usual sense (they do not care for the high-risk ill) for the purpose of assessing risk from pandemic influenza, and that more generic guidance for non-healthcare workplaces is appropriate.

    - For facilities providing direct care to ill patients at risk for influenza, more useful information can be found in *Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings during an Influenza Pandemic* **http://www.pandemicflu.gov/plan/healthcare/maskguidancehc.html**

    - Since blood collection facilities deal specifically with well, low-risk donors it seems reasonable, with regard to the use of personal protective equipment, to define our operations per OSHA as medium risk workplaces "that require frequent close contact between employees or with the general public. Under these circumstances, OSHA provides the following guidance.

        a) "Employees who have high-frequency, close contact with the general population that cannot be eliminated using administrative or engineering controls, and where contact with symptomatic ill persons is not expected should use personal protective equipment to prevent sprays of potentially infected liquid droplets (from talking, coughing, or sneezing) from contacting their nose or mouth. A surgical mask will provide such barrier protection.

        b) Use of a respirator may be considered if there is an expectation of close contact with persons who have symptomatic influenza infection or if

employers choose to provide protection against a risk of airborne transmission.

c) It should be noted that wearing a respirator may be physically burdensome to employees, particularly when the use of PPE is not common practice for the work task.

d) In the event of a shortage of surgical masks, a reusable face shield that can be decontaminated may be an acceptable method of protecting against droplet transmission of an infectious disease but will not protect against airborne transmission, to the extent that disease may spread in that manner."

- *Work from Home*
  - Consider surveying staff to identify those who believe they can work from home (ie, telecommute), and the proportion of their work they feel can be accomplished from home.
  - Assess information technology infrastructure to support work-from-home rules.
  - Verify that the Internet capacity of the facility will accommodate the increase in staff who would be working remotely. Note: it is anticipated that during a pandemic there may be extraordinary strains on Internet systems due to high usage.
- *Cross-Training*
  - Consider implementing procedures now to cross-train and periodically assess staff for maintenance of competency on critical tasks most likely to result in disruption of production capacity.
  - Review regulatory requirements relating to use of qualified staff.
  - Note: during the September 11, 2001 crisis, many facilities that used cross-trained staff found this practice to be problematic and now report that they would limit use of cross-trained staff as much as possible in future disasters, including a pandemic. This may have been related to the "on-the-fly" training methods used and underscores the importance of using structured initial and ongoing cross-training and repeated reassessment of competency.
- *Vaccination*
  - Encourage annual immunization of staff. Consistent/repeated annual influenza immunization may be associated with some protection from even those strains not specifically included in annual influenza vaccines. (Note, however, that annual influenza immunization has not been shown to provide protection against the novel H1N1 strain.)
  - Provide general immunization education (flu and pneumococcal) to employees during the prepandemic period. In all educational efforts to encourage acceptance of annual influenza vaccine, address and attempt to dispel common myths about the vaccine

causing influenza-like illness or having a high adverse event rate, as well as any misperceptions about contraindications.

- Note: The Advisory Committee on Immunization Practices (ACIP) published its recommendations for priority access to annual influenza vaccination in the MMWR Volume 55, Early Release June 28, 2006 (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr55e628a1.htm). Facilities should periodically check the CDC Web site for changes to such immunization recommendations.
- Effective January 1, 2007, The Joint Commission (TJC) requires accredited facilities to provide access to annual influenza vaccinations on site (at no cost). In addition, TJC will require facilities to establish an annual influenza vaccination program that includes at least staff and licensed independent practitioners; educate staff and licensed independent practitioners about flu vaccination, nonvaccine control measures (such as the use of appropriate infection control precautions), and diagnosis, transmission and potential impact of influenza; annually evaluate vaccination rates and reasons for nonparticipation in the organization's immunization program; and implement enhancements to the program to increase participation. Individual blood collection facilities and transfusion services should be aware of this activity and consider adopting such strategies prospectively.

- Advocate for the inclusion of essential operational collection and testing facility and transfusion service staff in high-priority vaccine groups before state and local groups who will be making triage decisions in the likely event of vaccine shortages. Essential blood collection personnel (including two-thirds of personnel identified by a blood donation facility) are already included in the first tier of groups targeted for pandemic vaccination included in the federal *Guidance on Allocating and Targeting Pandemic Influenza Vaccine.* This guidance also gives top tier vaccine priority to two-thirds of personnel at acute care hospitals who would be identified by their institution as critical to provision of inpatient health care services. However, state and local health departments will play a critical role in ultimately deciding who will be eligible for limited vaccines.
- Develop a triage plan for personnel to be offered vaccine according to guidelines from public health in the almost certain event of shortages.
  - Facilities should consult legal counsel about liability issues related to various strategies to promote staff immunization. Note: Influenza immunization is now covered under the no-fault National Vaccine Injury Compensation Program (see http://www.hrsa.gov/vaccinecompensation).

- *Antiviral Drugs*
  - The primary strategy at the national level for use of antivirals drugs during pandemic influenza has been, and remains, for treatment. The efficacy of prophylactic antiviral drugs is speculative for a pandemic strain, and preventive therapy consumes more medication than does treatment. The availability of antivirals during a pandemic is problematic, but collection facilities may consider facilitating access by critical staff

to prophylactic drugs during a pandemic should such a strategy be endorsed in the public health community and adequate supplies become available.

- Advocate before state and local groups making triage decisions for inclusion of critical staff in high-priority groups for limited supplies.
- Counsel affected staff regarding medication use in this circumstance.
- Consult with legal counsel regarding liability issues relating to strategies to promote staff use of antiviral medication.

- *Prioritization of Activities* – Collection facilities and transfusion services engage in multiple tasks that need to be prioritized for possible suspension during a pandemic.
  - Each facility should establish a high-level command and control center. Personnel directly required for operations should not serve at the command and control center level. It may be difficult for a person responsible for operational tasks during a crisis also to be responsible for crisis decision-making.
  - Examples of tasks that may be considered for lower priority include: autologous and directed donations, tissue recovery and processing, marrow/stem cell donor recruitment, cord blood programs, research and development, etc.
  - In extreme situations with staff shortages that could affect a facility's ability to provide a safe and adequate blood supply, suspension of some level of testing and processing (eg, universal leukocyte reduction and nucleic acid testing (NAT) for WNV, hepatitis B (HBV) and human immunodeficiency virus (HIV)) might be considered so that technical staff can be diverted to activities with better risk:benefit ratios. Regulatory implications must be considered.
  - When determining which activities to perform, it should be based on risk:benefit analysis. Consider diverting resources to activities that have the best risk:benefit ratio.

Blood Safety and Availability

Possible FDA Actions – 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, infectious disease testing, reagent outdates and many other current good manufacturing practice processes. The task force strongly believes that FDA should provide the blood community with guidance in this arena in advance of a pandemic. Without advance notice, facilities may be hindered in providing a safe and adequate blood supply. 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 changes on short notice. A potentially useful example of guidance FDA issued to address blood needs in an emergency circumstances is *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 Sept. 11, 2001 (http://www.fda.gov/cber/infosheets/dstrbld.htm).

- *Donor Criteria* – In the event of severe shortages, FDA may issue emergency donor criteria policies to expand the donor base. For example, during a pandemic the agency might consider amending donor criteria, including the following nonexhaustive list:
  - Donation intervals
  - Weight limits
  - Hemoglobin criteria
  - History and travel deferrals
  - Infectious disease testing requirements
    - For example, WNV and/or HIV and HCV NAT might be suspended if reagents or personnel are limited.
    - Testing could be waived for frequent repeat donors in the event of severe donor, reagent or personnel shortages.
- *Triage of Available Components* – Decisions about transfusion in individual cases are best made at the bedside by the attending physician in consultation with the medical director of the transfusion service. It is probable that conflicts in judgment will occur in the face of limited supply. Collection facilities and hospitals, together, need to plan for this eventuality.

  Restriction of use to reasonably stringent evidence-based transfusion triggers at the hospital level has the potential to mitigate pandemic-associated shortages of great magnitude in institutions that do not currently enforce such triggers. If hospitals and their clinicians do not adopt this approach, the burden for triage will be placed primarily on regional collection facilities whose medical directors will not have the medical advantage of assessing the clinical reasonableness of competing requests for blood components. In this setting, it is likely that regional collection facilities will distribute components to hospitals in proportion to their availability, which will penalize those hospitals exercising the most clinically appropriate utilization control. This is unfair to those institutions and the patients they serve.
  - **Collection facilities** should be aware of and/or encourage the development of explicit plans in hospitals served.
    - Collection facilities should have contingency approaches for the distribution of available components to transfusion services in the event of severe shortages.
  - **Transfusion services** should work with their blood suppliers and others in their hospitals to develop explicit triage plans. The issues around triage are not unique to pandemic influenza, and evidence-based criteria for optimal blood use under routine conditions and in the face of shortages are the ongoing responsibility of transfusion services. The prospect of widespread shortages during a pandemic makes this activity particularly important now, because changing physician behavior, even under the best of circumstances, is a difficult and time-consuming task. In developing recommendations and strategies for possible triage of blood components, transfusion services should consider the following:
    - Planning for triage of patients for limited blood component inventories will

require creation of teams of hospital infection control personnel, transfusing physicians, nurses, laboratory (and transfusion service) managers and directors, transfusion medicine physicians, hospital medical directors, hospital administration, risk managers and medical ethicists. The Transfusion Committee (including representatives of the hospital's blood suppliers and transfusion experts) and the facility Disaster Committee should also engage in this planning.

- It is important that efforts relating to the transfusion service are coordinated with other aspects of institutional planning to prevent duplication of effort.
- Key hospital administrative personnel and the chain of notification in the event of an acute blood shortage should be identified.
- The criteria that will be used to decide which patients get components in the face of shortages should be agreed upon prospectively.
- Transfusion services need explicit component triage plans for RBCs, platelets and plasma-containing components ready for implementation in the prepandemic period. In developing criteria, extensive consultation with transfusing physicians will be needed so they accept and understand the criteria and their stringency.
- Hospitals preparing surge plans should determine who will define what represents elective surgery, admission, or component use, and what the roles of the transfusion service and blood provider will be in these discussions.
- Half of all blood used in trauma care goes to the 1% to 2% of patients requiring massive transfusion (>10-20 RBC units) who will also require a disproportionate fraction of nursing care. Nearly half of these patients die in spite of heroic efforts. Ethical considerations for limiting the amount of blood used for massively bleeding trauma patients during shortages related to influenza should be explored.
- Ethical considerations for withholding transfusions for patients whose prognosis is very poor, with or without transfusion, should be explored. For example, patients with relapsed leukemia that is not thought to be treatable may not be able to receive transfusions.
- Consideration should be given to pediatric cases. There will need to be communications with the extracorporeal membrane oxygenation (ECMO) directors to determine if the poor prognosis of some patients precludes those patients from being put on ECMO in the event of blood shortages. Consideration should take into account that transfused pediatric patients tend to do better than transfused adult patients, favoring the diversion of blood components for pediatric care.
- Some treatments, such as marrow transplants for congenital diseases such as chronic granulomatous disease, may be delayed. For treatments or surgeries that are semi-urgent, a committee, including clinicians, may need to be formed to make decisions and/or apply an institution-specific scorecard system to determine the priority of semi-urgent cases.
- Hospital ethicists need to be intimately involved in the triage planning process. They should be available for consultation in complex cases, eg, where despite the

lifesaving nature of the surgery, the patient is deemed because of other health-related issues to be a poor surgical or medical candidate for utilization of competing health-care resources.

- A significant amount of blood given to nontrauma patients is not medically indicated. Studies of RBC,[1] platelet[2] and plasma[3] use support this contention. Guidelines reflecting evidence-based medicine should be discussed prospectively, agreed upon and then enforced during shortages. If appropriately followed, such guidelines will provide a simple mechanism for reducing blood usage.
  - The pressure on available blood components will likely come first on platelets, because of their short shelf lives, and will require consultation between blood bank directors and clinicians.
  - Strict guidelines for RBC usage for medical patients should be established and enforced. Transfusion services should consider limitation of RBC transfusions to those otherwise stable medical patients whose hemoglobin is <7 g/dL unless they can also be demonstrated to have other co-morbid factors. This is consistent with findings in a critically ill ICU population in the Transfusion Requirements in Critical Care randomized trial.[1]
  - Strict guidelines for prophylactic platelet transfusion medical patients should be established and enforced. Withholding prophylactic transfusions can be supported in nonbleeding medical patients unless the platelet count is <5000/μL or there is active bleeding at higher counts.
  - Surgical use of platelets should require prospective consultation with the transfusion service before issuance, as should use of frozen plasma and cryoprecipitate in the face of limited supplies.
- Hospitals may want to encourage use of blood recovery procedures for appropriate patients, as well as protocols for use of hemostatic agents to reduce the demand on the allogeneic blood inventory.
- Any time Rh-negative RBC units, in particular, are in short supply, blood centers may encourage hospitals to give Rh-positive units to Rh-negative patients lacking anti-D (male patients, females beyond childbearing potential and most people requiring massive transfusion). This step saves the few available Rh-negative units for patients who really need them.
- Because many hospital blood bank directors are neither full-time nor experienced blood bankers, it would be helpful to educate providers on the following acceptable practices:
  - Minimize the duration and frequency of transfusion of group O RBCs to non-group-O patients.
  - Accept platelets and cryoprecipitate of any ABO group when type-specific units are not promptly available.
  - Accept leukocyte-reduced blood components as sufficient to prevent cytomegalovirus (CMV), when CMV-negative unit(s) of the correct type may not be promptly available.

        - Use Plasma Frozen within 24 hours After Phlebotomy in lieu of FFP when FFP in the patient's ABO group is not promptly available.
        - Consider transient use of group A plasma for massive plasma transfusion in group AB patients.
    - In the event of a pandemic, the hospital may have to limit/restrict access to the facility. A policy needs to be developed for the delivery of blood components to a location other than inside the facility in the event of a facility lockdown.
- Recently, some medical societies, state governments and others have issued documents relating to the allocation of scarce medical resources in emergency circumstances. These documents provide useful background information and points to consider for hospitals and blood centers attempting to plan for triage needs. See, for example,
    - Devereaux, AV et al. Definitive Care for the Critically Ill During a Disaster: A Framework for Allocation of Scarce Resources in Mass Critical Care. *Chest*. 2008; 133:51S-66. This article is available at http://www.chestjournal.org/cgi/content/abstract/133/5_suppl/51S
    - *Standards and Guidelines for Healthcare Surge during Emergencies.* California Department of Public Health. The guidelines, comprising four volumes, along with training materials and a reference manual, are available online at http://bepreparedcalifornia.ca.gov/epo.

Supply Chain Issues

- Facilities may face difficulties in obtaining necessary supplies in the event of a pandemic. Facilities need to create a list of critical supplies (and suppliers), defined as those required to produce a labeled blood component.
- Facilities, and especially the group purchasing organizations supplying the blood community, should develop strategies to address supply issues for a variety of essential products, including the following:
    - Infectious disease testing materials.
    - Immunohematology reagents.
    - Bags, apheresis kits and automated collection equipment.
    - Component laboratory equipment and supplies used for manufacturing.
    - Other products that may represent "rate limiting" supplies in the event of supply chain disruption. These need to be catalogued and included in the planning process.
- Facilities, and especially the group purchasing organizations supplying the blood community, should establish liaisons (with emergency contact information) with individual manufacturers to address pandemic-related issues.
- Facilities, and especially the group purchasing organizations supplying the blood community, should actively communicate with vendors and gather information regarding their plans for pandemic influenza, including the following:

  - "Preemptive production" of stockpiles if pandemic influenza is identified outside North America, anticipating its spread to the US and Canada.
  - The ability to assist with expansion of collection facility and transfusion service inventories.
  - Emergency transportation contingencies.
  - Emergency communication with customers.
  - Process for manufacturers to provide medical equipment repair service.
- Facilities should address their ability to store, in appropriately regulated environments, additional stockpiles of critical supplies and the optimal location of stockpiles, anticipating there can be disruption of transportation in a severe pandemic. To be effective the stockpile should be accrued incrementally, in consultation with manufacturers, well in advance of the onset of a pandemic, to avoid competition for already limited inventories by collection facilities and transfusion services.
- The need for stockpiling, or staged inventory enhancement, is highlighted by a survey of the members of the AdvaMed blood sector (representing the largest manufacturers of reagents, blood bags and apheresis instruments and disposables), which raises questions about the integrity of our supplies chains at the time of a severe pandemic. According to the survey results:
  1. The number of sites for manufacture of goods for US delivery is generally 2 or fewer, with lot release generally occurring from only one site.
  2. Supplies of finished goods are generally 4-8 weeks of use, with production lots at less than 8 weeks, and lead times for production decisions to manufacture of 4-8 weeks and more.
  3. These data suggest that in a severe pandemic lasting longer than 8-12 weeks, supplies may become depleted if collection facilities and transfusion services maintain inventories of 2-6 weeks, as many do.
- Facilities, and especially the group purchasing organizations supplying the blood community, should monitor developments relating to restrictions of interstate and international commerce and determine if such restrictions could affect access to essential supplies.

<u>Local and State Public Health</u>

- Local and regional emergency management agencies (EMAs), as opposed to federal authorities, are typically responsible for responding to requests for scarce resources during disasters, and this is explicitly the case for pandemic influenza. Facilities should contact local and regional public health departments and EMAs prospectively to request that blood be considered a critical element of the health-care infrastructure so that blood centers can receive priority access to needed fuel, transportation, power and communications assistance in the event of a pandemic. Facilities should reference the National Response Framework's Emergency Support Function #8

(http://www.fema.gov/emergency/nrf/), which highlights the critical role of blood in supporting the health-care infrastructure.

- Facilities should contact their state and local health departments now and review disease and laboratory reporting in order to clarify requirements and reporting mechanisms, as well as to connect with the surveillance programs that will be monitoring influenza activities and any concomitant health events that may arise with or without an influenza pandemic situation. Blood collection facilities and transfusion services should become part of the integrated surveillance systems that already exist and are being built involving public health, hospitals, practitioners and clinical laboratories.
- Facilities should routinely monitor pandemic influenza surveillance information to inform implementation of predefined strategies. Facilities should be included in their regional electronic health alert networks, and monitor messages on a routine basis.
- Facilities should also communicate with state and local authorities regarding the need to exempt blood drives from designation as a public meeting or mass meeting if social distancing measures are anticipated.
- State EMA offices can be located at www.fema.gov/about/contact/statedr.shtm

Communications Planning

- Facilities should carefully monitor developments regarding a possible pandemic. Facilities should prepare related communications to share with a variety of audiences regarding the possible impact of a pandemic on the blood supply. Communications with the following groups should be planned:
  - Donors
    - Established donors
    - Donor sponsors
    - Public (potential donors in the face of shortages)
  - Collection facility staff
  - Hospital administration/transfusion service staff
  - Stakeholders (ie, Board of Directors)
- Collection facilities and transfusion services should ensure that communications channels with the following groups are opened prospectively, and managed appropriately during pandemic influenza.
  - Regular donors
  - Blood drive sponsors
  - Staff
  - Customers
  - Suppliers

  - Local and state health departments
  - Local emergency preparedness agency
  - Media
  - Board of Directors
- Facilities should ensure that their public messages are consistent with the CDC's pandemic messages and are tailored as necessary for appropriate audiences. Prepandemic training is essential for constructing messages that will meet the following criteria:
  - Public messages should be as simple as possible (eg, sixth grade level; three phrases, three messages, 30 words in less than 10 seconds).
  - HHS message maps can be used as a guide (available on CD).
  - Facilities should identify a media point person and alternative(s).
- Facilities should use messages consistent with the Task Force's messages whenever possible and appropriate. Pandemic hysteria should not be used as a recruitment tool and blood centers are urged to use caution in saying that blood is needed because of the flu.

References

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3. Gajic O, Dzik WH, Toy P. Fresh frozen plasma and platelet transfusion for nonbleeding patients in the intensive care unit: Benefit or harm? Crit Care Med 2006;34(Suppl):S170-3.