Defense Health Board

Select subcommittee on infectious disease control

Convalescent Plasma (CP) Therapy Guidelines

Defense Health Board Meeting

April 23-24, 2008

The Bottom Line

The Subcommittee urges DoD to consider development of convalescent plasma therapy as part of the national pandemic influenza plan, and as an important adjunct with other treatments. The Subcommittee further emphasizes the development of convalescent plasma therapy is a national effort and the Department should co-partner on this issue with other leading national health organizations.

Background

Because of limited H5N1 vaccine production, resistance to Oseltamivir and other antivirals, and the possibility that a different influenza strain may emerge as the pandemic strain, the use of convalescent plasma therapy and its applications for pandemic influenza were considered by members of the DHB Subcommittee.

Background

On 5-6 February 2008, the DHB Subcommittee on PI Preparedness met to consider guidelines on the use of convalescent and immune plasma, particularly in the event of PI or other military-relevant diseases.

Rationale for DoD to consider CP

- Active duty personnel at risk for exposure to natural or bioterror infectious disease epidemic
- DoD has capacity to collect, produce, and transfuse large volumes of CP from military personnel (convalescent or vaccine)
- Convalescent plasma can be used with DoD and/or civilian populations

Feb 5, 2008 Discussion

- Historical Use of Convalescent Plasma, Serum and Blood Products for the Treatment of Toxins and Pathogens - Dr. Casadevall
- Blood Products for Spanish Influenza Pneumonia: A Future H5N1 Treatment - CDR Luke
- National Program to Treat Argentine Hemorrhagic Fever (Junin virus) with Convalescent Plasma - Dr. Enria
- Human Antibody Response After Recovery from H1, H3, and H5 Influenza or Vaccination - Dr. Treanor

Feb 5, 2008 Discussion

- Observations from the Transfusion Medicine Service of the National Institute of Health - Dr. Leitman
- Convalescent Plasma Production from an Industry Perspective - Dr. Katz
- Regulatory Issues for Producing and Administering Convalescent Plasma for New and Emerging Infectious Diseases - Dr. Williams
- Clinical Guidelines, Data Collection and Reporting, and Investigational New Drug (IND) Application - Dr. Hoffman

National Level Recommendations

Publish a peer-reviewed article discussing alternative therapies for pandemic influenza focusing on convalescent plasma therapy with collaboration from members within DoD. The article should provide established knowledge, current gaps in knowledge, guidance, and awareness on convalescent plasma therapy to healthcare communities at a national level.

National Level Recommendations

Establish regional blood banks as a control point for plasma collection to ensure the availability of plasma to individuals requiring plasma therapy. Requires more efficient plasma screening and guidelines. Further dialogue between DoD and FDA required.

National Level Recommendations

DoD act as a vested partner with other leading national public health institutions to contribute to the development of national standardized guidelines utilizing convalescent plasma therapy as an alternative for pandemic influenza.

National Level Recommendations

Investigate further applications of convalescent plasma therapy for use with other infectious diseases where there is no known alternative therapy.

National Level Recommendations

Identify gaps in capabilities for plasma collection, distribution, and tracking. DoD can work as part of an inter-agency group to identify gaps in capabilities for efficiently distributing and implementing convalescent plasma therapy.

DoD Relevant Recommendations

DoD should propose and carry-out a research initiative for the purposes of providing data and information about convalescent plasma therapy's effectiveness against Adenovirus, and determine logistical processes and appropriate equipment involving treatment with convalescent plasma therapy.

DoD Relevant Recommendations

Identify gaps and capabilities within DoD to effectively implement convalescent plasma therapy within the Services.

DoD Relevant Recommendations

Consider utilizing these guidelines beyond pandemic influenza and implement convalescent plasma therapy as an alternative treatment for novel, natural or man-made bio-agents and/or novel, emerging biological threats in future research and practice

Conclusions

The Subcommittee concludes that a national effort is essential to explore convalescent plasma therapy as an adjunct treatment. The DoD, in its national security role, has a stake in ensuring guidelines and infrastructure are in place within the Department if use of convalescent plasma is needed.

Conclusions

The Subcommittee further concludes that within the national context of an approach to convalescent plasma therapy, DoD is not and should not serve to lead the effort, but DoD has a vital stake and interest in acting as a co-partner with other national health organizations such as CDC, Department of Homeland Security (DHS) and NIH.

In preparing these recommendations, the Subcommittee has engaged in regular discussions and has received a series of briefings by experts from NIH, CDC, the National Vaccine Program Office, FDA, and DoD, among others.