Magen David Adom Blood Services

Use of Blood and Blood Products in Disasters-WP-5

Summary of the Workshop

Prof. Eilat Shinar, MDA blood services, Israel

Prof. Noga Manny, Hadassah Medical Center, Israel

Identifying the Needs of Medical First Responder in Disasters (NMFRDisaster)

Theme 10 – Security; Call – FP7-SEC-2007-1

NMFRDisaster - Identifying the Needs of Medical First Responder in Disasters

Coordinator: Magen David Adom (Israel)

Partners:

- Al-Quds Nutrition And Health Research Institute (Palestinian Administered Areas)
- Ambulance Zorg Nederland (Netherlands)
- Centro per La Scienza, La Società e La Cittadinanza- CSSC - (Italy)
- Charles University (Czech Republic)
- Croce Rossa Danese- Danish Red Cross -(Denmark)
- Fundacion Rioja Salud (Spain)
- SAMUR Servicio de Asistencia Municipal de Urgencia y Rescate (SPAIN)
- Shield Group Inc. – Security and Counter Terrorism Management (Netherlands)
- SINERGIE Formazione e Consulenza Professionale (Italy)
- Magen David Adom (Israel)

Duration: 1 year (01.05.2008 – 30.04.2009)

Contents

BACKGROUND

As part of the NMFRDisaster project, and following our background paper (1), a workshop was held in November 24-25 of 2008, in Kfar Hamacabia, Ramat Gan, Israel (WP-5). In this meeting key problems such as the Use of Blood and Blood Products in Disasters and the need to have preparedness plans in order to meet surges in demand for blood components, needed by casualties of natural domestic disasters and acts of terrorism, were addressed (see below).

The workshop was attended by representatives from the consortium members, as well as 30 senior experts in Emergency Medicine, Blood services management and Transfusion Medicine in Israel.

WORKSHOP PROGRAM and PARTICIPANTS:

A. Following greetings from the Deputy to the Director General of the Israeli Ministry of Health, MDA president, the project's and the workshop's coordinators, the following sessions were held:

Day 1: 24th November:

1. Use of Whole blood and blood Component in Transfusion Therapy at the battle field and in field and conventional transfusion centers
2. Alternatives/additions to conventional blood components therapy

Day 2: 25th November:

1. Preparedness for Natural and Man-made disasters
2. Rapid testing techniques
3. Visit and tour of MDA blood services center

B. Participants:

The following experts sent presentations for the participation in the workshop:

1. Members of the consortium (in alphabetical order):
    a. Ambulance Zorg, the Nederland
        i. Dr. Charles Lelkens, the Netherlands Military Blood Bank
    b. El-Quds Nutrition And Health Research Institute, Palestinian Authority

i. Mr. Sabri Safadi, El Quds University

c. Charles University, Czech Republic:
   i. Lt. Col. Milos Bohonek, MD, PhD, the Central Military Hospital, Prague,
   ii. Dr. Martin Pisacka, the Reference Laboratory for Immunohematology in Institute of Hematology and Blood Transfusion in Prague
d. Fundacion Rioja Salud, Spain
   i. Dr. Roberto García de Villaescusa, MD, PhD
e. MDA blood services, Israel:
   i. Prof. Eilat Shinar, MD, director
   ii. Dr. Vered Yahalom, MD, deputy director
f. MDA project coordination:
   i. Mr. Chaim Rafalowski
   ii. Mr. Assi Devilanski
g. SAMUR Servicio de Asistencia Municipal de Urgencia y Rescate, Spain
   i. Dr. I. Rodríguez Miguel MD
   ii. Ms. Paloma C. Rey Paterna
h. Shield Group Inc. – Security and Counter Terrorism Management
   i. Mr. Aaron Richman

2. Additional Professionals from the participating members' countries
   a. Dr. Emma Castro Izaguirre, MD, The Spanish Red Cross Transfusion Center, Madrid, Spain.
   b. Dr. Eldad Dann, MD, Rambam Medical Center, Haifa, Israel
   c. Prof. Noga Manny, MD, chairperson of the Advisory Committee on Transfusion Medicine to the Israeli Ministry of Health
   d. Prof. Uri Matrinowitz, MD, Sheba Medical Center, Israel
   e. Dr. Neomi Rahimi-Levene MD, Assaf-Harofeh hospital, Israel

3. Guest professionals:
   a. Prof. Steven M. Becker, the University of Alabama, Birmingham, USA

4. Scientists Representing Israeli Biotechnology companies:
   a. Dr. Amir Arav, Core Dynamics

b. Dr. Baruch Rivetz, Orgenics LTD

5. Local professionals in Israel, such as:
    a. Representatives form the IDF (Medical Corps and Home Front Command)
    b. Members of the Israeli Consulting committee for the Organization of Blood Services during Emergency situations
    c. Senior staff of MDA blood services center

REVIEW OF THE MAJOR ISSUES PRESENTED:

1. Session 1& 3: Use of Whole blood and blood Component in Transfusion Therapy at the battle field and in field and conventional transfusion centers

The national and /or local response plans used in some of the participating members' countries (Spain, Israel and the Check Republic) were presented and discussed (2, 4-6).
All the presenting authors agreed on some common principals, regarding preparedness plans for disasters and the use of blood and blood components in such events: Blood services worldwide must be prepared to meet surges in demand for blood components, needed by casualties of domestic disasters and acts of terrorism (2).
Based on the Israeli experience during 26 years of hostility actions, suicide terrorist attacks and other Multi-Casualty events the projected use of blood units will be 3 units of blood and 3 units of blood components (plasma, platelets and cryoprecipitate) if all casualties are taken into consideration, or 8 units of blood and 9.7 units of blood components will be needed for the moderate/severely wounded patients.
Dr. Eldad Dann, the Blood Bank director of the Rambam Medical center in Haifa, Israel, presented their experience, from a point of view of a 3rd level major trauma center (3). In a study aimed to analyze the issues of patient misidentification and excessive blood request and to develop recommendations for the management of such episodes, a retrospective analysis of nine explosion attacks was performed. Out of the 450 casualties involved in the nine consecutive events 82 (18%) died on the explosion site and 368 were admitted to nearby trauma centers.
Red blood cell units were typed and cross-matched for 70 patients.
Seventy-three per cent of the blood supplied over the first 24 h was administered during the first 2h. The cross-matched/transfused ratio was
2.52 – 1.42 respectively, reflecting the overestimation of blood requirement by the Emergency Medicine experts during the mass casualty episodes. The importance of usage of error-reduction design wristbands and a designated "blood officer" from the hospital blood bank staff was emphasized, to avoid potential misidentification upon samples collection or during blood administration.

The Spanish Red Cross Blood Services put special emphasis on correctly determining blood requirements in different events, providing transport for blood from one centre to another, and sending a common message to all the country's blood centers, as well as the general public, about the situation of the blood supply in the affected area (4).

The three important lessons learned by this service were:

1) Blood collections must be controlled so as not to exceed the real requirements
2) Blood centers must always maintain sufficient stocks (5-7 working days for MDA and the Spanish Red Cross, respectively)
3) A national stock coordination plan is necessary
4) Public appeal should only be conducted at the initiative of the blood services only, to match supply with demand and prevent wastage

In addition it was stated that to satisfy the blood requirements during the initial 24 hours:

a) All blood that is initially dispatched should be type O packed red cell
b) The quantity dispatched to a centre should not exceed the amount of blood required for one day (taking all blood types into account)
c) The initial dispatch of blood products should be carried out by the centre which can most quickly deliver them

Although, currently it seems that the majority of situations do not require extensive use of platelets or plasma, which seem in severe trauma cases be only necessary in special circumstances, the workshop participants thought it could be interesting and useful to conduct a muti-center study, looking at the usage of blood components in severe trauma cases, especially in view of the new treatment regimen of component therapy (1:1:1) recommended lately in the literature (8).

Development of an emergency plan should include the following strategies:

1) Alternative means of communication with hospitals and the coordinating centre.
2) Alternative means of transportation.
3) Coordination with local, regional and national authorities. This important issue was also stressed by the participants of the Czech Republic, where a Resolution of the Czech Republic National Security Council was recently passed (Res. No 19 from April 15th. 2008), where the Ministries of Health and Defense were entrusted with the enforcement of "The Crisis Setup of Health System" - a Method of blood crisis policy. The aim is to guarantee sufficient as well as efficient supply of blood products and blood derivates in any place of the country during any crisis situation, such as mass

accident, disaster, terrorist attack or war. The responsible government institute, the Ministry of Health, cooperates with the Ministry of Defense. The system includes 7 state "blood crisis centers" (BCC), 1 military and 6 civilian and each of 7 BCCs is responsible for supplying defined territory.

4) The maintenance of equipment, testing kits and other supplies for the collection, professing and testing of blood (1).
5) Measurements need to be planned to assure attendance of an adequate number of staff numbers, since in some events it could be reduced. In such cases there should be a plan to redistribute the staff and /or hold the minimal activity needed to to ensure essential blood collection and supply (5).
6) The maintenance of power supplies, water and telephone services, as will be crucial throughout the disaster both to internal and external stakeholders with key messages being developed for different stages of the crisis (4-5).
7) A coordinated national program can stabilize in-hospital inventories during routine activities, ensure instant access to precisely defined inventories, facilitate sufficient supply in times of disasters, and minimize outdating and wastage.
8) A plan can be established, to reduce current usage of blood through appropriate use programmes, which may contribute to better control of the scarce inventory and avoided shortage, in most cases. The plan should ensure that transfusions are appropriate, and are based on national. As well as current guidelines or standards from professional bodies (Council of Europe, British Guidelines, CAT, etc.) (6).
9) The organization of blood donors and volunteers, to send appropriate messages to the public, and provide, where possible, a safe environment for donors to donate and for staff to come to work (2,5). This should also include crowd control measures (4).
10) Strategies for working with the media.
11) The participants from the Check Republic added the issue of having a 3000 units of frozen RBCs group 0, as a mean of support in times of emergencies. As this is a high resources method to maintain and operate, it will be interesting to investigate the actual use and cost-effectiveness of such components' inventory
12) Central blood services, as well as hospital blood banks should be included in drills and training exercises of different set-up of man made sot natural disasters.

SAMUR-PC is considering the possibility of implementing the use of blood and blood components in the management of patients with major trauma.

Supporting a Consensus Conference on Appropriate Use of Blood Components in Normal and in Disaster situations particularly in relation with regulatory concerns, can be an important tool for authorities and health professionals (7).

2. Session 2: ALTERNATIVES TO CONVENTIONAL BLOOD COMPONENTS

As a prelude to the session dealing with alternatives to the Transfusion Therapy using traditional blood components, a comprehensive review of the Coagulopathy which occurs during Massive Trauma was presented by Prof. Uri Martinovitch, the head of the Institute of Thrombosis and Hemostasis and the National Hemophilia center of the Israeli Ministry of Health at Sheba Medical Center, in Tel- Hashomer (9).

It was emphasized that bleeding is a major cause of preventable death in both military and civilian injury from trauma, accounting for over 40 -50% of all mortality. In recent years new insights were gained into the process of combined massive surgical bleed from large and small vessels and the development of an early complex coagulopathy, which is an independent predictor for early mortality. The modern notion is that trauma-related coagulopathy is not a state of disseminated intravascular coagulation (DIC), but a condition with excessive activation of the coagulation cascade at the sites of injury, and an accelerated consumption of both coagulation proteins and platelets, that enables the use of systemic hemostatic agents such as fibrinolytic inhibitors , recombinant activated FVII-(rFVIIa), prothrombin concentrates etc. The combination of coagulopathy, acidosis and hypothermia, recognized as the "lethal tirade" of trauma, requires an early and aggressive comprehensive "hemostatic resuscitation", together with treatment of hypothermia and correction of acidosis (to at least above 7.2 but preferably higher). The common practice for blood component therapy, including the threshold hemoglobin for transfusion is currently being revised based on new data and the experience of the American Army in Iraq, and the new protocol supports the use of a 1:1 PRBC: FFP. Other components as cryoprecipitate (or fibrinogen in Europe) and platelets should also be considered at the same time. The use of rFVIIa can probably be considered early in the course of trauma and before the deterioration of the patients into an irreversible state, despite the fact that there is still limited data from controlled trials.

It should be remembered that conventional blood tests will not provide a swift enough answer to guide decision making as they can be lengthy and do not necessarily represent the in vivo picture. As monitoring the coagulopathy treatment modalities, using "on-line" equipment, whenever possible, is an important therapeutic tool, Dr. Rahimi-Levene, director of the blood bank of Assaf Harofe hospital in Israel presented their experience using Thromboelastography (TEG), a technology able to demonstrate to the treating physicians the clot formation and strength (10) (Figure 1). The test is performed in the blood bank, allows prompt on time decision making and can be viewed online in remote sites (including the operating theater). The use for blood components (FFP, cryoprecipitate or fibrinogen and platelet concentrates can be readily assessed and the test can be repeated until the patient is stabilized and has received proper replacement therapy.

Figure 1: Thromboelastograph

Since coagulopathy is an important component in the survival of trauma patients and since most of the hemorrhagic mortality occurs even before the admission to the hospital, it seems rational to study the use of an early hemostatic resuscitation in the pre-hospital settings, with the intension to prolong the "golden hour". Emergency hemostatic packs containing chitosan hemostatic bandage (Hemcon® USA), bicarbonate, tranexamic acid, fibrinogen concentrate and rFVIIa can be used in such studies, provided interest will be shown by EMS systems.
In view of the need for more and earlier use of blood components, especially for treatment of both military and civilian trauma victims, two the interesting approaches, of The Netherlands army and an Israeli company were presented to the participants (11-12):

1) Dr Charles C.M. Lelkens, a Royal Netherlands Navy CO and Medical Director of the Netherlands Military Blood Bank presented their experience of using frozen blood components of universal donor red cells, plasma and platelets (11).
   The system includes a -80°C frozen inventory of the most essential blood components readily available after thawing (and washing if required), enables to safely reduce shipments along vulnerable supply lines and abandon the backup "walking blood bank", without compromising the availability of blood products in theater. Moreover, all thawed (washed) blood products are in compliance with international regulations and guidelines.
   Since August 2006, when the Netherlands started to participate in Afghanistan, more than 400 patients have been transfused with some 2500 units of frozen blood components, without any untoward effects.
   Further research of the quality and characteristics of such frozen blood components, both in vitro and in vivo, can be an interesting base for collaborative studies among some of the consortium members.
2) Another fascinating approach to improve the availability of cellular components was presented by Dr Amir Arav, from the company Core Dynamics, in Israel, regarding the use of Frozen and freeze dried blood in disasters (12).
   In view of the cumbersome process required for freezing and thawing RBC, and the logistic and economic challenges regarding to the transportation of and storage of such frozen units, the company is developing frozen and a freeze dried RBC single units, which is safe, easily transportable, and ready for use upon rehydration.
   The system is based on the principles of directional freezing, performed in a novel freezing device (aka MTG), which allows for improved control over ice crystals morphology during the freezing process. This freezing device enables successful freezing in the absence of cryoprotectant agents (CPAs) such as glycerol, DMSO, ethylene glycol and others. In addition, a dry thawing device (DTD) was developed which enables the thawing of 500ml samples within 2 minutes. A proprietary freezing solution based on saline supplemented with a sugar and an antioxidant, both non-toxic ingredients as been shown by early pre-clinical studies, has been developed as well. Experiments performed with RBCs units showed 100% recovery of the cells with less then 3% hemolysis after freeze thawing in the absence of CPAs using CD freezing and thawing devices. Furthermore, Autologous transfusions of fluorescent labeled 0.5L

samples performed on donkeys showed an in vivo recovery of 80% of the thawed RBCs 24 hours post transfusion and that the cells have maintained in the animals circulation for 3 months, equivalent to non frozen labels units.
Initial experiments performed on freeze drying small volumes of RBCs samples showed ATP and 2,3 DPG values similar to fresh samples but RBCs that were stored in hypothermia with CPDA-1 solution showed reduced ATP and 2,3 DPG values.
RBCs that were frozen and freeze dried had maintained their typing upon thawing or rehydration.
Further research of the quality and characteristics of such frozen blood components, both in vitro and in vivo, can be an interesting base for collaborative studies among some of the consortium members (see below).

3) Session 4: PREPAREDNESS PLANS FOR DISASTERS

In the session dedicated to preparedness for natural and man-made disasters few subjects were discussed:

a. **Protection gears for transfer of blood units and components:**
One of the major issue that has no trivial answer, to the best of the consortium members' knowledge, is the need to study the required Protective gears for whole blood units and components, during their transportation from the collection sites to the blood services, for further processing and testing, and during their shipment to the different hospitals, in scenarios with chemical, biological and/or radiological threats. A short presentation was made by Mr. Aaron Richman, from the Shield Group Inc. in the Netherlands (13), emphasizing that critical supplies, such as blood and other medical supplies, must be transferred between facilities, during a crisis incident involving a weapon of mass destruction. A thorough research must be conducted to address these matters and identify the optimal protective gears required to shield the blood units from agents that may penetrate the bags (i.e. gases and other volatile agents) without compromising the conditions necessary to preserve their function and performance, once they are transfused.

b. Blood supply during Earthquake:

Dr. Yahalom, deputy director of Magen David Adom, National Blood Services, Israel reviewed the preparedness plan required during an earthquake, which is a natural disaster that might turn into a demanding event for the local blood banks and Blood Centers, according to its location and consequences (14).

Such an event may disrupt the entire infrastructure, thus causing major damages. A careful estimation of the different risks, evaluation of the gaps, establishing a contingency plan and performing simulation of such an event will increase the preparedness of national blood services and hospital blood banks for an unexpected chaotic scenario that can not be predicted (yet) nor prevented. The different logistic issues that need to be addressed were reviewed in depth, including the need for previous knowledge of the vulnerable areas in each country, modes of construction, density and type of population, infrastructure of the Blood Center & hospitals (need for reinforcement of non constructive elements, power and water supply recovery plans) as well as the recovery plans for testing equipment and blood components processing, IT & Back up systems.

Alternative should be prepared for communication plans between the Blood Centers & the Hospitals, employees, blood donors, the integration of Volunteers in the country & abroad, and contacts between Government & other organizations in the country & abroad and the relations with the media.

Plans for alternative transportation should be in place, including evacuation plans & alternative site for blood services/ hospital blood banks including plans, establishing of SOP's, training and the need for increased personnel.

Blood Donors issues should also be taken into consideration after evaluating if there is a need for increased donations.

The amount of blood and components needed per casualty will depend on the types of injury, and unlike the needs after other severe trauma events usually occur in the following days.

Last, but not least the issues of psychological support for employees, blood donors, volunteers and their family members should be taken into consideration.

c. Blood supply during Pandemia

Prof. Shinar, director of MDA blood services reviewed the subject of blood needs and supply during Pandemic flue, as a model to a public health threat. In such event there might be sudden increases in the demand for blood, accompanied by restriction or even total elimination of the ability to collect, test, process or distribute blood. The situation may be aggravated if there will be a restriction form using the already available inventory of blood components (liquid and frozen), because it was collected during the incubation period of the disease.

Such situation may require immediate replacement or re-supply of blood from another region/country (15).

To this scenario one must add the threat for loss of critical reagents with short expiration date (RBC), difficulties in transportation of specimens to central laboratories, degradation in response time from central laboratories, loss of management and senior staff members, who need to find alternative solutions and operate accordingly (16).

A fully developed preparedness plan should there fore be ready, that will provide response for the protection of all the medical first-responders, including the blood bank personnel, a smart and timely program to recruit eligible blood donors, assure access to supplies, preservation of the function of equipment and facilities, keeping a functioning management system all with the aim to maintain an adequate blood supply.

4) Session 5: Rapid techniques

During major disasters one may expect a partial or complete disrupt of the entire infrastructure, including power, water and IT support, a shortage or loss of critical reagents with short expiration date (RBC), difficulties in transportation of supplies needed and loss of experienced laboratory technicians. Therefore methods are needed which will enable to conduct the requested tests on the donated blood units, before their supply to the hospitals. Such tests can be grouped in 2 categories:

a. Blood type determination:

Dr. M. Písačka, from the Reference Laboratory for Immunohematology
Institute of Hematology and Blood Transfusion
Prague, Czech Republic presented their experience of Rapid Blood Grouping Using Lateral Flow Device with Stable End-Point without Centrifugation (17).
As blood grouping, especially AB0 and RhD determination, is critical for the blood transfusion compatibility, such tests must be performed on units before transfusing them into recipients to prevent acute (and sometimes lethal) and delayed post-transfusion reactions.
While in regular times transfusion service centers and hospital blood banks are performing highly accurate blood grouping tests using hemagglutination methods on precise, though complicated semi- or fully automated instruments, simple alternative/s that do not rely on computer and electricity supply will be needed in case of disaster.
Simple alternatives exist, such as slide on which mixing of drops of blood and reagents on is performed on glass, ceramic or plastic surface, however, these methods have many disadvantages /infectious risks, possible cross-contamination, dots drying, missing of weak reactions, difficult reaction identification and result documentation.
Dr. Písačka presented their experience using a new rapid method was presented which contains potent and highly sensitive monoclonal antibodies /CE certified and uses lateral flow, providing stable end-point results without centrifugation within minutes. The currently available credit- card- size "MD Multicard“provide simultaneous testing for AB0, RhD, Rh subgroups and Kell antigen determination (Figure 2)

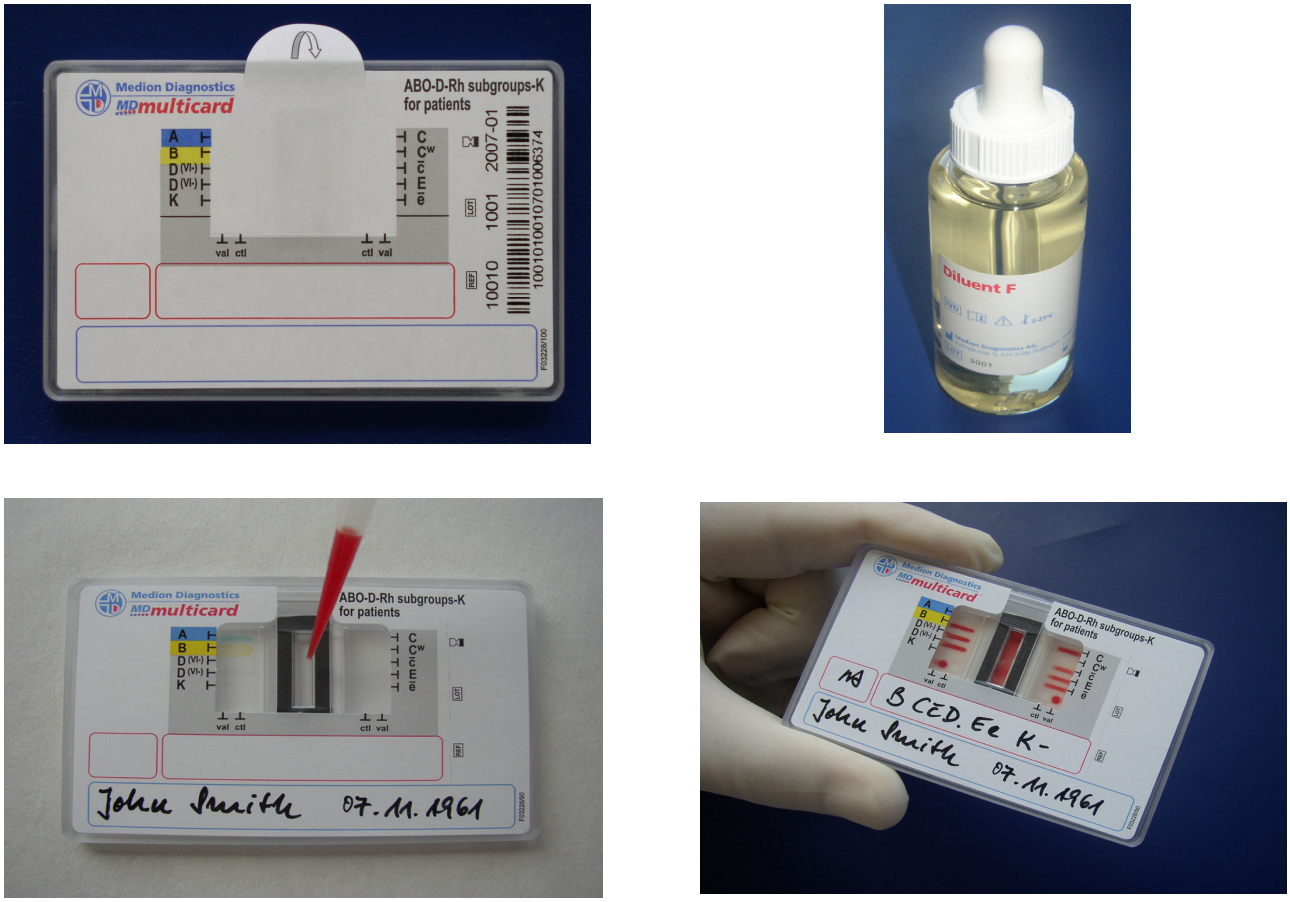

Figure 2: MD Multicard system

b. Testing for Transfusion-Transmitted Infectious Diseases:

As for blood grouping most blood services centers and major hospitals are using highly accurate Elisa and Nucleic Acid Testing (NAT) on precise, complicated semi- or fully automated instruments. Here again a simple alternative/s method that do not rely on computers and electricity supply will be needed in case of disaster.

Dr. Baruch Rivetz, a PhD from Orgenics LTD, in Yavne, Israel presented their kits of field-oriented rapid diagnostics for early diagnosis of HIV infection (18). During the scope of development of rapid in vitro diagnostics for infectious diseases, on rapid diagnostic platforms aimed at low-equipped or non-laboratory settings and point-of-care testing, the company developed two rapid 4th generation HIV test devices, which simultaneously detect antibodies and antigen and differentiate between them. The system does not require additional

instrumentation and therefore is deployable in multiple settings, from centralized laboratories and blood banks to remote point-of-care test locations. The performance of both assays, demonstrated in an extended series of clinical trials, showed the capability of detecting HIV infection earlier than HIV antibody-only tests do and of identifying those who are acutely infected with HIV.

5) Future projects for submission

In this section, some of the subjects that caused interest among the consortium members will be summarized. These members thought these issues are important to provide assistance to the Medical First-time Responders in Transfusion Medical and Trauma fields during Disasters, and have the potential to be submitted as interesting research projects for future collaboration among the participants of the workshop.

1) Monitoring the adequate usage of blood units and components in Trauma patients with severe coagulopathy and bleeding.
   Although, currently it seems that the majority of situations do not require extensive use of platelets or plasma, which seem in severe trauma cases be only necessary in special circumstances, the workshop participants thought it could be interesting and useful to conduct a muti-center study, looking at the usage of blood components in severe trauma cases, especially in view of the new treatment regimen of component therapy (1:1:1) recommended lately in the literature (8)
2) Building a training program for the medical first responders in central blood services and hospital blood banks in drills and training exercises of the various man-made and natural disasters. The Emergency department MDA can lead this program and can adapt it to the different disasters in different countries.
3) Further research is needed regarding the quality and characteristics of the frozen and a freeze dried RBC single units, developed by Core dynamics, Israel, toward a safe, easily transportable, and ready for use upon rehydration. Such a study performed both in vitro and eventually in vivo, can be an interesting base for collaborative studies among some of the consortium members.
   A more detailed suggestion is included in here:
   "Freeze thawing RBC units without Glycerol-Core dynamics

Red blood cells (RBC) save lives! RBC units are administered routinely into patients expressing a wide range of conditions (e.g. anemia, bleeding, chronic diseases, surgery, etc).

In order to answer this constant need for blood supply the blood banking system has developed. Currently, RBC units are mostly preserved in a liquid state up to a maximal duration of 42 days, depending on the preservative solution used. Less then 1% of the collected blood is being frozen. The use of frozen RBC units is limited due to the inefficiency of the current methods for long term preservation. The cumbersome process required of adding glycerol to a unit and freezing it is time consuming and expensive. Due to the toxicity of glycerol the unit has to be washed upon thawing and prior to transfusion. Thawing and washing is time consuming (between 1-2 hours). Due to the requirement to thaw and remove glycerol from the unit prior to transfusion it cannot be used in acute scenarios such as a battle field or disaster areas.

Core Dynamics has developed a freezing devise (MTG) which is based on the principles of directional freezing, thus allowing control of ice crystals morphology during the freezing process. This freezing devise has enabled us to successfully freeze in the absence of intracellular cryoprotectant agents (CPAs). Overcoming this issue has made freezing without glycerol possible. Core Dynamics also utilizes a proprietary freezing solution, named IMT-1, based on saline supplemented with Dextran 40 and a new additive named EppiGaloCatechine Gallat (EGCG) which is an antioxidant produced from green tea leaves. Furthermore, Core Dynamics has developed a dry thawing device which enables us to thaw 500ml samples within 2 minutes.

Experiments performed on freeze thawing packed RBC units with IMT-1 solution have shown 100% recovery and less then 2% hemolysis upon thawing (without any washing process). In addition, in vivo experiments were performed on donkeys. In these experiments venous blood drawn out of donkeys, the RBC were stained with FITC prior freezing and the blood was mixed with IMT-1 solution and either transfused without additional processing or after freezing and thawing using Core Dynamics technology. The transfusions were autologous. After transfusion blood samples were taken from the donkeys at the following time points: immediately, after 2 hours, after 4 hours, after 24 hours continuing with weekly sampling for up to 3 months. The results have shown that 24 hours after transfusion between 60%-80% of the transfused RBC were in circulation and that the transfused cells declined gradually in a similar manner to RBC that were not frozen over the next 3 months.

All donkeys had normal physiological performance after transfusion and none of them showed any adverse affects.

Pre-clinical studies such as genotoxicity studies, repeated dose transfusions in rabbits and increased dose transfusions in pugs showed that the antioxidant used in the solution, which is not approved for IV administration to be safe.

Further safety and in-vitro studies are required in order to finalize the frozen thawed RBC procedure and to be able to start and use it as a fully developed product which will make the use of frozen RBC in acute situations a reality. Performing these studies in the setting of a blood bank will allow the incorporation of the system into the current blood management system."

4) As monitoring the coagulopathy treatment modalities, using "on-line" equipment, whenever possible, is an important therapeutic tool, Dr. Rahimi-Levene, director of the blood bank of Assaf Harofeh Medical Center, wrote a preliminary aqbstract regarding a possible multi-center trial for the use of the Thromboelastography (TEG) technology in severly bleeding patients.

The more detailed suggestion is included in here:

"TEG – MONITORING & TREATING BLEEDING PATIENTS

Naomi Rahimi-Levene MD, MHA

Director of the Blood Bank, Assaf Harofeh Medical Center, Zerifin, Israel

The hospital Blood Bank is a transfusion service, providing blood in every day life and in extreme situations. Disasters are unexpected, their extent is unpredictable and therefore one must prepare in advance for the worst scenario. In a catastrophic event many massively bleeding patients will have to be treated simultaneously, sharing sometimes limited available resources. Once the patient is receiving blood products decisions have to be made as to which products the patient needs and how much of each. Conventional blood tests will not provide a swift enough answer to guide decision making as they can be lengthy and do not necessarily represent the in vivo picture.

Thromboelastograph (TEG) is a technology demonstrating clot formation and strength. Historically TEG has been used for monitoring open heart surgery and liver transplants. In our hospital TEG is performed in the blood bank and can be viewed online in remote sites (including the operating theater and the emergency room if needed). The anesthetists have been tutored in interpreting the TEG and in a short time the need for FFP, cryoprecipitate

(fibrinogen) and platelet concentrates can be assessed, allowing prompt ontime decision making. In an event in which communication online is cutoff the TEG can be transferred and setup in the operating theater, allowing decision making on the spot. The test can be repeated until the patient is stabilized and has received proper replacement therapy.

We propose utilizing the TEG as an aid in treatment of the acutely bleeding patient. A TEG will be performed on a prehospital sample (executed in up to one hour after taken). Repeat TEGs will be performed as long as the patient is bleeding, in parallel to conventional hemoglobin, platelet count, PT, APTT and fibrinogen.

On cessation of bleeding a TEG will be performed again.

Decision making on basis of repeat TEGs will be assessed in order to expose the patients to minimum blood products."

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10. Rahimi-Levene Naomi: TEG – Monitoring & Treating Bleeding Patients. Assaf Harofeh Medical Center, Zerifin, Israel
11. Lelkens Charles C.M., from the military blood supply presented the experiences gained in the Afghan theater, Royal Netherlands Navy CO and Medical Director of the Netherlands Military Blood Bank
12. Arav Amir. Frozen and freeze dried blood in disasters, Core Dynamics, Israel
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Annexes

1. **Workshop program**
2. **Workshop abstract book**

Magen David Adom Blood Services

Use of Blood and Blood Products in Disasters- Background Paper

Prof. Eilat Shinar, MDA blood services, Israel
Prof. Noga Manny, Hadassah Medical Center, Israel

Identifying the Needs of Medical First Responder in Disasters (NMFRDisaster)
Theme 10 – Security; Call – FP7-SEC-2007-1

NMFRDisaster - Identifying the Needs of Medical First Responder in Disasters

Coordinator: Magen David Adom (Israel)

Partners:
- Al-Quds Nutrition And Health Research Institute (Palestinian Administered Areas)
- Ambulance Zorg Nederland (Netherlands)
- Centro per La Scienza, La Società e La Cittadinanza- CSSC - (Italy)
- Charles University (Czech Republic)
- Croce Rossa Danese- Danish Red Cross -(Denmark)
- Fundacion Rioja Salud (Spain)

- SAMUR Servicio de Asistencia Municipal de Urgencia y Rescate (SPAIN)
- Shield Group Inc. – Security and Counter Terrorism Management (Netherlands)
- SINERGIE Formazione e Consulenza Professionale (Italy)
- Magen David Adom (Israel)

Duration: 1 year (01.05.2008 – 30.04.2009)

Contents

BACKGROUND

Responsible Blood Services Agencies (RBSA) worldwide must be prepared to meet surges in demand for blood components, needed by casualties of natural domestic disasters and acts of terrorism.

Situations such as Hurricanes and Tsunamis, Wildfire, Floods, Earthquakes, as well as Pandemic influenza may create an increased need for blood and blood components. Man - Made hazards such as industrial accident (fire, building collapse and hazardous material spill), Explosive, Chemical, Biological, Radiological or Nuclear events can be added to this list (1).

In addition civilians and military personnel worldwide have increasingly become targets for bombing and other acts of terrorism (2). Events in Indonesia, India, Britain, Spain, Egypt's Sinai Desert, and the attacks on the World Trade Center and the Pentagon in the United States, have prompted reviews of the capacity of different health care systems to respond to domestic disasters and acts of terrorism (3).

In the framework of the project dedicated to identify the needs of medical first responder in disasters, a working part was included regarding the use of blood and blood products in such events.

Disaster definition:

Different international organizations define disaster in a similar ways:

IFCRC: The International Federation of Red Cross and Red Crescent Societies define a disaster as "a sudden, calamitous event that seriously disrupts the functioning of a community or society and causes human, material, and economic or environmental losses that exceed the community's or society's ability to cope using its own resources. Though often caused by nature, disasters can have human origins (4)."

EM-DAT: The Emergency Events Database similarly defines disasters as situations or events which "overwhelm local capacity, necessitating a request to national or international level for external assistance. (A disaster is) an unforeseen and often sudden event that causes great

damage, destruction and human suffering. Though often caused by nature, disasters can have human origins" (5).

As this section of the project deals with the needs of medical first responders regarding the use of blood and blood components, a special attention should be given, in the scope of this background paper, to the definition of a Disaster in the blood services.

AABB: The American Association of Blood Banks states that "unless otherwise stated, the word disaster refers to any domestic disaster or act of terrorism that

• Suddenly requires a much larger amount of blood than usual

OR

• Temporarily restricts or eliminates a blood collector's ability to collect, test, process, and distribute blood

OR

• Temporarily restricts or prevents the local population from donating blood, or restricts or prevents the use of the available inventory of blood products and thus requires immediate replacement or resupply of the region's blood inventory from another region

OR

• Creates a sudden influx of donors, requiring accelerated drawing of blood to meet an emergent need elsewhere (6)."

Past lessons:

Previous international and domestic disasters have led to the following lessons:

1. There is a need to ensure that facilities maintain inventories of blood units and components at all times in all locations.
2. The required combined inventory of both RBSA and hospitals blood banks should be determined, for both regular activities and emergency situations, and closely monitored.
3. There is a need to control collections in excess of actual need in response to a disaster.
4. There should be a clear and consistent message to the blood community, donors, and the public regarding the status of the blood supply (both locally and nationally) during a disaster.
5. Countries should have a general response plan and continuous disaster planning, including participation in disaster drills and close coordination with regional, national, and international response agencies.
6. There is a need for an overall inventory management within the affected country, including a unified approach to communication among blood facilities, medical emergency services and hospitals regarding the needed amount, transportation of and existing alternatives to blood and blood components during a disaster (6-7).

REVIEW OF MAJOR EXISTING DATA

1. Overview of a response plan

Different countries have put together national and /or local response plans, which may be centered either on RBSA and /or on the local facilities in the affected area. The plans include recommendations for a national task force, which will consider the national response and recommend an action strategy including, but not limited to, the shipment of blood to the affected areas, and the coordination and dissemination of a message to the national blood community and donors.

A very good example is that of the AABB, which has created an Inter-organizational task force to be operational in Disasters, and which published a very comprehensive Operations Handbook on Domestic Disasters and Acts of Terrorism Disaster. The information was updated on October 2008, and is available at the organization website (6).

The response plan should include blood collection, processing and testing agencies, as well as Hospital blood banks and contain subjects such as:

Communication strategies- to ensure that there will be effective, communicate with both internal and external key parties during an emergency

Collection options- at designated facilities, adjusted to the type and scenario of the disaster

Transportation Options-regarding transportation to and from the collection sites, as well as blood supply to the hospitals

Managing Donors, Volunteers, and Crowds

Safety Concerns-regarding issues such as blood donors' eligibility, tests performed

Security Concerns – of blood donors, collection teams, blood services laboratories and other facilities and hospital blood banks

Human Resources- in order to ensure the continuity of operations at the Blood Collection facility, blood services components and testing laboratories and hospital blood banks, and balance it with the needs of staff tending to their own families

Information Systems and Records Management - to enable continuity of operation and assure data protection

Regulatory Concerns

Disaster Operations Handbook – Should Be Prepared at the Hospital blood banks levels

2. Blood collection in Disasters

Some disasters, both natural and man-made, can be predictable, and may include early warnings which will allow the RBSA to prepare larger inventories, to evacuate and/or take shelter before the disaster occurs (i.e. hurricane, tornado, and war acts). Some may happen as a total surprise, without any warning (i.e. terrorist attacks, earthquakes, industrial HAZMAT events, etc.). The sudden onset of the latter event(s), together with the potential disruptions of the general infra-structure may cause a sharp increase in the immediate demands for blood components, thus creating a genuine challenge for the RBSA and hospitals (6 and references therein).

1. In most severe natural disasters significant, even catastrophic damages may occur, posing generally a risk to blood facilities directly and to other medical structures in their path. In addition the event could significantly hamper collection activities if a large area is deemed uninhabitable. Blood collection schedules may be disrupted, depending on the severity of the disaster and the size of the destruction path.

2. Industrial or chemical events may be the result of an accident (e.g. chemical manufacturing plant accident, rupture of a storage tank, train derailment) or as a deliberate action by terrorists. In such events blood collections at the blood center may be lost, and transport of blood collected at local blood drives may be adversely affected. In addition some militarized and industrial chemicals may require specific decontamination of buildings and vehicles and the administration of antidotes to people in the affected areas.
   RBSA should be prepared to minimize the negative impact of a chemical incident, ensure the re-establishment of operations, and protect staff, donors, and volunteers. Depending on the type of agent involved in the event, the blood center may face infectivity issues for staff, volunteers, and donors, need for contamination of facilities and vehicles and deferral of donors.

3. During biological events and/or bioterrorism attack the blood center may be required to conduct an aggressive call-back of donors who develop symptoms after a blood donation, because of the various incubation periods of different agents. Mandated quarantine measures or self-initiated actions by the population could result in loss of blood donations. In addition such measures, as well as travel restrictions may prevent or hinder blood center employees' ability to travel to work and collection sites, and may affect access to the supply chain for critical supplies, equipment, and fuel.

4. A radiological or nuclear event that may occur as accidental or terroristic dispersal of radioactive material. A "private case" may happen in blood banks that operate Cesium-137 blood irradiators.
   Nuclear explosion however, may combine large-scale blast damage with dispersal of radioactive material. Such events may have severe impact of blood donors' availability and deferral. Where radiation is widely dispersed, blood collections would be curtailed if the public (staff and donors) were advised to shelter in place for a period of time during assessment and early radioisotope decay. Blood donors

may need extra screening or laboratory testing (blood lymphocyte count) concerning whether they have taken anti radiation medication or have evidence of radiation exposure by symptoms (e.g., vomiting) (8-10).

5. Following explosive events, either resulting from an accident or due to terrorist or criminal bomb, an immediate increased need for blood and blood components' is expected for about 20% of the total number of casualties (7,11-13)

6. There is no real prediction on the impact of a Pandemic influenza on blood collections and supply. Although a reduction in the need for Red Blood Cells (RBC) is expected, significant blood shortages (especially of platelets) may occur because of a shortage in healthy donors. In addition, the situation may have an impact on the availability of the blood banks employees and on the organization and execution of blood drives (14-17).

However, in order to meet the needs in any of the above mentioned disaster, RBSA should activate surge strategies to manage donors and volunteers. Donors should be discouraged from appearing en masse until the medical need has been assessed but a plan should be prepared to control significant crowds. Local authorities may direct the blood center to implement its shelter-in-place plan or evacuate, depending on the biological agent (6).
In addition research should be performed to evaluate the needs for "protected gears" for the blood bags to and from the collection centers to the blood services laboratories and to the hospitals blood banks in different disaster setups.

3. Needed Quantities of blood and blood components

Although the overall quantity of blood and components needed by hospitals during disasters may not constitute a large amount, when compared to the monthly or annually demands, the sudden onset of the event(s) and the potential disruptions of the general infra-structure may caused a sharp increase in immediate demands, thus creating a genuine challenge for the responsible blood services agencies and suppliers.
In disastrous situations the most frequently quoted quantity of blood units is 2-4 units of RBC and 1.5 components / casualty, required for victims of civilian trauma or military actions (7,11-13,18). The data from Israel till 2006 suggested that the “rule of thumb” in planning an adequate response of a national blood supply should be 1.3 RBC and 1.0 component/ patient, if all casualties are included or 6.7 RBC and 4.5 component/ severe or moderately injured patients. These estimates coincide with analyses made after the World Trade Center and

Pentagon attacks (18), Oklahoma City bombing (19), war casualties in Sarajevo (20) and others (21). However, in view of recent reports in the literature, regarding better understanding of the mechanism of the coagulopathy in trauma, and the new approaches in its management, the use of blood components should be further investigated and re-considered (22-23).

Potential Impact on the Blood Supply

1. **natural disasters**

Depending on the projected path and force of the hurricane, tornado or flood, blood may be needed to treat casualties, which may number from a few to scores. However, there may be a slight decrease in elective surgeries shortly before and after the storm, followed by a spike in such surgeries once hospitals in the region resume full operations.

The impact on the blood supply following an earthquake could be directly affected by the severity of the event. Blood usage may not be initially significant, as hospitals may temporarily suspend elective surgeries. However, an increased demand may occur once survivors are evacuated to the different hospitals in the coming days, and/or when operations are back to normal.

RBSA should make special preparations to ensure that operations can be quickly resumed following such a natural disaster, and that adequate communication channels exist with the hospitals.

2. **Industrial/chemical/biological events**

If the industrial accident involves the blood center the blood supply should be quarantined until its safety, purity, and potency can be determined. Accidents that do not directly involve the blood center may or may not require increase in the blood support, depending on the nature and number of injuries. The public often will respond by donating blood out of a desire to help.

Most chemical events do not increase the immediate demand for blood products, although some compounds may have complications requiring blood product support later.

3. **Radiation toxicity and nuclear events:**

These events may cause suppression of hematopoiesis, thus victims may need support with RBC, platelet, and granulocyte transfusions, mostly with irradiated and leukoreduced cellular blood components. Highly exposed persons (3–10 Gy) may be considered for

hematopoietic stem cell transplantation, requiring HLA typing, donor matching, stem cell collection, and transfusion support after transplant.

National and International coordination of supply and demand for blood components and hematopoietic progenitor cell units would be required as part of the overall emergency response.

4. Explosive events:

Immediate mortality may be high, and some survivors would require resuscitation and surgery, with associated transfusion support. As previously mentioned data from Israel as of 2006 indicate that in planning an adequate response of a national blood supply should be 1.3 RBC and 1.0 component/ patient, if all casualties are included or 6.7 RBC and 4.5 component/ severe or moderately injured patients. In theses events 73% of the blood supplied over the first 24 h was administered during the first 2 h. The cross-matched/transfused ratio was 2.52 – 1.42, reflecting the overestimation of blood requirement in these mass casualty episodes.

A comprehensive program for managing blood operations in emergency situations and a coordinated national program can stabilize in-hospital inventories during routine activities, ensure instant access to precisely defined inventories, facilitate sufficient supply in times of disasters, and minimize outdating and wastage

Local inventories of blood components would need assessment for adequacy and augmentation. Surges of blood donors have occurred after such events, and coordinated public announcements about the blood supply are helpful to strike the appropriate balance between supply and demand. (7)

5. Pandemic Influenza

The scenario of Pandemic influenza describes a situation when a new influenza virus will emerge, while people have little or no immunity to it, the agent will be easily spread from person to person, while there will be no vaccine.

The impact of a pandemic flu on the blood supply is a topic of much discussion. No one can predict the next pandemic flu, either in timing or impact. Generally accepted planning estimates a reduction in the need for RBC by as much as 25%, referencing the 2003 Toronto experience with severe acute respiratory syndrome (SARS). It is believed that the requirements for platelets will remain unchanged, as chemotherapy patients will continue to need platelet support. The impact on frozen products is of less concern because of the extended shelf life of these products. Even if the demand for some blood products declines,

significant blood shortages (especially for platelets) may occur because of a shortage of healthy donors (15-16).

4. Safety of blood components:

The availability of blood may be the primary concern in a disaster, but the safety of the blood supply is also paramount. Most countries declare that adherence to regulations is crucial, and every effort should be made to follow the current good manufacturing practice regulations and standards employed.

Based on the American experience from September 11th 2001, a 5.2 increase was observed in 1st-time blood donors (24), and donations confirmed positive for human immunodeficiency virus (HIV), hepatitis C virus (HCV), and hepatitis B surface antigen nearly tripled between 1 week before September 11 (0.1%) and 1 week after the attacks (0.3%), largely explained by the increase in first-time and lapsed repeat donors.

Furthermore, during a disaster situations may dictate the need for regulatory exemptions, due to technical inability to prepare and store blood components, to perform (all) the needed tests, etc.

For such events different and new approaches should be considered.

4.1 Manual testing

1. Transfusion transmitted Diseases:

Few makers had development various serological assays for Transfusion transmitted Diseases such as HIV, HCV and HBV on rapid diagnostic platforms aimed at low-equipped or non-laboratory settings and point-of-care testing (25)

A search should be made for test kits that accommodate as many samples as possible, but which does not require infra-structure and additional instrumentation, and can therefore be deployable in multiple settings, from centralized laboratories and blood banks to remote point-of-care test locations.

2. Blood grouping:

Blood grouping, especially AB0 and RhD determination, is critical for the blood transfusion compatibility.

Correct AB0 type of the donor and recipient blood prevents acute intravascular post-transfusion hemolytic reaction which could have potential of fatal outcome in case of incompatible transfusion.

Transfusion service centers and hospital blood banks are now performing the blood grouping on semi- or fully automated instruments, based on different principles /agglutination with centrifugation is the most common, others are agglutination by sedimentation, agglutination with magnetization of red cells, column (gel) test and solid phase test (26). These tests are highly accurate but dependent on complicated instrumentation, precise organization of sampling and identifying samples and computer and electricity supply. Most of above mentioned tests are also available in manual versions, but these are also dependent on availability of electricity power at least.

On the other hand a simple alternative is available- slide test using mixing drops of blood and reagents on glass, ceramic or plastic surface. But this test has many disadvantages /infectious risks, possible cross-contamination, dots drying, missing of weak reactions, difficult reaction identification and result documentation.

A search should be therefore initiated in order to find a testing procedure which does not require infra-structure and additional instrumentation, and can therefore be deployable in multiple settings, from centralized laboratories and blood banks to remote point-of-care test locations.

4.2 Recommended Training and Assignment Sheet

RBSA should developed a handbook of strategies and approaches to domestic disasters and acts of terrorism to ensure that blood collection and distribution efforts run smoothly and are managed properly, and that the public receives clear and consistent messages regarding the status of the blood supply.

"The exercises should be followed by a written knowledge assessment to ensure competency and to evaluate the course. The organization should schedule annual refresher training for all staff, along with quarterly or semiannual disaster drills that include resource-sharing groups."

4.3 Un-tested blood for infectious markers

The last alternative could be the decision not to test blood units collected under extreme fierce conditions (e.g. facility evacuation and shutdown, surge of blood collected over testing facilities, with increased need for the blood and components). This very responsible decision should be taken by the leading RBSA, together with the national health authority, and if possible be based on pre-collected data of blood donor epidemiology in that country/region.

5. Alternatives to conventional blood units and components:

Today, most RBC units are preserved in liquid state for a maximum duration of 42 days, depending on the additive solution used. Less than 1% of the collected blood is frozen for long term storage. Frozen inventories of plasma and cryoprecipitate are easy to build and maintain. However, the issue of having inventories of frozen cellular blood components for disasters is a subject of continuous discussion and debates, also taking into consideration the long, vulnerable supply lines and unpredictable points in time where these products are needed

1. **Red blood cells (RBC)** can be frozen in glycerol solutions and stored for many years. Thawed RBC must have the glycerol removed, but the recovered cells have normal survival in humans. Freezing has been used to store RBC of rare phenotypes for more than 40 years. In the 1960s and 1970s, when medical technology and blood use were expanding rapidly and liquid whole blood and RBC storage were limited to 3 weeks, many attempts were made to expand the use of frozen RBC for meeting the needs for a stable blood supply and to have RBC reserves for emergencies. These attempts have largely been abandoned because of the cost of freezing, storing and processing, better management of the larger and longer lived RBC inventory, concerns about the safety of stored RBC that have not received the most up-to-date testing and the losses associated with the short shelf life of thawed RBC. Despite the introduction of new automated frozen RBC processing systems, which will potentially allow extending the outdating of thawed RBC to 2 weeks, there still will not materially effect the costs or losses associated with the use of frozen RBC. As a result of the long cumbersome and expensive washing process frozen thawed RBC units cannot be used in acute scenarios such as a battle field or disaster areas. In addition, transportation of frozen units is

expensive and introduces logistic challenges, while not having a significant effect on the logistics of blood supply (27)

2. **Frozen cellular blood components:** Some institutions have created systems of frozen blood components of universal donor red cells, plasma and platelets (28). This -80°C frozen inventory of the most essential blood components readily available after thawing (and washing if required), enables them to safely reduce shipments and abandon the backup "walking blood bank", without compromising the availability of blood products in theater. Moreover, the authors declare that all thawed (washed) blood products were in compliance with international regulations and guidelines.

   Other publications claim that the frozen blood reserve can likely support normal hospital red blood cell (RBC) demands during typical (3-4 days) seasonal shortages, provide a reduced supply for up to 10 days, or meet an unexpected transient increased RBC demand without requiring intensive support from the regional blood center. However, they also emphasize that the frozen blood supply is not designed to meet the massive transfusion demand associated with extreme or sustained disasters. Rather, it serves as a short-term bridge-over supply until blood center support can be reestablished (29-30)

3. **A-cellular oxygen carriers red cell substitutes,** such as hemoglobin solutions and perfluorocarbon emulsions have been evaluated throughout the years (31-32). Although it was shown that products can maintain normal levels of oxygen consumption, CO2 production, and circulatory dynamics in primates in the virtual absence of the red blood cell, clinical trials with most of them have been discontinued due to the lack of efficacy and severe side effects in clinical trials. Alternative uses for oxygen carriers continue to be explored.

4. **Alternatives:**

In view of these draw backs a search should be therefore initiated in order to find a freezing and thawing procedures which do not require time, highly qualified man-power, infra-structure and additional instrumentation, and can therefore be deployable

in multiple settings, from centralized laboratories and blood banks to remote point-of-care test locations.

ISSUES FOR THE INTERNATIONAL AND EUROPEAN AGENDA

Response to disasters tends to have an international influence, requiring close collaboration of many groups and their involvement in the response efforts.

It has been shown to be the case in both natural and man-made disasters. Disasters which happened lately both in developed as well as in developing countries, brought members of the non-affected areas to offer help and support those affected toward a fast recovery. Although a wide range of differing cultural and ethical values may exist, in the professional blood banking community such diversities have no influence on the will to help and support the needed countries/societies. However, it is true that the lack of international agreements relevant to disaster response may hamper the support efforts, and there is a place for an international guidelines that can be accepted among fellows countries /professional societies regarding the mutual recognition of professional standards, so blood units and components can be supplied and accepted, from one area to another. We feel that there could be better preparedness and therefore response to disasters among the different members in the European and International blood banking community, if such standards will be put in place.

Today many blood banks work according to either CE or FDA guidelines, using similar (and sometimes compatible) Data Management Systems that may facilitate mutual support. However, a preliminary planning should take place regarding this mutual recognition, and generally accepted guidelines for different stages and severity in Disasters should be decided upon, as part of a universal contingency plan. A comprehensive review and the creation of an official document clearly stating the professional guidelines for collection, testing, inventory management and supply could greatly improve the Transfusion Medical treatment that countries hit by disaster can provide to the population involved. Such guidelines will have to take into consideration the existing disparities between countries and regions. The existing Guidelines and preparedness plans of the AABB inter-organizational task force or those of the International Federation of Red Cross and Red Crescent Societies are actually used in the different countries, while they could become universal and international legally binding

documents. This could improve the Disaster response plans and provide better approach to disasters, especially in the view that their occurrence may only increase over the coming years.

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ANNEX 1: MDA WORKSHOP PROGRAM

Identifying the Needs of Medical First Responder in Disasters NMFRDisaster
Theme 10 – Security; Call – FP7-SEC-2007-1

WP-5: Use of blood and blood products in disasters
Coordinator: Prof. Eilat Shinar
MDA blood services director

The workshop took place in 24-25/11/08 in Israel

A. Workshop plan:

1. Following the project kickoff meeting, which took place in Jerusalem on May 2008 it was decided that the workshop of WP-5 will be conducted in Israel.

2. It was decided that the workshop will include 2 days of presentations and discussions, followed by summary and recommendations for future actions, to be submitted to the Commission.
3. The program will hold 3 sessions every day. In each session 4 presentations of 20-30 minutes each will given by international experts, followed by a 30 minutes Q & A panel discussion.
4. The suggested daily planned itinerary will be:
   Session 1-09:00-11:00
   Session 2-11:30-13:30
   Lunch- 13:30-14:30
   Session 3-14:3017:00-

5. The following subjects are suggested:

   1. Use of Whole blood and blood Component in Transfusion Therapy at the battle field and in field and conventional transfusion centers
   2. Rapid testing techniques
   3. Alternatives/additions to conventional blood components therapy
   4. Preparedness for Natural and Man-made disasters
   5. Visit to MDA blood services center

B. Participants:

We suggest that participants in the WP-5 workshop will be:

a. Members of the consortium:
   a. Fundacion Rioja Salud, Spain
   b. SAMUR, Spain
   c. AmbulanceZorg, the Nederland
   d. MDA blood services, Israel
   e. El Quds University, PA
b. Additional recommended Professionals from the participating members' countries (1member/country)
c. Additional professionals from the Palestinian Authority and/or the Palestinian Red Crescent
d. Local professionals in Israel, such as:
   a. Representatives form the IDF (Medical Corps and Home Front Command)
   b. Members of the Israeli Consulting committee for the Organization of Blood Services during Emergency situations

Abstracts

ABSTRACT
Use of blood and blood products in disasters

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Transfusion support is an essential component of clinical medicine, with transfusion being life-saving in many acute situations and many chronically ill individuals receiving regular transfusion therapy. It is therefore critical that national blood transfusion services (BTSs) recognize the potential impact of a disaster on their blood supply systems and put contingency plans in place to ensure the maintenance of core services in the event of such disaster. The development of a contingency plan to ensure the effective use of available blood when blood stocks have fallen to very low levels is critical to ensuring transfusion support for patients on disaster situations. The Blood Services Plan concentrates on the impact of a disaster could have on the Blood Services and the action necessary to mitigate the impact. As far as possible, the Blood Services will ensure continuity of supply but preserving life-saving supplies where necessary. Blood Services will need to provide, where possible, a safe environment for donors to donate and for staff to come to work. However it is likely that the number of blood donors able and willing to donate will be severely reduced. Staffing numbers will also be reduced and activity in some areas will be reduced to essential activity only with staff being redistributed in order to support this essential activity. Communication will be crucial throughout the disaster both to internal and external stakeholders with key messages being developed for different stages of the crisis.

Another key principle of the plan is that shortage can, in most cases, be avoided by reducing the current usage of blood through appropriate use programmes. It´s essential the appropriate use of blood and the use of effective alternatives in every clinical practice where blood is transfused, avoiding the unnecessary use of blood and blood components (fresh frozen plasma and platelets) in medical and surgical practice, ensuring that the transfusion was appropriate based on current guidelines or standards from professional bodies (Council of Europe, British Guidelines, CAT, etc.). Every effort will be made to mitigate the impact on the supply (through targeted collection, marketing and media messaging strategies). However, if stocks reduce to such an extent that life-saving demand is predicted not to be met either immediately or in the coming weeks, then it is likely that the Blood Services will have to restrict usage and conserve red cells and components to life-saving transfusions only. This may be implemented even before stocks actually fall to critical levels. This will be difficult to gauge at the beginning when the precise impact of the disaster is unclear and we therefore anticipate modeling the situation in real time. As more information is obtained at the start of the disaster, e.g. the response from donors, impact on demand etc, it will be possible to assess the emerging impact on stocks.
Supporting a Consensus Conference on Appropriate Use of Blood Components in Normal and in Disaster situations particularly in relation with regulatory concerns, can be an important tool for authorities and health professionals.

BLOOD BANKS AND TRANSFUSIONS IN CATASTROPHES

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Blood Centres must have their own established plan, which is coordinated at local and national level, that allows them to respond when faced with any local disaster or terrorist acts that affect blood supplies.

To all intents and purposes, catastrophe is a situation which abruptly results in much higher than normal requirements for blood products; blockades or restrictions on the capacity to collect, process, analyze or distribute blood; or situations which create a sudden influx of donors to cover the necessities in another place.

The plan must contemplate important aspects such as: correctly determining blood requirements; providing transport for blood from one centre to another, and sending a common message to all the country's blood centres, as well as the general public, about the situation of the blood supply in the affected area.

Experience in catastrophes has taught us three important lessons:

5) Blood collections must be controlled so as not to exceed the real requirements
6) Blood centres must always maintain sufficient stocks (for seven days)
7) A national stock coordination plan is necessary

The following assertions must be accepted to satisfy the blood requirements during the initial 24 hours:

d) All blood that is initially dispatched should be type O packed red cell
e) The quantity dispatched to a centre should not exceed the amount of blood required for one day (taking all blood types into account)
f) The initial dispatch of blood products should be carried out by the centre which can most quickly deliver them

The majority of situations do not require extensive use of platelets or plasma, and will only be necessary in special circumstances.

The plan should develop the following strategies:

13) Alternative means of communication with hospitals and the coordinating centre.
14) Alternative means of transport.
15) Coordination with local, regional and national authorities.
16) The maintenance of supplies for treating blood.
17) The maintenance of power supplies, water and telephone services.
18) The organization of blood donors and volunteers. Crowd control.
19) Strategies for working with the media.

Massive bleeding in trauma and surgery:

The complex nature of traumatic coagulopathy

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Bleeding is a major cause of preventable death in both military and civilian trauma, accounting for over 40 -50% of all mortality. The process which begins as a "surgical bleed" from injured vessels may rapidly evolve into a combined massive surgical and diffuse "coagulopathic" bleeding from large and small vessels, due to early development of a complex coagulopathy. The severity of coagulopathy is an independent predictor for early mortality, which in the presence of coagulopathy is above and beyond that expected from the severity of injury alone. In recent years we have gained new insights and significantly expended our knowledge on the complex process of trauma-related coaguloathy and its treatment. For years the convention was that trauma-related coagulopathy is a state of disseminated intravascular coagulation (DIC), a notion that blocked the use of systemic hemostatic agents such as fibrinolytic inhibitors , recombinant activated FVII-(rFVIIa), prothrombin concentrates etc. in these patients. Our animal experiments done in collaboration with the Israeli and American Armies were the first to challenge that convention. We have shown in a severe animal trauma model that despite the similarity of coagulation results to those found in DIC, there were no histological findings suggesting DIC even administration of large doses of rFVIIa . Our findings were confirmed, with and without rFVIIa, by numerous experimental trauma models. The new insight, with the improvement in the understanding of the targeted mechanism of action of rFVIIa at the site of injury and the accumulation of experience on safety of this drug in hemophilia patients, led to the introduction of rFVIIa in trauma patients. The first cases of successful use of rFVIIa in trauma patients with "inevitable exsanguinations" reported from Israel, paved the way to a rapid expansion of the research and use of rFVIIa and other hemostatic agents in trauma, which were considered contraindicated in "hypercoagulable states". Several mechanisms contribute to the complex coagulopathy in trauma and it is now clear that abnormalities in the basic coagulation tests (PT, aPTT, Fibrinogen and platelet count) are only the tip of the ice burg of a more complex and potentially devastating process. Following trauma there is an excessive

activation of the coagulation cascade at the sites of injury which causes a accelerate consumption of both coagulation proteins and platelets which in many cases are also rapidly degraded by hyperactive fibrinolytic system (Hyperfibrinolysis). The administration of large volumes of fluids and multiple packed RBC units further dilute coagulation factors and platelets ("Dilutional" coagulopathy). In that respect, the use of colloids, in particular high molecular weight starch, may directly interfere with fibrin polymerization, platelets function and clot strength. Acidosis and hypothermia, which are common in severe trauma patients, markedly impairs thrombin generation, fibrin polymerization and platelet function especially when coexist. The combination of coagulopathy, acidosis and hypothermia has long been recognized as the "lethal tirade" of trauma. Since the presence of coagulopathy correlates with early mortality, an early and aggressive comprehensive "hemostatic resuscitation" addressing its various components, must be adopted. Emphasize should be given to the prevention and treatment of hypothermia and acidosis. A more judicious use of fluid administration is recommended which should be guided by physiological parameters avoiding unnecessary high blood pressure ("permissive" resuscitation") that may cause re-bleeding due to popping out of fragile clots. This approach will also minimize dilution coagulopathy and may cut down the use of colloids. The common practice for blood component therapy, including the threshold hemoglobin for transfusion is currently being revised based on new data and the experience of the American Army in Iraq. It is suggested that component replacement therapy be given early in the resuscitation phase of severe trauma patients , in ratios of at least 1:1 FFP to PRBC (given concomitantly) and some times even higher . Other components as cryoprecipitate (or fibrinogen in Europe) and platelets should also be considered at the same time. Recent unpublished data, suggests that hyperfibrinolysis is a major challenge early in the course of trauma. The results from several controlled trials in various surgical patients, which have shown a significant reduction of blood loss, blood requirements and even mortality with the preventive use of fibrinolytic inhibitors, have convinced the European Expert Panel on the management of bleeding to apply the same approach in bleeding trauma patients. This is true for lysine analogues (tranexamic acid and EACA) but not aprotinin, which recently had been shown to cause serious and even fatal adverse events.

Recent data from animal models of dilutional coagulopathy has shown that administration of high dose of fibrinogen concenrate can normalize clot structure and firmness and decrease bleeding and mortality. Accumulating data from cardiac surgery and obstetrics support the important role of fibrinogen in the control of massive bleeding. Preliminary animal models and clinical data raise

the possibility that the hemostatic concentration of fibrinogen in such cases is much higher than recommended by various guidelines, Current recommended target of 1gr/L is probably sufficient to prevent bleeding in congenital afibrinogenemia patients or control hemorrhage in mild bleedings but it is not sufficient in massive bleeding. The natural level of fibrinogen in women before births, which is about 5gr/L, is hinting on the hemostatic concentration of fibrinogen required to control massive bleeding. This was recently supported by data from post partum hemorrhages and cardiac surgery. Fibrinogen was also effective in restoring clot structure and firmness in a pig model of severe trauma with thrombocytopenia, resulting in a decrease in bleeding and mortality. Interestingly, fibrinogen was even superior to pigs' platelet transfusion, which raise the hope that fibrinogen may replace platelets in bleeding thrombocytopenic patients. Further studies are required to prove this assumption.

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Since our first description in 1999 of the use of rFVIIa in trauma patient a growing body of evidence suggests that the drug is a safe and effective as an adjunct treatment for massive bleeding in trauma and surgery. Indeed, most recent guidelines for the treatment of massive bleeding (American Association of Anesthesiology, the European Expert Panel and the British recommendations) support its use these patients despite the limited data from controlled trials. The use of rFVIIa should probably be considered early in the course of trauma and before the deterioration of the patients into an irreversible state.

It has been shown that "last ditch" use of rFVIIa in trauma and surgery successfully controlled the bleeding in most cases but did not prevent mortality. It is important to understand that rFVIIa needs certain preconditions for its effect such as a certain level of platelets, fibrinogen and other coagulation factors .We demonstrated in animal model of trauma and also in trauma patients that rFVIIa can bypass the coagulopathic effect of hypothermia but not acidosis. The correction of acidosis (at least above 7.2 but preferably higher) restores the response to rFVIIa . The preconditions for rFVIIa administration are summarized in the Israeli guidelines published 2005 in JTH..

Finely, since coagulopathy is an important component in the survival of trauma patients and since most of the hemorrhagic mortality occurs very early, even before the admission to the hospital, it seems rational to start the hemostatic resuscitation in the pre-hospital settings. Results from animal model of sever liver laceration in the pre-hospital setting suggest that the use of rFVIIa alone or in conjunction with hypotensive resuscitation can prolong the survival from minutes to hours. In a different fatal model of aortic laceration only the combination of the two – rFVIIa and hypotensive resuscitation – could cause

prolongation of survival up to several hours. These encouraging data raise the hope that early pre-hospital hemostatic treatment may prolong the golden hour to few hours and allow for more trauma victims to be admitted to the hospital. New protocols of combined pre-hospital hemostatic treatment are currently under evaluation by few armies. Emergency hemostatic packs containing chitosan hemostatic bandage (Hemcon® USA), bicarbonate, tranexamic acid, fibrinogen concentrate and rFVIIa are provided to IDF special operating forces of during certain missions.

Most of the recommendations for the treatment of massive bleeding in trauma are based on extrapolation from controlled clinical trials in surgical patients, limited controlled clinical trials and case series/ reports in trauma. Since controlled trials in trauma are problematic, difficult and almost impossible to perform in the pre-hospital (and especially combat) settings, good animal studies that mimic the prehospital phase are of great importance.

The Netherlands military blood supply system. Features and experiences in the Afghan theater.

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Commander (MC), Royal Netherlands Navy
CO and Medical Director of the Netherlands Military Blood Bank

Even in the twenty-first century the major cause of death on the battlefield still is massive blood loss because of trauma. With an increasing involvement in the past two decades of the Netherlands armed forces in worldwide armed conflicts, it became very clear that having blood products available in theater at all times was of absolutely vital importance.

Shelflives of blood components under normal conditions are extremely limited. Furthermore, we have to deal with long, vulnerable supply lines and unpredictable points in time where these products are needed. Therefore, the Netherlands military blood supply was build around a system of frozen blood components of universal donor red cells, plasma and platelets.

A -80ºC frozen inventory of the most essential blood components readily available after thawing (and washing if required), enables us to safely reduce shipments and abandon the backup “walking blood bank”, without compromising the availability of blood products in theater. Moreover, all thawed (washed) blood products are in compliance with international regulations and guidelines.

Since August 2006, when the Netherlands started to participate in the ISAF / OEF mission in Afghanistan, more than 400 patients have been transfused with some 2500 units of frozen blood components, without any untoward effects.

Earthquake and blood supply – A challenge

Vered Yahalom MD
Magen David Adom, National Blood Services, Israel

An earthquake is a natural disaster that turn into a demanding event for the local blood banks and Blood Centers, according to its location and consequences.
Estimating the risks, evaluating the gaps, establishing a contingency plan and performing simulation of such an event will increase the preparedness of national blood services and hospital blood banks for an unexpected chaotic event that can not be predicted (yet) nor prevented. Preparations for such an event need to address many logistic issues as well as medical and psychological aspects including:

1. Knowledge of the vulnerable areas in each country
2. Modes of construction
3. Density and type of population
4. Infrastructure of the Blood Center & hospitals
    a. Need for reinforcement of non constructive elements
    b. Power supply
    c. Water supply
    d. Testing equipment
    e. IT & Back up systems
5. Alternative communication plans
    a. Blood Centers & Hospitals
    b. Different blood center sites
    c. Employees
    d. Donors
    e. Volunteers in the country & abroad
    f. Government & other organizations in the country & abroad
    g. Media
6. Alternative transportation plans
7. Evacuation plans & alternative site for blood services/ hospital blood banks including plans, establishing of SOP's, training and the need for increased personnel.
8. Donor issues:
    a. Need for increased donations
    b. Need for selective blood types donations
    c. No need for increased donations
9. Blood Supply
    a. Amount of blood /patient
    b. Components required
    c. Alternative blood suppliers
10. Supplies
    a. Supplies for blood donations (Blood bags, Hgb cue vets etc.)
    b. Testing Reagents & other laboratory supplies
    c. Food & water workers
11. Shelter & Psychological support
    a. Workers & Volunteers
    b. Workers & Volunteers Families
    c. Donors

Field-oriented rapid diagnostics for early diagnosis of HIV infection

Baruch Rivetz, PhD
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Despite decades of aggressive prevention efforts and advances in effective treatment, HIV infection and AIDS as a sequential outcome remains a worldwide pandemic. Primary (acute) HIV infection can display as a common febrile illness with nonspecific symptoms, hence, it may lead to inadequate and misdiagnosis. Patients are typically highly infectious during the early stages of the acute phase due to enormous viral burden in blood and genital secretions. An estimated one-quarter to half of those infected patients are unaware to their status and put others at risk. These estimates are even higher in poor-resource areas with no central labs. Traditional HIV screening that is mostly aimed at detecting later stages of infection frequently fails to detect these highly infectious individuals. Therefore, establishing the diagnosis of primary HIV infection is clearly of public health importance and it is essential to enable opportunities to halt further transmission and obtain therapy that improves morbidity and mortality for infected patients.

Orgenics LTD, currently a professional diagnostics division of Inverness Medical Innovations, Inc., has 25 years of experience in the development of rapid *in vitro* diagnostics for infectious diseases. Along the years, Orgenics developed various serological assays for HIV infection on rapid diagnostic platforms aimed at low-equipped or non-laboratory settings and point-of-care testing. Recently, addressing the limitations of the existing rapid tests in detecting early infection, on one hand, and limitations of the HIV 4th-generation machine-dependent assays, on the other, Orgenics developed two rapid 4th generation test devices, which simultaneously detect antibodies and antigen and differentiate between them. One test, ImmunoComb HIV 1&2 TriSpot Ag/Ab, distinguishes between HIV-1 and HIV-2 antibodies and HIV p24 antigen. This test kit accommodates up to 36 samples, does not require additional instrumentation and therefore is deployable in multiple settings, from centralized laboratories and blood banks to remote point-of-care test locations. The second test device, Determine® HIV-1/2 Ag/Ab Combo, is an individual 4th generation HIV lateral flow assay that provides clear visual results in twenty minutes. The performance of both assays, demonstrated in an extended series of clinical trials, showed the capability of detecting HIV infection earlier than HIV antibody-only tests do and of identifying those who are acutely infected with HIV. This is achieved by detecting separately the presence of viral p24 antigen before the appearance of antibodies to the virus, a feature that most of the current 4th- generation assays fail to deliver since they provide a single combined undifferentiated signal. Moreover, the sequential use of these tests, the Determine® HIV-1/2 Ag/Ab Combo as an initial screening test and ImmunoComb HIV 1&2 TriSpot Ag/Ab as a confirmatory test, can provide a field-oriented and economical alternative laboratory based tests.

Frozen and freeze dried blood in disasters

Arav Amir, Core Dynamics, Israel

RBC units are routinely transfused as a life saving treatment for multiple clinical indications ranging from the treatment of acute bleeding during surgery or trauma, to the treatment of chronic anemia and different forms of cancer. Today, most RBC units are preserved in liquid state for a maximum duration of 42 days, depending on the additive solution used. Less than 1% of the collected blood is frozen for long term storage. The cumbersome process required for adding glycerol to a unit and the necessity to wash it upon thawing due to its toxicity is a time consuming, cumbersome and expensive process. As a result of the long washing process frozen thawed RBCs units cannot be used in acute scenarios such as a battle field or disaster areas. In addition, transportation of frozen units is expensive and introduces logistic challenges.

Core Dynamics (CD) goal is to develop a frozen and a freeze dried RBC unit which is safe, easily transportable, and ready for use upon rehydration.

CD has developed a novel freezing device (aka MTG), which is based on the principles of directional freezing. The MTG allows for improved control over ice crystals morphology during the freezing process. This freezing device enables successful freezing in the absence of cryoprotectant agents (CPAs) such as glycerol, DMSO, ethylene glycol and others.

Overcoming this issue has created a new opportunity for freezing RBCs without glycerol and hopefully enabling the freeze drying of RBCs. In addition, we have developed a dry thawing device (DTD) which enables the thawing of 500ml samples within 2 minutes. A proprietary freezing solution based on saline supplemented with a sugar and an antioxidant, both non-toxic ingredients as been shown by early pre-clinical studies, has been developed as well.

Experiments performed with RBCs units showed 100% recovery of the cells with less then 3% hemolysis after freeze thawing in the absence of CPAs using CD freezing and thawing devices. Furthermore, Autologous transfusions of fluorescent labeled 0.5L samples performed on donkeys that were labeled with a fluorescent marker showed an in vivo recovery of 80% of the thawed RBCs 24 hours post transfusion and that the cells have maintained in the animals circulation for 3 months, equivalent to non frozen labels units.

Initial experiments performed on freeze drying small volumes of RBCs samples showed ATP and 2,3 DPG values similar to fresh samples but RBCs that were stored in hypothermia with CPDA-1 solution showed reduced ATP and 2,3 DPG values.

RBCs that were frozen and freeze dried had maintained their typing upon thawing or rehydration.

USE OF BLOOD AND BLOOD COMPONENTS IN OUT-OF-HOSPITAL MEDICAL EMERGENCIES

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ABSTRACT

SAMUR-PC is an out-of-hospital Emergency Medical Service in Madrid that deal with the medical response in emergency situations in the streets and public facilities inside the metropolitan area. This include the medical response to mass casualty incidents with seriously injured victims involved.
SAMUR-PC attended to over 120.000 emergencies in 2007. In the last 5 years, 2095 victims of major trauma (ISS>15) has been assisted.
In recent years, there has been a research effort in the knowledge of the physiopathology and treatment of hipovolemic shock. However, the basics of the treatment of these patients have changed little over the last years. They are still the control of external blood loss, to correct hypovolemia and restore tissue perfusion.
SAMUR-PC is considering the possibility of implementing the use of blood and blood components in the management of patients with major trauma.
The study makes a review of the bibliography supporting the idea and lists the technical, logistical and legal drawbacks to face.

Key Words: Shock, Resuscitation, Blood components

Management of a National Blood Inventory in Peace and Disasters - The Israeli Experience

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Blood services worldwide must be prepared to meet surges in demand for blood components, needed by casualties of domestic disasters and acts of terrorism. Israel's national blood service, operated by Magen David Adom (MDA), has extensive experience managing blood collections and supply in emergencies. This review summarizes the structure and function of MDA's national blood program, and relates its' experience to other practices that have been reported in the medical literature.

Between 2000-2005, 7497 victims (85% civilians) were involved in 1645 terrorist attacks in Israel. On-site triage resulted in 967 (13%) who died at the scene, 615 (8.2%) that had severe injuries, 897 (12%) were moderate and 5018 (67%) mild. Requests for blood averaged 1.3 blood units and 0.9 components/casualty, or 6.7 units and 4.5 components/ severe and moderately injured. Public appeals for blood donations were managed centrally, to match supply with demand and prevent wastage.

This experience illustrates the advantages of a comprehensive program for managing blood operations in emergency situations. A coordinated national program can stabilize in-hospital inventories during routine activities, ensure instant access to precisely defined inventories, facilitate sufficient supply in times of disasters, and minimize outdating and wastage.

Rapid Blood Grouping Using Lateral Flow Device with Stable End-Point without Centrifugation

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Blood grouping, especially AB0 and RhD determination, is critical for the blood transfusion compatibility.

Correct AB0 type of the donor and recipient blood prevents acute intravascular post-transfusion hemolytic reaction which could have potential of fatal outcome in case of incompatible transfusion.

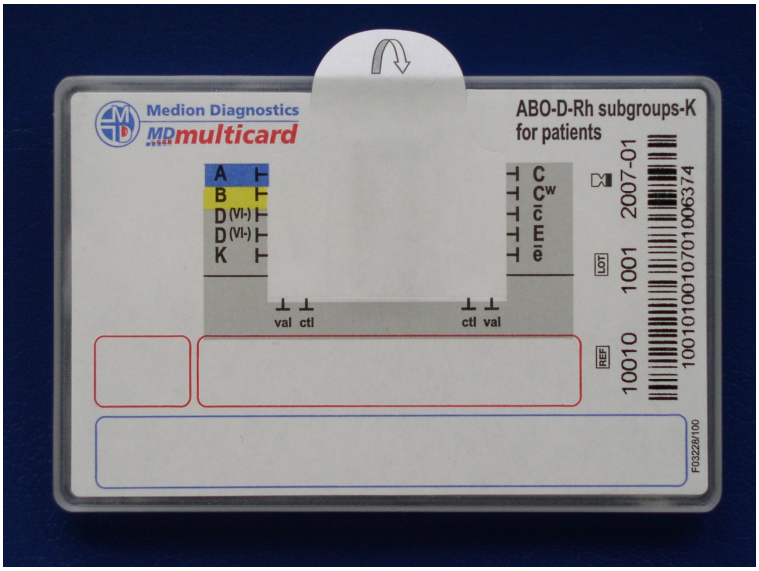
Matching for RhD /the most immunogenic antigen of red blod cell/ and eventually for other clinically important antigens /other Rh, Kell/ could prevent or reduce delayed post-transfusion hemolytic reaction /extravascular/.

Transfusion service centres and hospital blood banks are now performing the blood grouping on semi- or fully automated instruments, based on different principles /agglutination with centrifugation is the most common, others are agglutination by sedimentation, agglutination with magnetisation of red cells, column (gel) test and solid phase test/. All these test are highly accurate but dependent on complicated instrumentation, precise organisation of sampling and identifying samples and computer and electricity supply. Most of above mentioned tests are also available in manual versions, but these are also dependent on availability of electricity power at least.

On the other hand a simple alternative is long time available: slide test using mixing drops of blood and reagents on glass, ceramic or plastic surface. But this test has many disadvantages /infectious risks, possible cross-contamination, dots drying, missing of weak reactions, difficult reaction identification and result documentation/.

A new rapid method has been recently developed: lateral flow assay providing a stable end-point results without centrifugation within minutes. Currently the „MD Multicard“ for simultaneous AB0, RhD, Rh subgroups and Kell determination is available. This „credit card“ size format device contains potent and highly sensitive monoclonal antibodies /CE certified/. The typing procedure is very simple. Only blood sample and one diluent solution is needed. In first step the blood diluted in specific solution is added to application zone of the card followed by addition of the same solution after 30 seconds. Distinct results are visible during few /cca 2/ minutes and remain stable for very long time /depending on storage conditions – in 2-8°C for several months/.

This new test is highly sensitive and specific. Several evaluation studies were performed in blood transfusion centres including our institute. The test is sufficiently rapid and robust and thus suitable for emergency diagnostics and for work in conditions when electricity supply is limited.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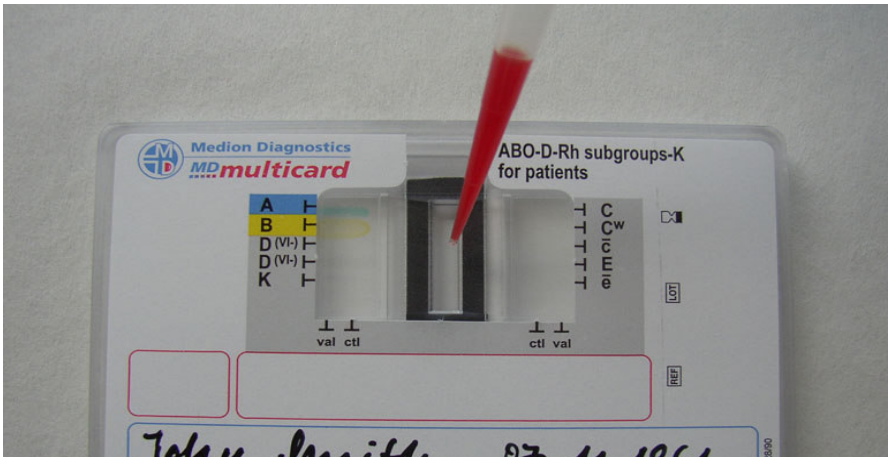
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1. Remove protective label.

2. To the application zone: add 2 drops (100 µl) of a suspension of Diluent F and:
   - anticoagulated whole blood
   - native blood
   - erythrocyte sediment.

After 30 s: Add 6 drops (300 µl) of Diluent F 3. to the application zone.

After 5 min: Read and record results4.

TEG – MONITORING & TREATING BLEEDING PATIENTS

Naomi Rahimi-Levene MD, MHA
Director of the Blood Bank, Assaf Harofeh Medical Center, Zerifin, Israel

The hospital Blood Bank is a transfusion service, providing blood in every day life, but also in extreme situations. Disasters are unexpected, their extent is unpredictable and therefore one must prepare in advance for the worst scenario. In a catastrophic event many massively bleeding patients will have to be treated simultaneously, sharing available resources. Conventional blood tests will not provide a swift enough answer to guide decision making as they can be lengthy and do not necessarily represent the in vivo picture.
Thromboelastograph (TEG) is a technology demonstrating clot formation and strength. Historically TEG has been used for monitoring open heart surgery and liver transplants. In our hospital TEG is performed in the blood bank and can be viewed online in remote sites (including the operating theater). The anesthetists have been tutored in interpreting the TEG and in a short time the need for FFP, cryoprecipitate (fibrinogen) and platelet concentrates can be assessed, allowing prompt on time decision making. In an event in which communication online is cutoff the TEG can be transferred and setup in the operating theater, allowing decision making on the spot. The test can be repeated until the patient is stabilized and has received proper replacement therapy.

THE ACTUAL PRACTICE OF BLOOD CRISIS POLICY IN THE CZECH REPUBLIC

Lt.Col. Milos BOHONEK, MD, PhD, Central Military Hospital Prague, CZ

In the Czech Republic, which has over 10.000.000 inhabitants, there are collected and transfused about 450.000 RBC units / year. The blood collection and processing are performed on relative close system of 65 blood centres, with 2.500 – 30.000 collections of whole blood units annually.

Based on the Resolution of the Czech Republic National Security Council (Res. No 19 from April 15th. 2008) was the Ministry of Health and Ministry of Defence entrusted with the enforcement of "The Crisis Setup of Health System" - the Method of blood crisis policy. The aim is to guarantee sufficient as well as efficient supply of blood products and blood derivates in any place of the country during any crisis situation, such as mass accident, disaster, terrorist attack or war. The responsible government institute, the Ministry of Health, cooperates with the Ministry of Defence.

The system ensures 7 state "blood crisis centres" (BCC), 1 military and 6 civilian. The central role has military blood transfusion centre in the Central Military Hospital Prague, which is called "Central informative and logistic centre" (CILC). Each of 7 BCCs is responsible for supplying defined territory. BCC must have own system of contracts with local blood banks. The important part of the system is transport of blood components during the crisis situations. BCCs are responsible for transport, in case of troubles BCCs can ask the Ministry of Health for help with the transport coordination. The BCCs have duty to keep at least 200 RBCs and 200 plasma units and 2000 g of human albumin at disposal for national crisis policy program. CILC collects actual information from each BCC about available blood a plasma units. This information is updated daily in the morning. In addition, BCCs must have the emergency stocks for blood collection (blood bags, tubes) and blood testing: 2000 – 2500 sets, depending on BCC territory.

The important role in this system plays the blood bank with frozen blood in Central Military Hospital Prague, which is designed for 3000 units of frozen RBCs group 0. The closed system Haemonetics APC-215 is used, RBCs are stored in -65°C in mechanical freezers and shelf life after reconstitution in solution AS-3 (Nutricel) is evaluated to 21 days.

The crisis level could be proclaimed by central or local health care authority or by the government. Depending on crisis level the BCC solves it together with CILC on its own level or in cooperation with the Ministry of Health. Any crisis status is coordinated by CILC.

The Method is training periodically; the major accent is put on the communication.

The first experience with the real functionality of the Method we made in the September 2008 with the humanitarian supply of RBCs and FFP to Georgia.