NATO COMEDS
Blood Panel Updates

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Chair, NATO Blood Panel
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BloodP – Top three

Blood Planning – The size of the problem

1. Interoperability
2. Logistics
3. Accelerate Capability Delivery

“Blood security” to enable resilience and freedom of action – for both military and civilian populations

NATO STANDARD

AMedP-1.1

MINIMUM REQUIREMENTS FOR BLOOD, BLOOD DONORS AND ASSOCIATED EQUIPMENT

Edition A Version 1

SEPTEMBER 2018

1.1. AIM

The aim of this agreement is to:

a. Protect blood donors as well as recipients, where blood and blood products are exchanged between NATO Forces, by introducing minimum requirements for blood donation, testing, labeling, transport and storage.

b. Facilitate interoperability among NATO Forces.

NATO STANDARD

AMedP-1.1

MINIMUM REQUIREMENTS FOR BLOOD, BLOOD DONORS AND ASSOCIATED EQUIPMENT

Edition A Version 1

SEPTEMBER 2018

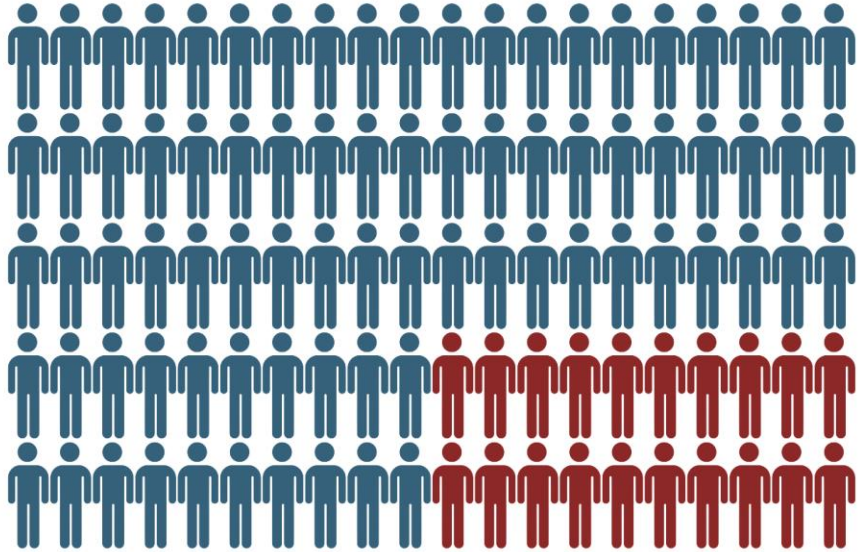
1.5. DONOR/RECIPIENT BLOOD GROUP IDENTIFICATION

1. The individual's ABO and Rh (D) blood group is to be clearly stamped on discs of indestructible material, and the marking will show the classification of blood, according to the ABO and Rh (D) systems.

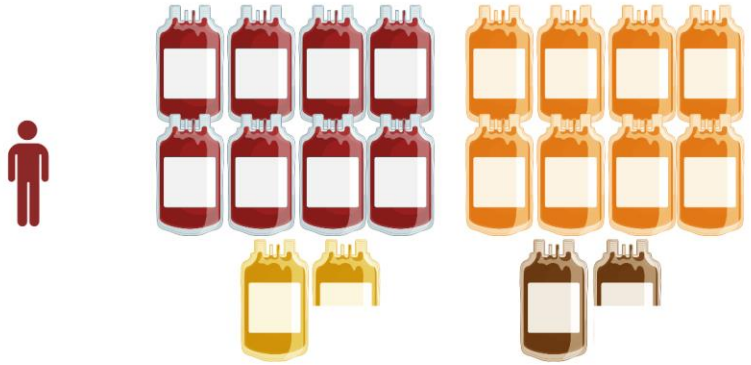
2. This marking is to be the same as that used for the Individual Identity Card.

3. The ABO and Rh (D) blood groups shown on the disc and ID Card shall not be accepted as a substitute for blood typing of the donor or recipient.

20% Hospitalised patients require Transfusion

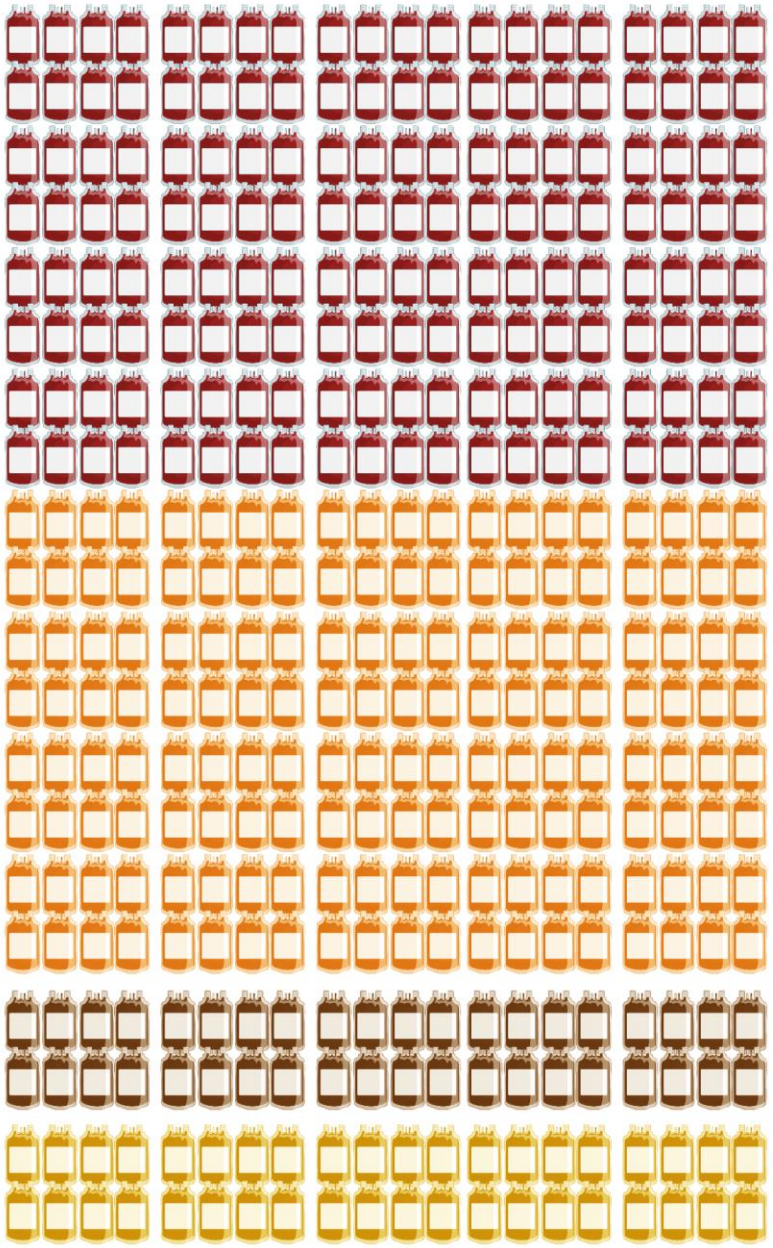


8 Whole Blood Equivalents (WBE*) per transfused patient



*WBE = 1 RBC, 1 FFP, 0.2 CRYO, 0.2 Plt or 1 WB

= 160 RBC, 160 FFP, 40 CRYO, 40 Plt



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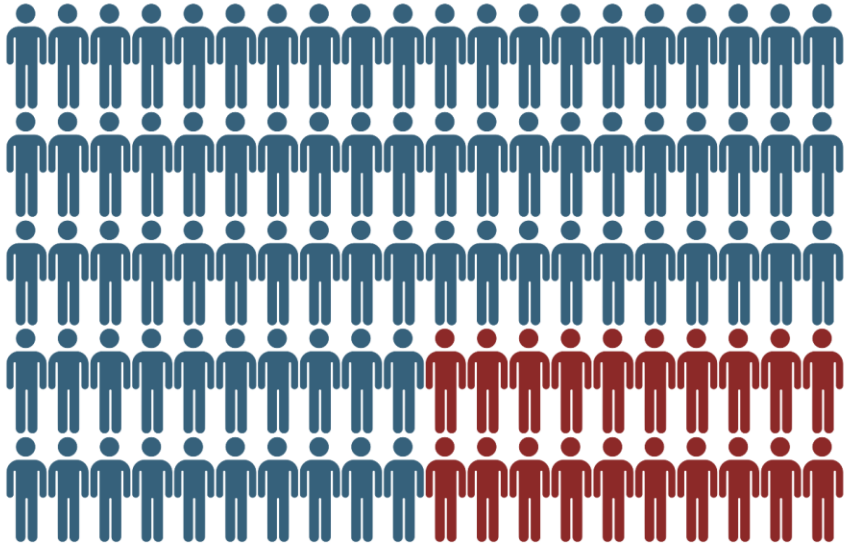

8 Whole Blood Equivalents (WBE*) per transfused patient

*WBE = 1 RBC, 1 FFP, 0.2 Cryo, 0.2 Plt or 1 WB

= 160 WB

Scorer T 2022

Blood Planning – the size of the problem
Warfighting

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NATO BLOOD PANEL
MEMORANDUM TO MILITARY HEALTHCARE WORKING GROUP

25 July 2022

File reference: 20220725_MEMO_MHCWG_Blood_Planning_U.

NATO BLOOD PANEL (BloodP) MEMORANDUM TO NATO MILITARY HEALTHCARE WORKING GROUP ON BLOOD PLANNING 2022

4. The NATO BloodP makes the following recommendations for consideration by NATO COMEDS leadership: In preparation for warfighting[1], a planning factor of eight (8) units of whole blood (WB) or whole blood equivalents (WBE; 1 x red cells, 1 x plasma, 0.2 platelet, 0.2 cryoprecipitate) per hospitalized wounded in action (WIA), requiring blood products. Historically, 20% of WIA require blood products.

5. During Operate[1] (protect, engage, constrain), blood planning should be based on casualty estimate, also using blood eight (8) units of WB / WBE per casualty. Due to lower likelihood of need and logistical burden, a contingency capability (e.g. dried plasma or emergency donor panel (EDP)) could be considered to support at least one major haemorrhage casualty (10 WB or WBE) per R2/R3 MTF..

20% of casualties need blood → count on 8 Whole Blood Equivalents (WBE) each

Need contingency options prior to full combat operations = dried plasma, emergency donor panel (EDP) / Walking Blood Bank (WBB)

- Blood use adds up quickly

Blood Planning – the size of the problem
Operate – Protect, engage, constrain

- Blood use adds up quickly
  - *Logistics complicated by dispersal of R2s*

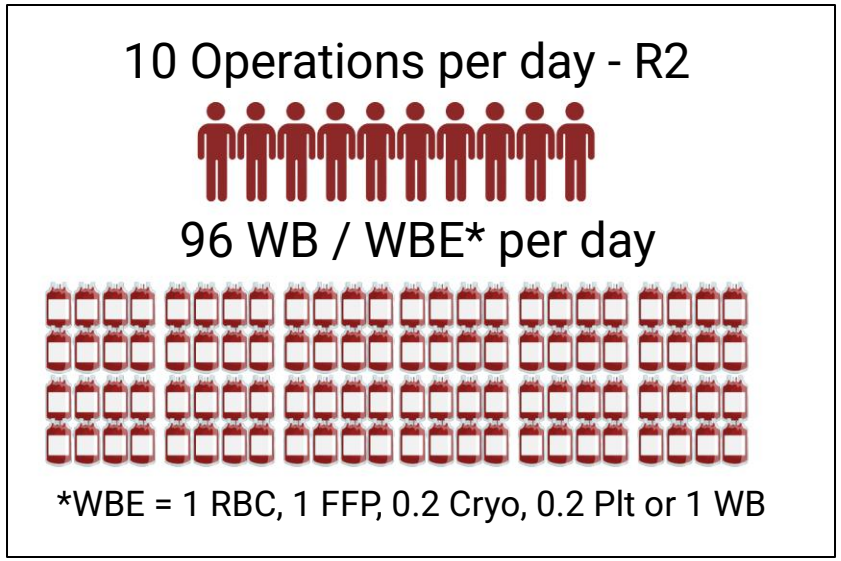
6. Additional factors should also be considered:

   a. **Capacity of the medical treatment facility (MTF)**. E.g. A R2E MTF (2:1:2:12) could perform a maximum of ten (10) operations a day. This is based on 2-hour surgeries and minimal down time, acknowledging this tempo would be unsustainable much beyond 24 hours. However, planning for this scenario should include at least 96 WB/WBE per 24 hours.
   b. **Casualty surge.** During an initial surge of WIA, the MTFs organic blood supply would be consumed rapidly. A surge in blood requirements could be mitigated to some extent by an appropriately scaled emergency donor panel (EDP) and/or walking blood bank (WBB) during the first days of warfighting.
   c. **Re-supply timelines**: Initial re-supply from home nations is likely to take minimum of 48-72 hours. This is likely to become extended (e.g. Maritime or loss of air superiority) and should be considered in blood planning.
   d. **Ongoing blood requirements.** A significant increase in blood supply to meet the ongoing requirements of a warfighting scenario is likely to take several weeks and significant resources. Planning for such a scenario should be recommended by national blood programs to reduce delays in providing blood producst and free up capacity in such a scenario.

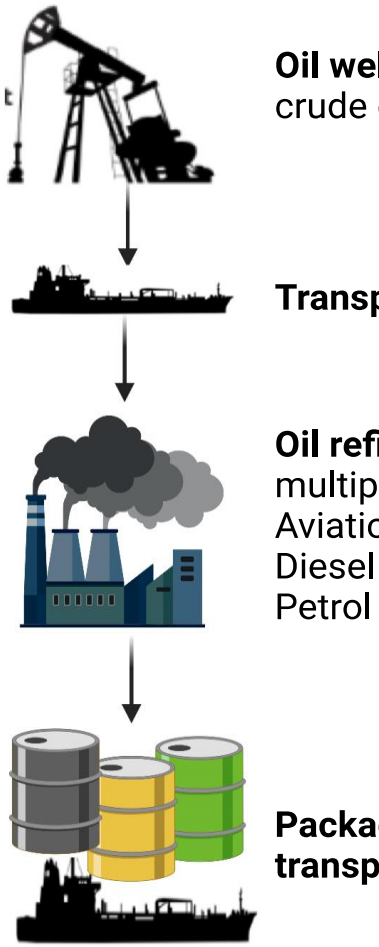
R2E MTF performing 10 operations/day → 96 WBE

Resupply over 48-72 hrs; EDP/WBB critical

Planning with National Blood Program essential!



COMMON FUEL



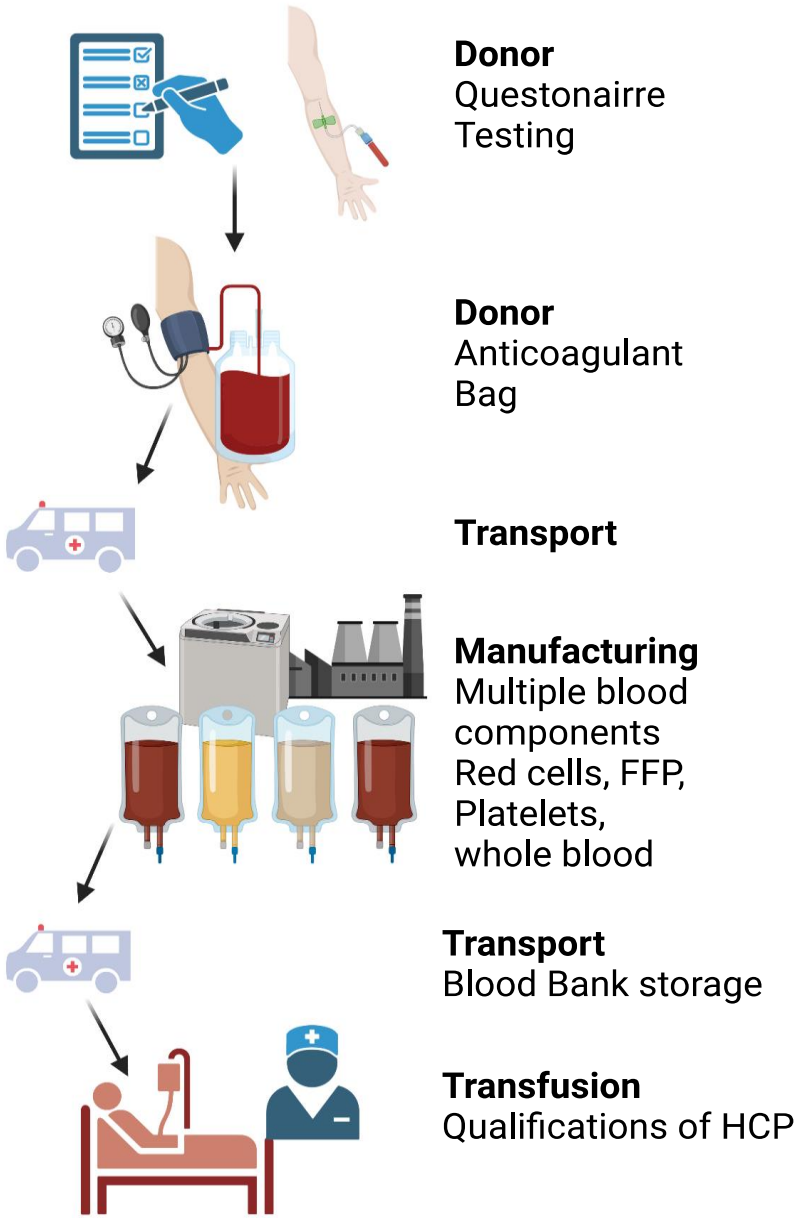
Oil well
crude oil extracted

Transport

Oil refinary
multiple fuels
Aviation fuel
Diesel
Petrol

Packaging & transport

COMMON HUMAN FUEL



Donor
Questonairre
Testing

Donor
Anticoagulant
Bag

Transport

Manufacturing
Multiple blood components
Red cells, FFP, Platelets, whole blood

Transport
Blood Bank storage

Transfusion
Qualifications of HCP

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Interoperability

	Pre-screened	Not pre-screened
Blood collected with intention to store	**Pre-screened WBB**	**Non-pre-screened WBB)***
Blood collected with intention for a known patient	**Pre-screened EDP**	**Non-pre-screened EDP***

*Table 1: Illustration of the four capabilities that can be defined following fresh whole blood collection. * Products with greater risk due to lack of pre-screening*

Starts with a common language

Minimum standards

Aim – Common HUMAN Fuel

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NATO BLOOD PANEL

MEETING RECORD

25 July 2022

ALL COMEDS MEMBERS, PARTNERS & OBSERVERS

NATO BLOOD PANEL

MEETING RECORD FROM THE SUMMER MEETING 30 JUN – 01 JUL 2022, BERGEN, NORWAY

Critical importance of donor pre-screening for EDP/WBB

6.3 The following definitions are proposed:

- **Emergency Donor Panel (EDP)**: Donor or donors from whom whole blood could be collected with intent to transfuse to a known patient.
- **Walking Blood Bank (WBB)**: Donor or donors from whom whole blood could be collected with intent for refrigerated storage (inventory).
- **Fresh whole blood (FWB):** Un-stored whole blood.
- **Cold stored whole blood (CSWB)**: Whole blood in refrigerated storage (temperature range +4°C +/- 2°C EU/UK))
- **Prescreened donor:** A donor screened and accepted following their home nations donor selection and testing criteria. This must include: donor qualification questionnaire, blood grouping (ABO) and transfusion transmitted infection (TTI) testing.

6.4 Note: Emergency Donor Panel (EDP) or Walking Blood Bank (WBB) donors should be prescreened to reduce the risk to both donor and recipient. In extreme situations where no alternative is available, non-pre-screened donors can be considered. The minimum requirements for a pre-screened EDP/WBB have been agreed by the BloodP at a previous meeting (Norway 2019).

6.5 All WB units collected from EDP or WBB (prescreening or not) is untested product. As such, there is a greater risk (e.g., from TTI) than with tested products. Rapid point of care TTI testing may be done for risk mitigation.

6.6 Blood collected from EDP if unused can be stored (subject to local policy) in the cold.

Interoperability – Understand

Interoperability:

- US developed survey based on WHO blood safety assessment methodology
  - Used to certify blood supply as “FDA equivalent” for US policy purposes
  - Tool may be useful for other nations

National Blood Surveys :

- REDCAP survey tool –Blood product/adjunct availability by RoC, conventional/SOF

Ministry of Defence

NATO Blood Panel

NATO OTAN

It is the intent of the NATO Blood Panel that NATO nations should have a "common blood policy" in blood transfusion. In order to achieve this a full understanding of current and future blood programmes is required in order to improve interoperability. This dashboard is designed to understand the status across NATO as well as individual nation's capability.

1. blood products
2. interoperability

Dashboard developed by

Analysis Directorate
Defence Statistics Health

Blood Interoperability

- Blood Panel and SOFMedP co-developed NATO SOF Blood Interoperability Directive
  - Purpose: standardise interoperability of blood far forward (BFF) in NATO SOF planning processes across the spectrum of peacetime to conflict
    - Includes common language minimum standards
  - Note: Does not resolve legal authorities and credentialing challenges
  - NSHQ developed NATO SOF Advance Resuscitation Course (ARC)
  - Note: NATO DCR, by NATO definition, can be accomplished without blood.

Timeline

- **10-1-2(+2) Timeline**
- **Advanced first aid** within **10 minutes** after injury, wounding, or onset of acute symptoms consisting of immediate life-saving measures applied by personnel trained in tactical combat casualty care;
- **Damage control resuscitation (DCR)** within **1 hour** after injury, wounding, or onset of acute symptoms consisting of DCR measures and prehospital and advanced life support commenced by medical professionals and/or physicians trained in emergency care;
- **Damage control surgery (DCS)** optimally within **1 hour, but not later than 2 hours** after injury or wounding consisting of procedures where the completeness of the immediate surgical repair might be sacrificed to achieve hemorrhage and contamination control and restore circulation to stabilize the patient's condition for further evacuation and treatment; and

2022/0216 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

After almost 20 years in place, the legislation no longer addresses the scientific and technical state of the art and needs to be updated to take into account developments that have taken place in the sector. While an evaluation of the BTC legislation[3] confirmed that it has brought very good levels of overall safety and quality in these sectors (less than one serious patient reaction for every 12,000 applications), shortcomings of the legislation were identified as follows:

- Patients are not fully protected from avoidable risks due to out-of-date technical rules;
- Blood, tissues and cells (BTC) donors and children born from donated eggs, sperm or embryos (offspring) are exposed to avoidable risks;
- Member States have divergent approaches to oversight that hampers cross-border exchanges of BTC;
- Full potential of BTC processed or used in new ways is not reached for patients;
- Patients are vulnerable to interruptions in EU supply of BTC.

Logistics

- Surge Capacity – not just blood
- Stockpiling
- Civ – Mil blood Supply dependence

6. Additional factors should also be considered:

   a. **Capacity of the medical treatment facility (MTF)**. E.g. A R2E MTF (2:1:2:12) could perform a maximum of ten (10) operations a day. This is based on 2-hour surgeries and minimal down time, acknowledging this tempo would be unsustainable much beyond 24 hours. However, planning for this scenario should include at least 96 WB/WBE per 24 hours.
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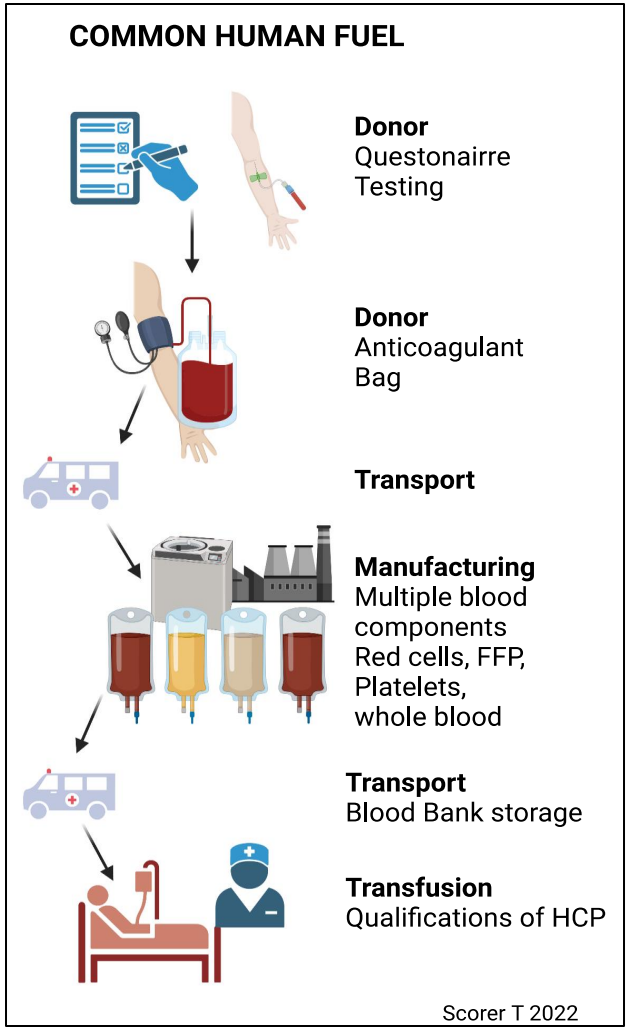
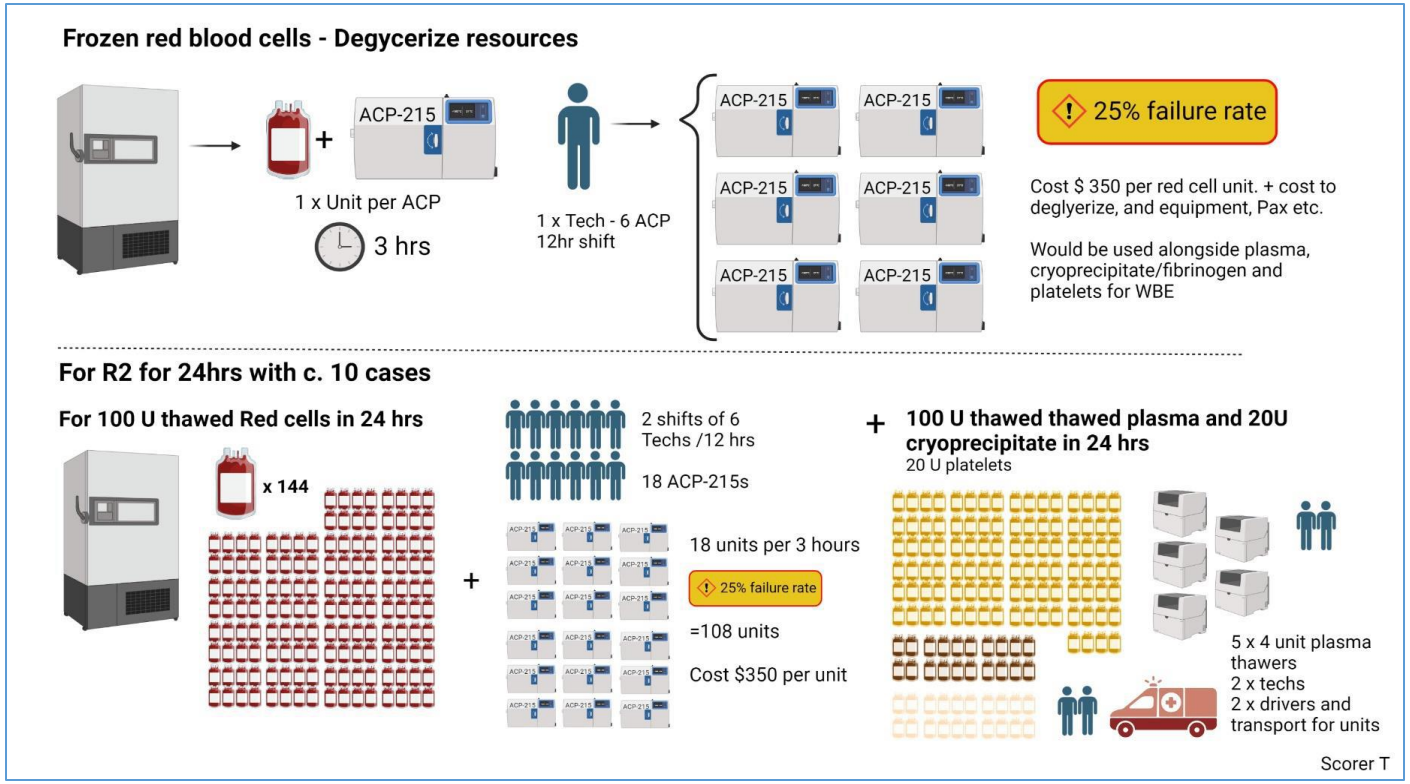


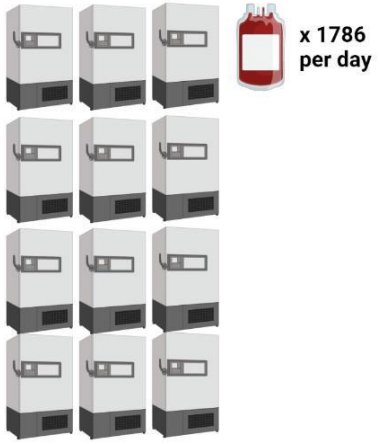
Blood Logistics

- *NATO Blood P recommends against relying on* **Frozen -80 Red Cells Stockpile**
  - **Technically feasible, logistically impracticable**

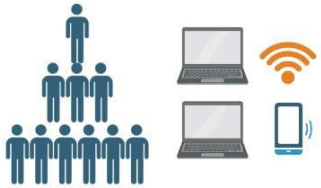


Blood Logistics

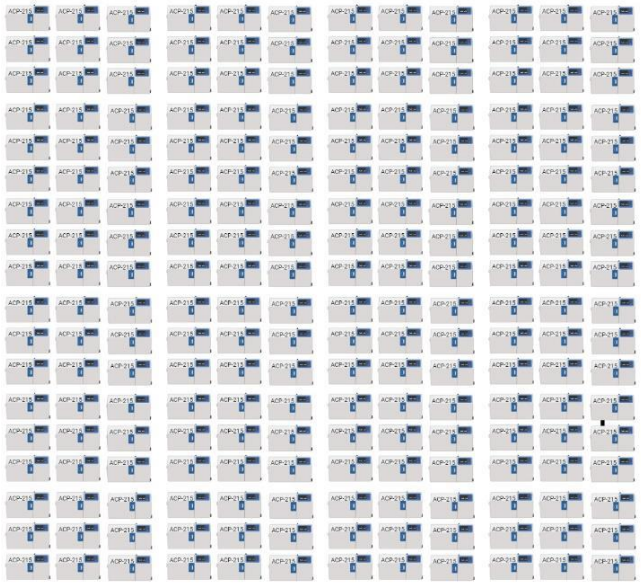
Scaling up to 10,000 U per week frozen red cells



x 1786
per day



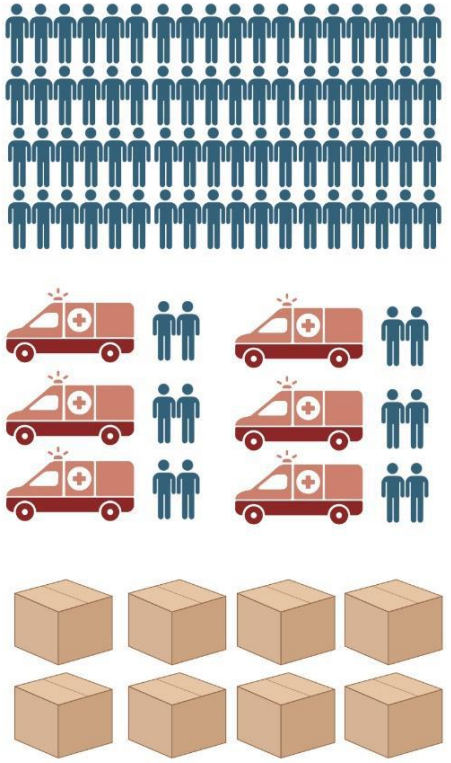
Command and control
IT system
Communications



224 ACP-215 with 74 techs in 2 shifts

Stores, power, laboratory space, transport, command and control

+ Frozen plasma, cryoprecipitate and platelets



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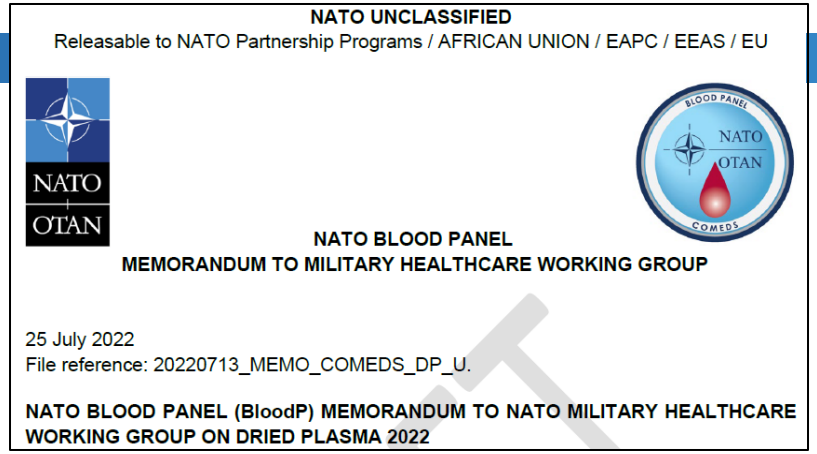
Accelerate Capability Delivery

Dried Plasma

- Major deficiency in DP availability in NATO
- Must expand available production
- Must accelerate regulatory approval for new products
- Must commit to procure DP to build viable industrial base

DP → the essential contingency product until WBE available at scale



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NATO BLOOD PANEL
MEMORANDUM TO MILITARY HEALTHCARE WORKING GROUP

25 July 2022
File reference: 20220713_MEMO_COMEDS_DP_U.

NATO BLOOD PANEL (BloodP) MEMORANDUM TO NATO MILITARY HEALTHCARE WORKING GROUP ON DRIED PLASMA 2022

Recommendations

5. The NATO BloodP makes the following recommendations for consideration by NATO COMEDS leadership:
   a. COMEDS should strongly encourage nations that currently produce DP products to develop contingency plans to rapidly expand to their maximum production capacity.
   b. COMEDS should strongly encourage member nations to accelerate regulatory approval of DP products in order to increase available supply to the NATO force. This should include military specific approvals, emergency use authorizations, extension of shelf life or other waivers depending upon National authorities
   c. Nations that can commit to procurement of DP units, based on desired volume during normal operations, should do so in order to facilitate market demand and accelerate industry engagement.
   d. Member Nations should develop own national production of DP to meet their national requirements.

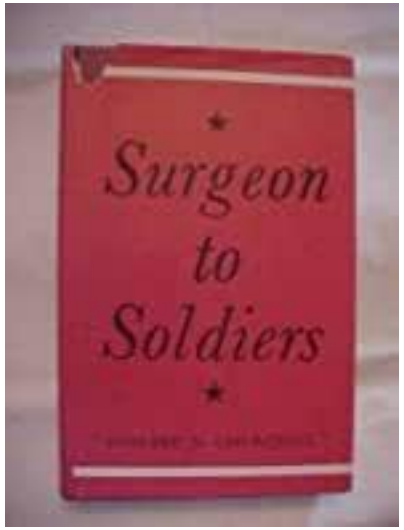
As long as plasma is available, intravenous glucose and saline should not be given to the patient who is in shock.

Plasma should be given in large quantities and rapidly until shock is controlled.

If hemorrhage has been a major factor, whole blood transfusion is indicated.

Dr. Edward Churchill

Surgeon to Soldiers, pg. 155



Terumo BCT Awarded $1.9 Million from the United States Government to Support Development of Freeze-Dried Plasma

Received: 29 July 2021 | Revised: 5 November 2021 | Accepted: 19 November 2021

DOI: 10.1111/trf.16772

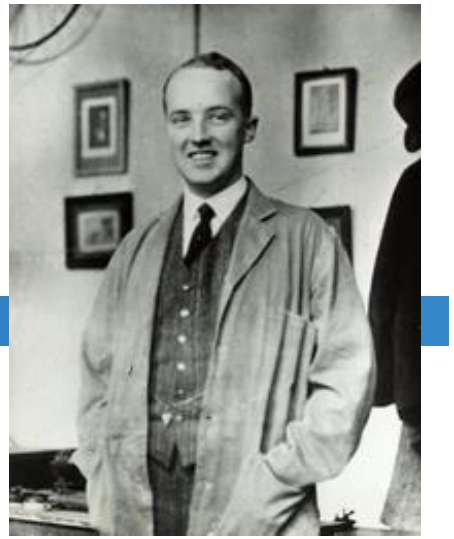
BLOOD COMPONENTS

TRANSFUSION

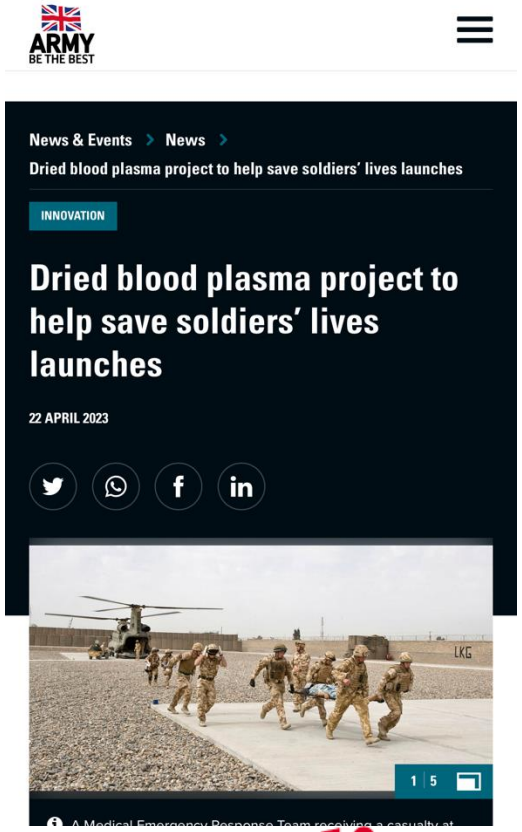
Retention of hemostatic and immunological properties of frozen plasma and COVID-19 convalescent apheresis fresh-frozen plasma produced and freeze-dried in Canada

William P. Sheffield[1,2] | Varsha Bhakta[1] | Anita Howell[1] | Craig Jenkins[1] | Katherine Serrano[1,3,4] | Nathaniel Johnson[5] | Yi-Chan J. Lin[6] | Karen Colwill[7] | Bhavisha Rathod[7] | Brianna Greenberg[8] | Anne-Claude Gingras[7,9] | David H. Evans[6] | Elissa Flaumenhaft[5] | Andrew Beckett[10] | Steven J. Drews[11,12] | Dana V. Devine[1,3,4]

Freeze Dried Plasma in Canada



- Dr. Charles Best developed a serum to treat “shock”
- Light weight, easy to use, ABO compatible
- Produced 430 000 bottles
- Discontinued due to hepatitis outbreaks



Received: 4 July 2022 | Revised: 1 September 2022 | Accepted: 11 September 2022
DOI: 10.1111/trf.17139

BLOOD COMPONENTS

TRANSFUSION

Frozen and freeze-dried solvent/detergent treated plasma: Two different pharmaceutical formulations with comparable quality

Andrea Heger | Gerhard Gruber

Discussion: The two pharmaceutical forms of OctaplasLG (frozen and freeze-dried) have comparable biochemical quality. Key features of OctaplasLG Lyo are rapid reconstitution time and storage flexibility, which may improve logistics and utilization, and have particular advantages in emergency situations and pre-hospital settings.

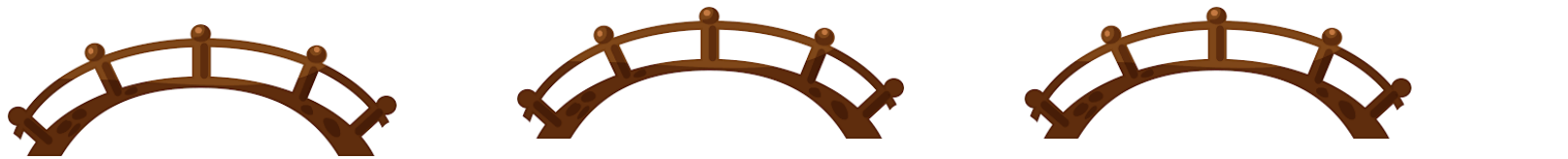
Discussion & Recommendations

1. Interoperability – Adopt Common ‘human’ fuel standards (Blood)
   - Definitions
   - Minimum testing, product handling standards
   - EDP/WBB standards, training
2. Logistics – Surge Capacity & Supply Chain management
   - Perform supply chain vulnerability & surge capability assessment
   - Stockpiling (National and Centralized): blood collection, storage, testing material
3. Accelerate Capability Development
   - Dried Plasma
   - EDP/WBB: civilian & military donor recruitment, training

Second World War Lessons

- During the 1939-45 War the four things that contributed to saving of life:
  - Blood Transfusion
  - Surgical teams operating well forward
  - Air evacuation direct to a base hospital, thus saving bumpy journeys by road
  - Nursing sisters working well forward in the a battle area

Sir Bernard Montgomery



TCCC **FDP** **Whole Blood** **DCS**

Questions