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National whole Blood Supply to Prehospital Setting- The Decision Making Process

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MDA in Israel

- Civil, statutory*, non-for profit organization
- 1915-1922: Looked after Jewish prisoners of WWI
- 1930: Founded by volunteers as "Rapid 1st Aid Society" in 1930 in Tel-Aviv
- 1950: *MDA law, The Israeli Knesset
- 2006: Full member of the IFRC/RC

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MDA Law,1950: The objectives of the Organization

To Operate the national blood services

To Provide pre hospital EMS for the population

National organization responsible for the disasters preparedness

National Society & auxiliary arm to the IDF, as part of the civil protection program

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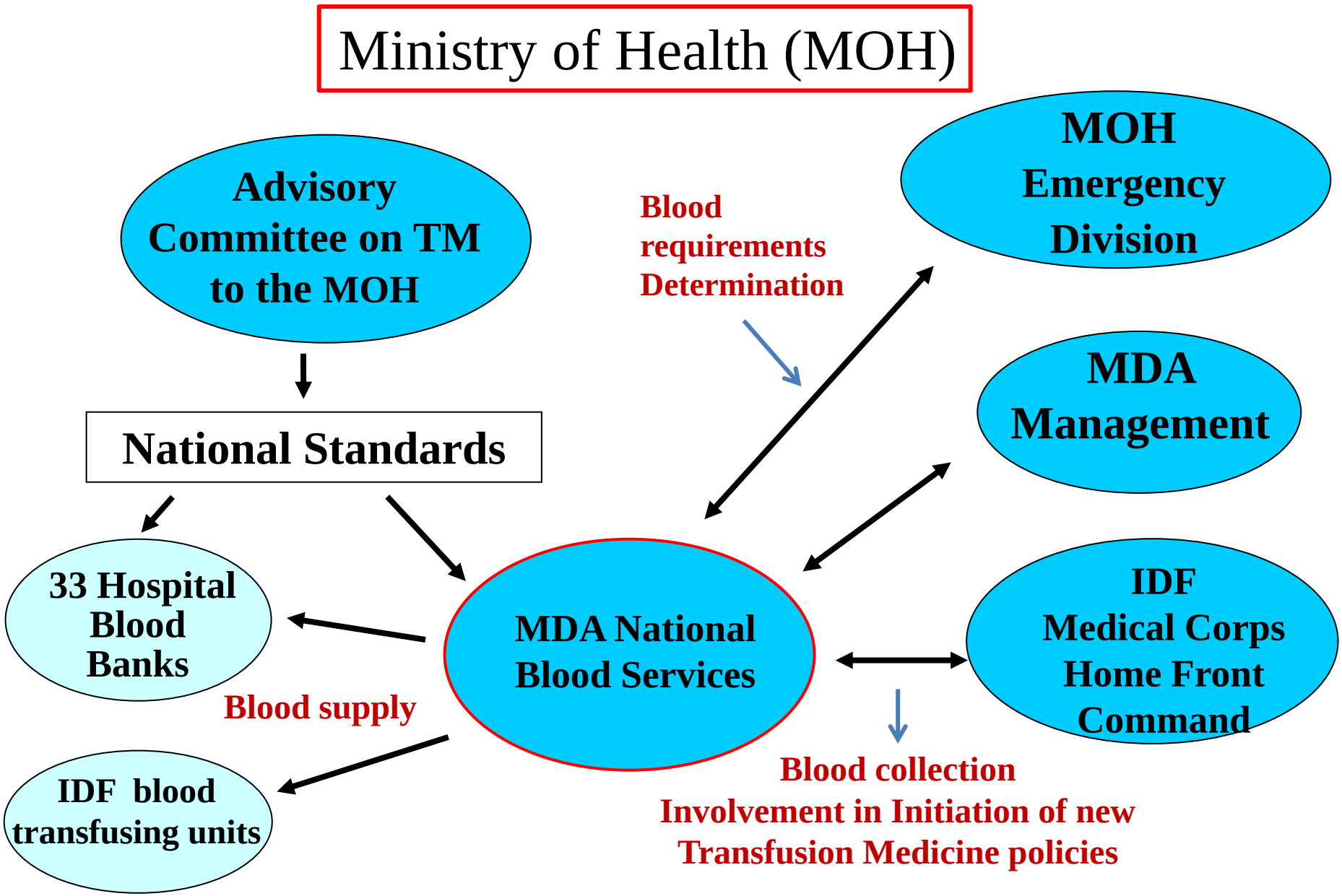
The Israeli National Blood Program



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Advisory Committee on Transfusion Medicine (TM) to the MOH

- Chairperson: Professor Emeritus (Director of 3rd level medical and trauma center blood bank)
- 3 Blood Bank Directors of hospitals with > 700 beds
- 3 Blood Bank Directors of hospitals with < 700 beds
- 3 Blood Bank Directors of hospitals with < 500 beds
- Represent of the MOH
- The Director of the National MDA Blood Services

- Most members are MD; 2 are PhD (Laboratory Directors)

Responsibilities of the Advisory Committee on TM to the MOH

- Write the National Standards for the operation of all Hospital Blood Banks, MDA blood services and the blood giving units in the IDF
- Update the Standards, Ad hoc (i.e Donor Acceptance criteria &/ or testing - ZIKA)
- Advocacy for new technologies (i.e PI/PR)
- Use of new therapy modalities (TXA, WB vs Components in the military or civilian pre-hospital setting and in the Trauma bays)

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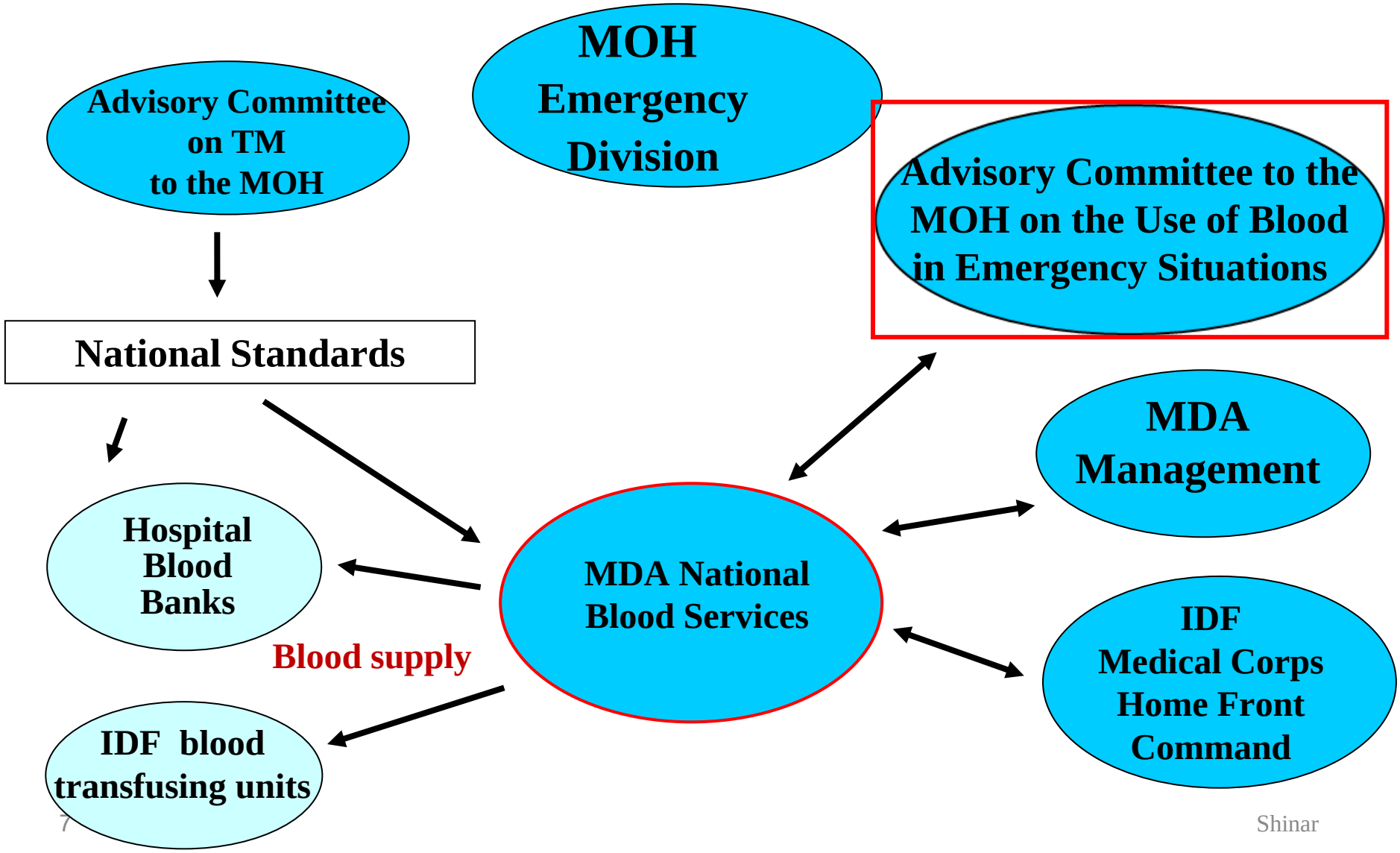
The Israeli National Blood Program in National Emergency Situations



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Advisory Committee to the MOH on the Use of Blood in Emergency Situations

- Chairperson: Director of the National MDA Blood Services
- Members of the Advisory Committee on TM
- Representatives from the IDF
  - Medical Corps
  - Home Front Command
- Representative of the HMO (Health Medical Insurance Organization)

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Responsibilities of the Advisory Committee to the MOH on the Use of Blood in Emergency

- Blood collections forum: 48h program- where and were not!
- Components' preparation: what, how many
- Testing: what, how to operate if needed to be changes from routine (repeat donors only?)
- Distribution: According to hospitals occupancy and severity of injuries
- Importing blood from other countries?

The procedures in the IDF: The Trauma Branch in the Medical Corps

- Identification of the need
- Review of the literature, research and consultation of the practices in national/international other military forces
- Approval of the IDF Surgeon General
- Submission to the Advisory Committee to the MOH, or to members (☺)
- Approval/Support by the Advisory Committee
- Writing Clinical Practice Guidelines (CPG)
- Purchase and Implementation
- Follow up of outcome, side effects

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Israel blood program

Area: 20,770 Square Km

Population: 8.9 M +3.5 M tourists/y

Total blood donations collected nationwide in 2017: 270,324 units (3.0%)

Of them, collected by MDA: 254,507 whole blood units

Blood components in hospitals (SDP):15,817

<u>MDA responsibilities:</u>

Collection of 1000 units/day

Preparation of blood components in 2 laboratories:

Tel Hashomer: 80% of production

Haifa: 20% of production

MDA 1 testing laboratory (Tel Hashomer)

Daily supply of blood to all hospitals and IDF

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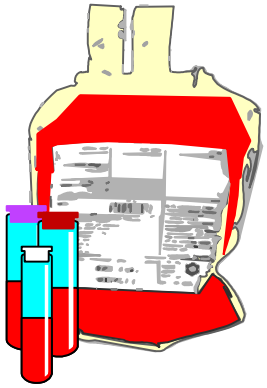
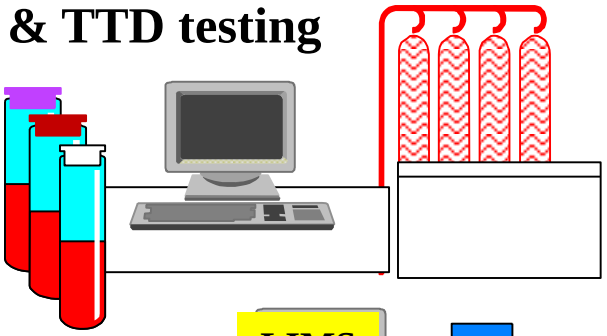
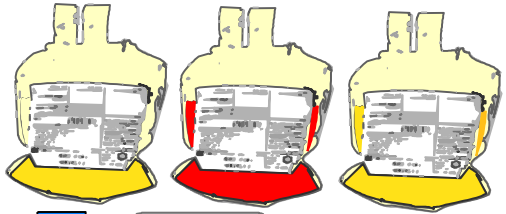
Donor Questionnaire
Discrete interview



Blood typing & TTD testing



Component preparation

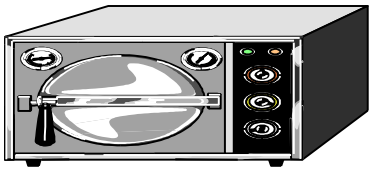


LIMS

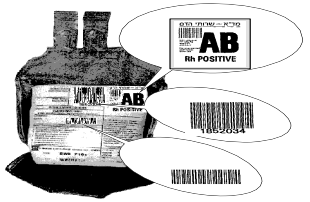
Progesa (MAK)

LIMS

Not for Transfusion



O.K.



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Aavailable Blood Components

Red Cells

- Homologous/ Autologous
- Packed Red Cells ± additive
- Frozen- thawed, “washed”
- Irradiated
- CMV negative
- Antigen Negative
- Sickle negative

Platelets

- Random/ Leukoreduced Platelet

Cryoprecipitate

Plasma

- FFP
- CDP
- ~~S/D treated plasma~~
- FDP

Pheresis Technology

- Single Donor Platelets (CMV, Platelets Ags. negative)
- Double Donor Platelets
- Plasma: AB, B
- Plasma: IgA def.

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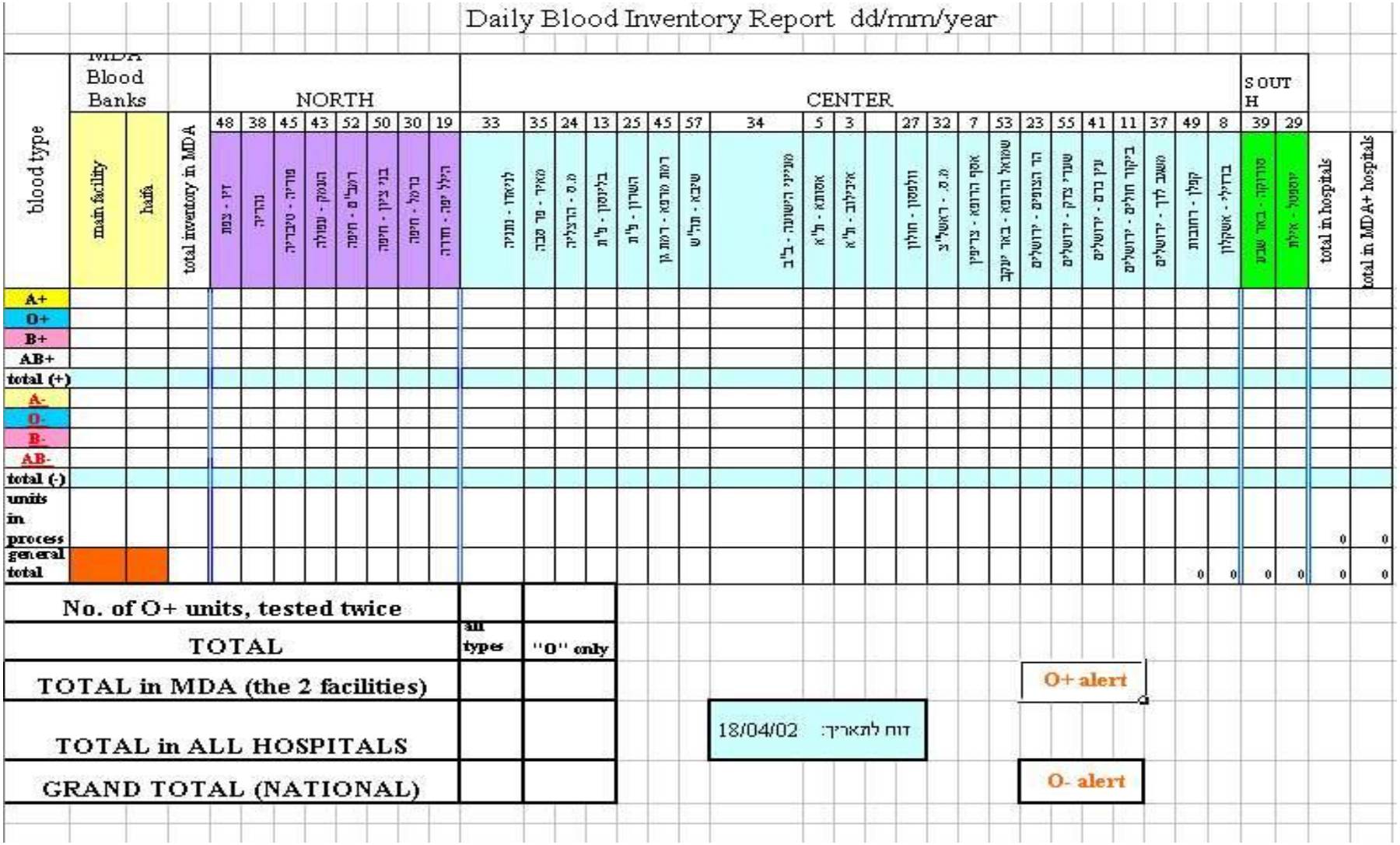
National Blood Inventory Monitoring



Daily Blood Inventory Report dd/mm/year

blood type	MDA Blood Banks			NORTH								CENTER																		SOUTH			
	main facility	haifa	total inventory in MDA	48 זיו - צפת	38 נהריה	45 פוריה - טבריה	43 העמק - עפולה	52 רמב"ם - חיפה	50 בני ציון - חיפה	30 כרמל - חיפה	19 הילל יפה - חדרה	33 לניאדו - נתניה	35 מאיר - פר סבה	24 מ.ס. - הרצליה	13 בלינסון - פ"ת	25 השרון - פ"ת	45 רמת מרפא - רמת גן	57 שיבא - תל"ש	34 סוראסקי הישענה - ב"ב	5 אסותא - ת"א	3 איכילוב - ת"א		27 וולפסון - חולון	32 מ.ס. - ראשל"צ	7 אסף הרופא - צריפין	53 שניאור הרופא - באר יעקב	23 הר הצופים - ירושלים	55 שערי צדק - ירושלים	41 עין כרם - ירושלים	11 ביקור חולים - ירושלים	37 משאב לב - ירושלים	49 קפלן - רחובות	8 ברזילי - אשקלון	39 סורוקה - באר שבע	29 יסמטל - אילת	total in hospitals	total in MDA+ hospitals
A+																																			
O+																																			
B+																																			
AB+																																			
total (+)																																			
A-																																			
O-																																			
B-																																			
AB-																																			
total (-)																																			
units in process																																		0	0
general total																																0	0	0	0	0	0

No. of O+ units, tested twice		
TOTAL	all types	"O" only
TOTAL in MDA (the 2 facilities)		
TOTAL in ALL HOSPITALS		
GRAND TOTAL (NATIONAL)		

O+ alert

דוח לתאריך: 18/04/02

O- alert

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Some examples of the procedures for the introduction of new technologies into the national blood supply and usage

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Subject	Decision or current practice
Universal leukodepletion	*ACTM-No, only by indications
Pathogen Reduction/Inactivation	ACTM-Yes; **MOH-No
WNV ID-NAT testing	ACTM-Yes; MOH-Yes
➢ Changing the Massive Transfusion Protocols (MTP)-	ACTM-Yes; MOH-Yes
➢ Introduction of FDP	Not requested by the IDF Yes-in the civilian EMS (National Trauma Council)
➢ LTOWB in the pre hospital setting	ACTM-Yes;

*ACTM=**A**dvisory **C**ommittee to the MOH on **T**ransfusion **M**edicine

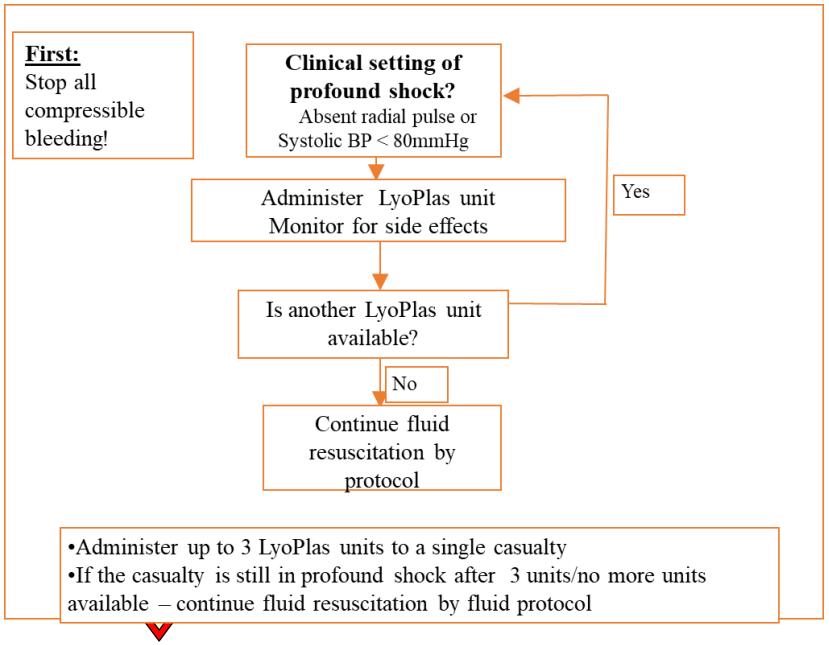
MOH=M**inistry **O**f **H**ealth

Process 1: Changing the Massive Transfusion Protocols (MTP)- 2008

- 2008: A multi-disciplinary paper was prepared by an Ad hoc committee of trauma experts, surgeons, anaesthesiologists and transfusion medicine experts. requesting to change the MTP used in the hospitals, at that time, which was based on transfusion of crystalloids first to the severely bleeding patient, followed by blood components much later.
- Based on this paper and other professional literature the MTP was presented and approved by the TM Advisory Committee, changed to 1:1:1 plus the use of TXA, and implemented in all the hospitals nationwide.

Process 2: Introduction of FDP

- 11.2012: Initiation by the Trauma Branch of the Medical Corps in the IDF, to use FDP in the battel field by a senior care tacker
- 2013: As FDP is a pharmacological agent (drug) and not a blood component, it was directly purchased by the Medical Corps as such from the German RC and introduced into the service
- Implementation:



Chen 2018
Shinar 2018

Process 2: Introduction of FDP(2)

- 204 patients received 252 FDP units, (42% to injured Syrian), 96% were uneventful*
- FDP units were transfused in the POI
- 4% of the injured also required PRBC transfused during air- wing evacuation
- Following the IDF experience MDA EMS introduced FDP in the MICUs in 2016, if ground evacuation time is expected to be longer than 20-30 minutes. This was approved by the National Trauma Council. So far 20 DFP units were transfused by the MDA EMS

* 109 reported by Shlaifer et al, J Trauma Acute Care Surg, 2017

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MDA Blood Services

Glassberg 2017
Shinar 2018

Process 3: WB

- 11.2013- Initiation by the Trauma Branch of the Medical Corps in the IDF, to use FDP in the battel field by a senior care tacker
- Submission the request to the Advisory Committee to the MOH to include WB in the MTP
- 👎 Unanimous refusal to the suggested change by us- conservative Blood Bankers, because the pre- hospital option includes PRBC O+ and FDP, and the in- hospital MTP includes provision of components:
  - platelets that had to be kept, shaking, at 22±2°c
  - thawed FFP and cryoprecipitate.
- Of course conditions that can not be met in the pre-hospital settings.

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Process 3: WB

However,

- Reports and publications based on the military experience in Iraq and Afghanistan, introducing the concept that bleeding patients should get what they lose = WB, as early as possible in the resuscitation, because it efficiently provides treatment for shock and coagulopathy.
- The scientific work done by Pidcoke et al (2013)* showing that refrigerated PLTs contained in WB units are compatible, if not a better, haemostatic product was a very reassuring finding .
- In addition WB is logistically easier- to- use product in the pre-hospital settings.
- 2017: ACTM decided to re-consider and approve usage of LTOWB in pre hospital settings

*Pidcoke et al, Transfusion 2013;53:137S-149S

Process 3: WB

Reminder:

- In the military pre-hospital settings in Israel lyophilized AB plasma and PRBC group O are available and transfused during transportation before the ABO group of the patients is known
- But unlike group O uncrossmatched PRBC, group O WB contains a substantial amount of plasma, containing Anti A and Anti B (IgM) which are incompatible with the RBCs of non–group O recipients
- As we did not find unanimous international standards for the titer, or for an automated testing method, we decided:
  - To define our own "low titer" and establish a validated method to perform the titration on automated equipment
  - To create a LTOWB donors database, and to regularly provide LTOWB units to the pre-hospital system in Israel

Process 3: WB

Study Questions:

- Can automated equipment be used to titer the O WB units?
- What titer should be used on the automated equipment to achieve the equivalent of <1:50 as determined by manual saline tube method (Reference Method)?
- Can commercial and /or in-house produced RBCs be used?
- Should the tests be performed with A1 and B, A2B or A1B RBCs?

PK 7300 in MDA blood Services Automated Blood Typing Laboratory

Process 3: WB
Study: Determination of the titer on the automated equipment

A total of 1,160 blood donors' samples were tested, under different conditions:

- The critical titer of anti-A and B for LTOWB was chosen as the equivalent of 1:50 determined by manual saline tube method with 5' RT incubation (Reference Method).
- The PK7300 instrument was programmed to dilute and test plasma from 660 donors: 20 samples for each of the following titers:1:32, 1:25 and 1:20
- 300 additional samples were tested for each 1:18 and 1:16 dilutions.
- Sample were incubated on the PK7300 at 25ºC for 1 hour with commercial and in-house reagents of A1B donors' RBC.

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Process 3: WB Conclusions

- About **15%** of O donors' samples diluted 1:18 on the PK7300 and 1:50 by the reference method did not agglutinate with A_1B RBC, therefore considered **LTOWB donors**.
- A_1B in-house produced RBC were more sensitive than commercial mix of A_1 and B cells, permitting its use in situations when commercial reagent may not be available.
- Using automated blood typing methods enables medium and large size blood establishments to perform the titration as part of their routine blood typing and to establish a LTOWB donor data base.
- This facilitates maintaining a consistent inventory and supply of LTOWB for the use in military or civilian pre or in-hospital settings, including rural areas.

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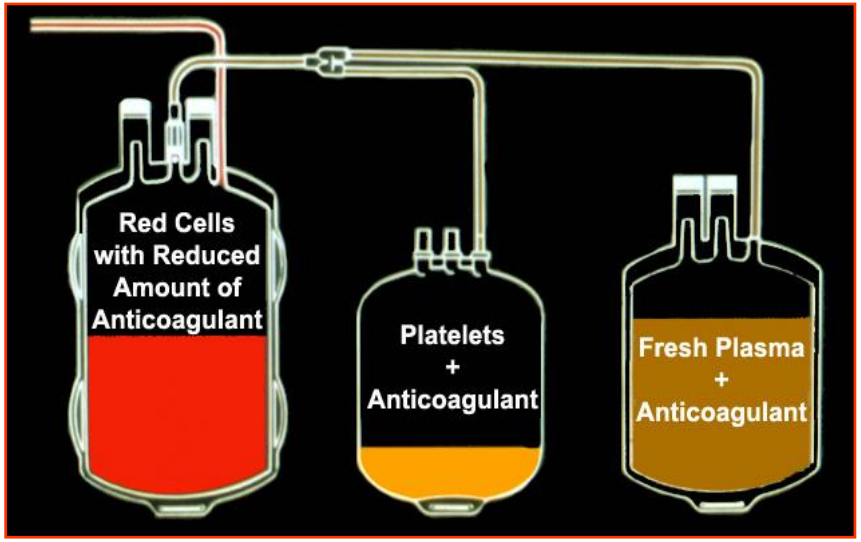
Implementations: Blood Donors & Drives

Mobile drives	93%
Donor rooms in MDA EMS stations	7%
240,000 volunteer blood donors/y	
Age 17-40y	75%
Male	71%
Israeli Born	78%
1st Time Donors	19%
Civilians	75%
Units collected in the IDF (2 drives /year in each unit)	26%

Implementation: O.N Hold of Blood components production



component	volume (ml)	Storage temp.	expiration
RBC	250	1-6 ºc	35-42 days
plasma	200	< 20 ºc	12 months
platelets	50	22-24 ºc	5 days
cryoprecipitate	30	< 20 ºc	12 months

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Tests for blood donations

1987-2017:7.27M units

1. **Blood typing:**

   ABO, Rh (PK 7300, Beckman-Coulter)

   2nd run at 1:18 to find LTOWB O+ donors

   RBC Antibody Screening (Innova, Ortho)

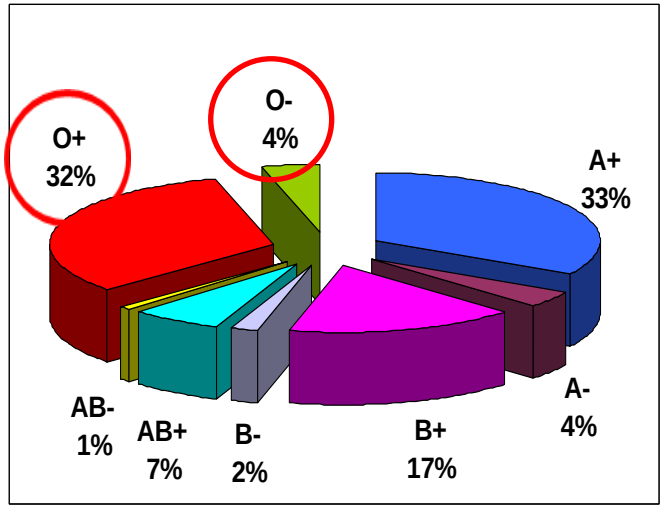
2. **Transfusion transmitted diseases:**

   HBV, HCV, HIV and HTLV (Chlia, Prism, Abbott)

   HBV, HCV, HIV (ID-NAT, Panther,Grifols)

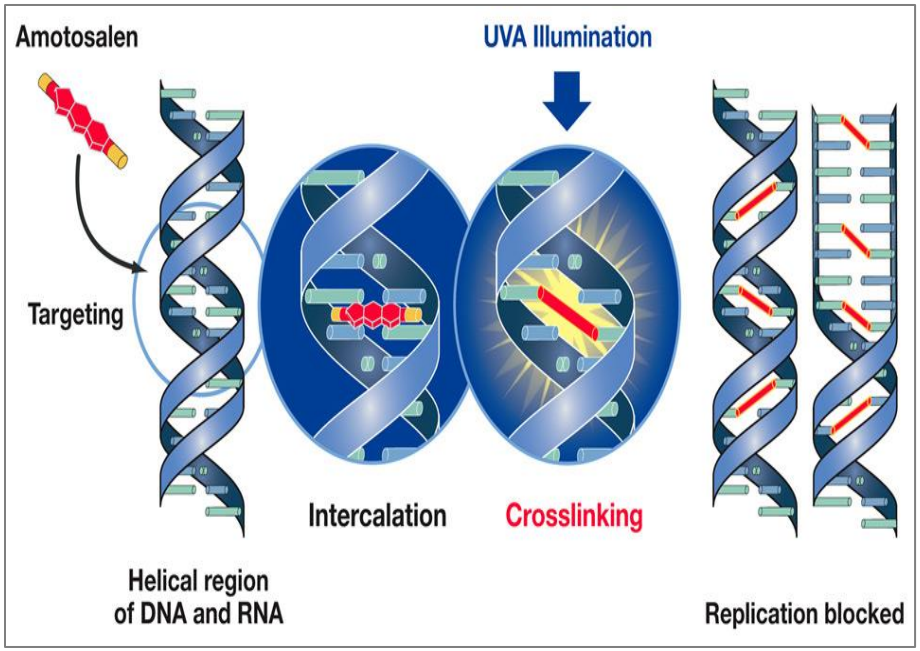
   Syphilis (Hemmaglutination, PK 7300, BC)

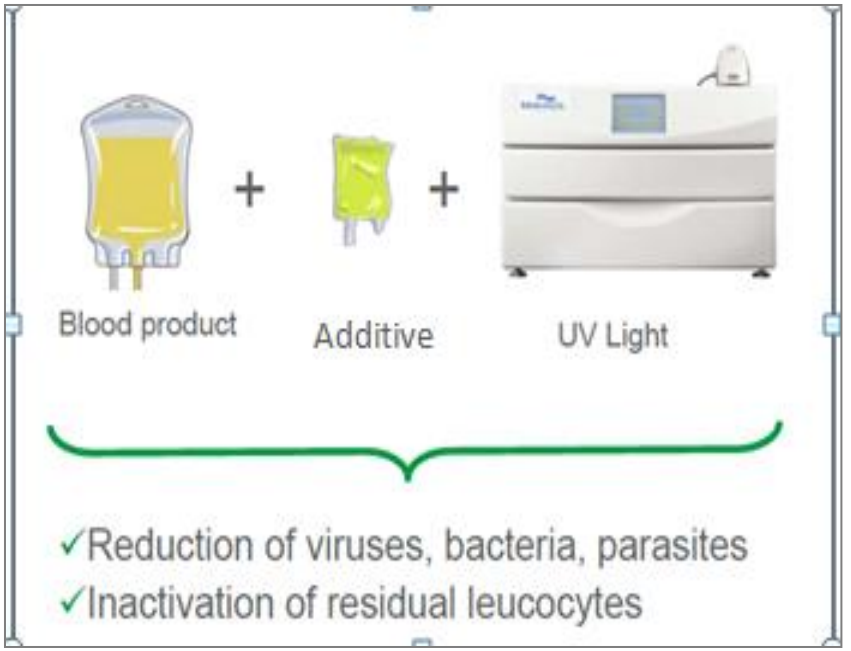
   CMV (Architect, Abbott)



Agent	Year	%
HBV	1970	0.18
HCV	1990	0.05
HIV	1986	0.002
HTLV	1995	0.002
Syphilis	1970	0.02
ID-NAT	2008	0.004
WNV-NAT	2017	0.003

New Technology: Pathogen Inactivation/Reduction=NOT YET





Intercept (Amotosalen):for platelets & plasma (CE & FDA approved)
Riboflavin (B2): for Whole Blood, platelets & plasma (CE approved)
Solvent/detergent: for plasma CE &FDA approved

Implantation:

- LTOWB are labelled as such and supplied to the military pre hospital system, to use up to 14 days from donation date
- After 14 days, the units that were not supplied to the IDF, and were not requested by the Hospitals, are routed back to Component for the separation to PRBC. The plasma is discarded.

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Summary

- The Israeli blood program is a model of a centralized national system, operated by a civil organization, with strong collaboration with the EMS, the IDF and the MOH
- The decision making process is mostly in the hands of both the Military and Civilian professionals, that recommend to the MOH if and when the change /need is based on qualified national and international experience.
- The Collaboration between experts from multi-disciplines is extremely important to introduce changes
- Always remember to involve your blood supplier as a partner. This will allow all of us to listen to each other and to sometime think out of the box

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MDA moto: "He who saves a single soul is likened to one who has saved an entire world"

(Sanhedrin, 4; 5) 3rd century

THOR

TRAUMA HEMOSTASIS & OXYGENATION RESEARCH

Phil Spinella

Andre Cap
Elon Glassberg
Mark Yazer

MDA Volunteer Blood Donors, Employees and Volunteers

Gier Strandenes

Milos Bohonek

Jacob Chen

You- for your attention

Thanks