

Covid-19 Convalescent plasma

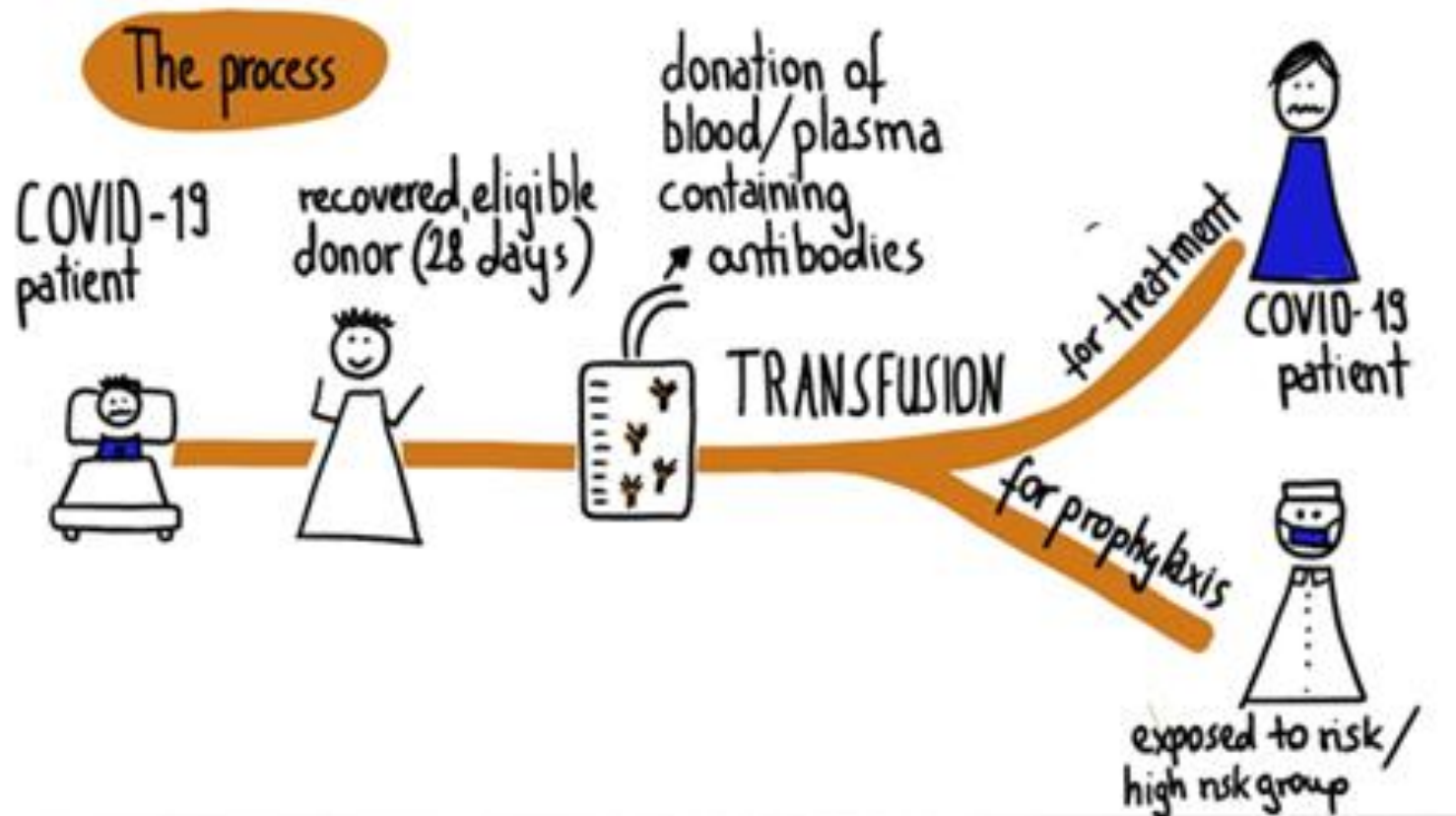
Orsi NAGY
DG SANTE/B4

European Commission, Substances of Human Origin



Convalescent Plasma treatment

Passing antibodies to patients in need



Collected by public blood services or NGO's

- public blood services or delegated NGO's (e.g., Red Cross)
- Local collection, from local donors to local hospitals
- 2 established, standardised ways of processing



- Whole blood collected, plasma then taken out
- Less efficient (200ml plasma/donation, max 4x/year)



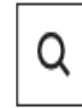
Plasma



- Direct (source) plasma collection
- More efficient (600-800ml plasma/donation, over 30x/year possible)
- Investment in equipment needed (current EU support possible)



Dependent on support from local donors ...



WORLD BLOOD DONOR DAY 2020 "SAFE BLOOD SAVES LIVES"

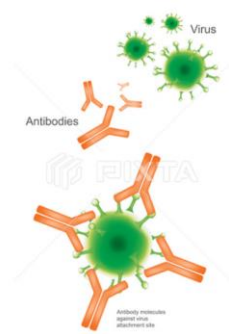
*"Donating plasma is therefore now more important than ever."
(S Kyriakides, 14/6 World Blood Donor Day)*

June 12, 2020

[more news...](#)

[find a bloodbank nearby...](#)



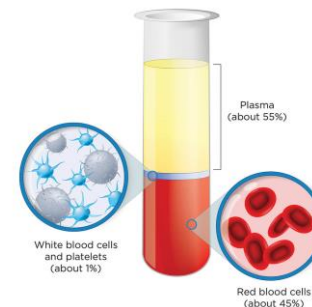


An accessible therapy

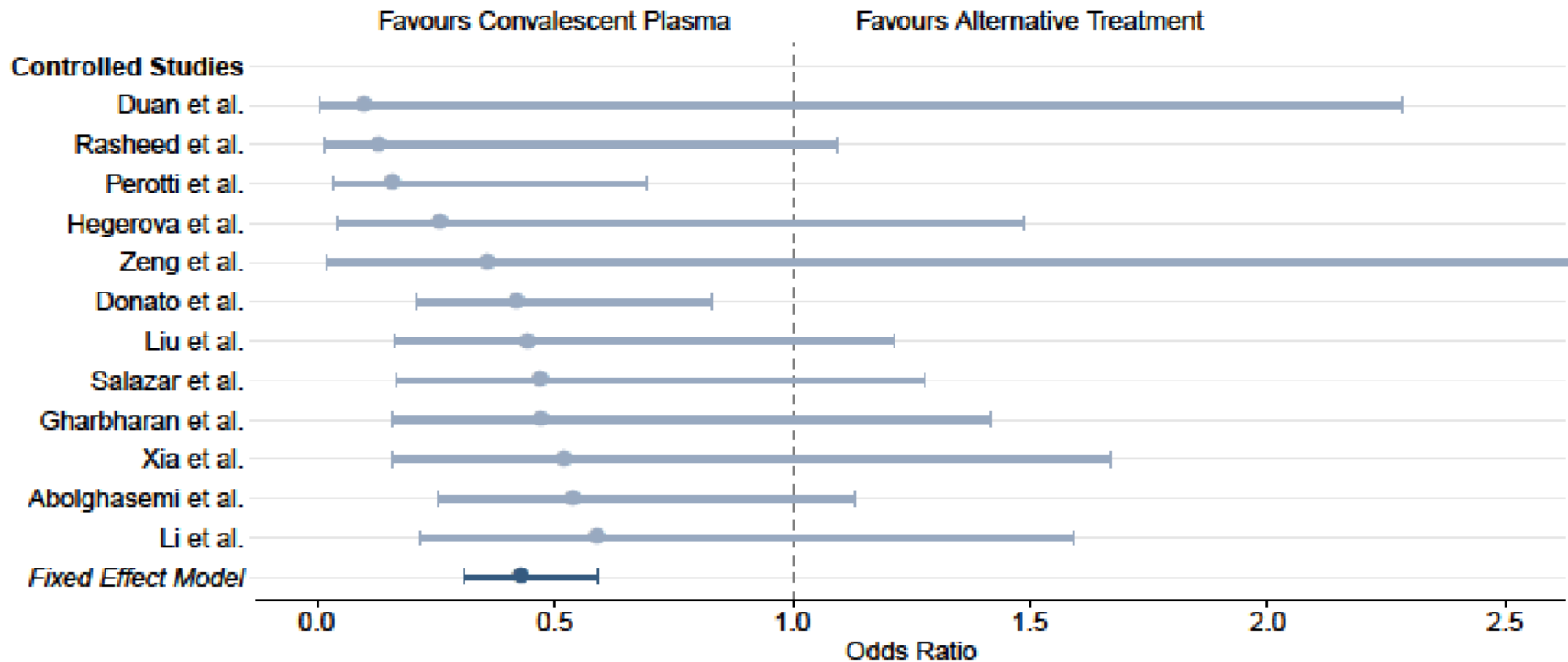
- Collected/supplied by established public blood services (**available**)
- Local process (**low risk of supply disruption**)
- Low Cost (X00€) allowing access (**affordable**)
- No patents, **open knowledge sharing**

- Welsh HTA body: 950£/unit
- US '300 USD/unit'

- Convalescent Plasma approach is **repeatable** for (some) future pandemics !



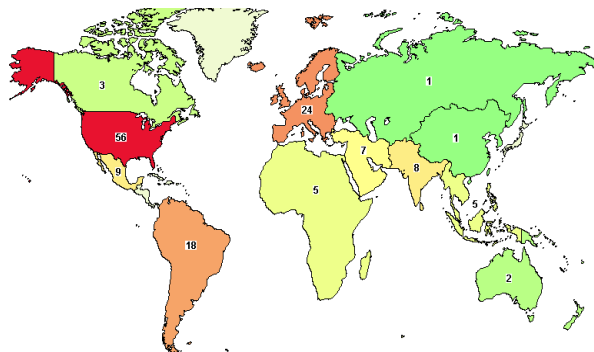
First studies show promising effect of CCP on mortality – meta analysis



Joyner MJ, Klassen SA, Senefeld J, Johnson PW, Carter RE, Wiggins CC, et al. Evidence favouring the efficacy of convalescent plasma for COVID-19 therapy. medRxiv. 2020:2020.07.29.20162917.

But much more evidence still needed

- ✓ Emergency Use Authorisation by US-FDA (EUA), based on evidence from 35,000 patients treated with CPP in expanded access programme
- ✓ Meta-analysis of existing (small scale) studies.
- ✓ ECDC overview of published results: [LINK]
- No fully randomized clinical trials - yet
- X 151 ongoing Registered Clinical Trials of Convalescent Plasma for COVID-19 (24 in EU)
- X EUnetHTA Rolling review: early stage for reliable conclusions. A lot of RCT expected to report end 2020, early 2021



The effect of COVID-19 convalescent plasma

- Early findings indicate:
 - AS safe as any plasma transfusion
 - Higher effectiveness if plasma is given in first 3 days
 - Higher effectiveness of plasma with higher antibody titer (35% reduction in mortality high vs low)



EU supports further meta-studies (Horizon2020)

eiba

EUROPEAN
BLOOD
ALLIANCE

Support-e
SUPPORTing high quality evaluation of covid-19 convalescent plasma throughout EUROPE

**Evidence gathering
must continue –
Commission support
initiatives**



WP5: With the participation of BE from Croatia, Ireland, Finland, Portugal, Roumania, Slovenia, Spain and Sweden

And direct collection outcome data (CCP registry)

DATA for Convalescent Plasma COVID-19

1. Registration · BE, Clinical use

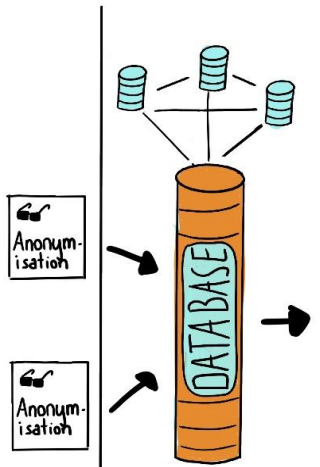
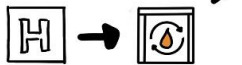
Donation module

2. Donation-level data
Input by Blood Est.mnts.



3. Treatment module

Patient-level clinical data
Input by Blood Est.mnts.



ACCESS

- safety + efficacy data for EU health professionals
- EBA analysis
- for research



powered by: EUsurvey, BDTI. EBA, DG SANTE, DG DIGIT

Open-access database to gather data from monitored use of convalescent plasma, as well as from randomised clinical trials

Aim: consolidate EU evidence on the safety and effectiveness of this promising therapy

Input: all EU/EEA blood establishments that wish to participate, via the EBA.

Go live: data collection module: April – continuous improvements. Last addition: dashboards

EU Covid-19 Convalescent Plasma Platform (EU CCP)*



Blood Establishments
requested to join

95

Blood Establishments
registered (filled form)

48



Countries

21



Donations
registered

5862

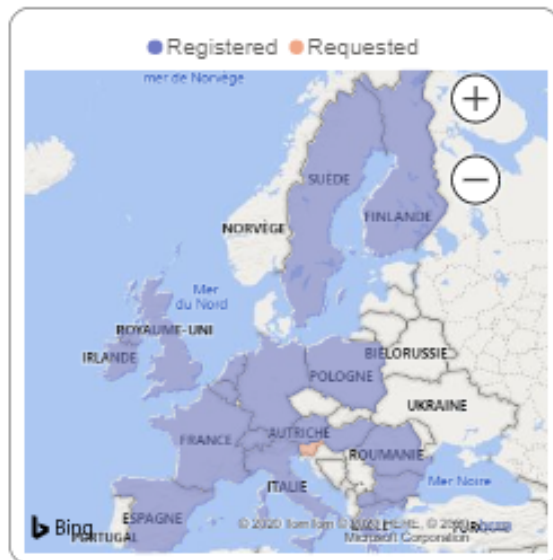


Transfused
patients

53



Click on the icons to navigate through the dashboards!



Donations Data Dashboards

DONOR



OVERVIEW



Blood Establishment and Clinical Protocols Dashboards

OVERVIEW



DONATIONS



PROCESSING



Clinical information - Patients Dashboards

OVERVIEW



PATIENTS



TRANSFUSIONS



OUTCOME



**Many BEs are in the early stages of entering their data so the data shown does not yet reflect the reality in the EU, particularly in relation to patients transfused.*

Last update: 01/10/2020

Need to support collection capacity blood services (EC Emergency Support Instrument)

Objectives

- Increase **current** and **future capacity** to collect CCP;
- Increase the **availability of CCP** -used locally or exchanged within MS;
- Facilitate the optimisation of CCP as a treatment for COVID-19 through **increased input of data to the EU CCP database**;
- Ensure adequate and **efficient collection and storage equipment, and trained staff**

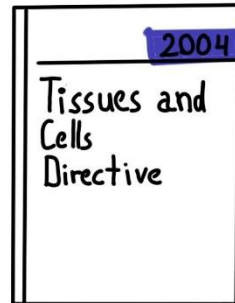
Eligible activities

- Equipment for collecting CCP:
 - Plasmapheresis machines;
 - Donor beds and bedside tables;
 - Collection sets and other disposables for CCP collection;
- Equipment for storage of CCP :
 - Freezer rooms;
 - Stand-alone freezers;
- ~~Testing and characterisation~~ of CCP – donations,

Applications from 15 Member States to finance collection capacity

Selected applicants will be invited in coming days

(Outcome data will become embedded in new BTC authorisations)



Revision in 2021 Commission work plan

- Towards a future proof legal framework
- One issue: need to assess clinical data on safety and **efficacy** of new ways of processing donations.

Scope for cooperation with HTA

- Sharing information on clinical evidence (review of literature, meta-analysis, etc.)
- EUCCP as a real world data platform – how can it provide high quality and relevant data for HTA bodies to assess the efficiency of the treatment
- Challenge: no manufacturer – public sector innovation

Conclusion

COVID-19 Convalescent Plasma (CCP) is a

- Promising therapy...
- that is accessible and low-cost...
- and requires further studying

National blood services need support to collect CCP and evidence



https://ec.europa.eu/health/blood_tissues_organ/covid-19_en
<https://www.euccp.dataplatform.tech.ec.europa.eu/>

Thank you