

PLASMA COLLECTION AND QUALITY MANAGEMENT

Evaluation of IgG levels in plasma

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- Europe is facing an ongoing shortage of human plasma, which is essential for the production of life-saving medicines.
- An aging population, low awareness about plasma donation, and logistical challenges are influencing the availability of plasma.
- Simultaneously, the demand for plasma-derived medicinal products (PDMPs) is steadily rising. These products continue to be crucial for patients with immune deficiencies and also play an emerging role in new treatments of serious medical conditions.

Study goals

To establish recommendations on how to efficiently collect plasma with a high yield, IgG and Total Protein (TP) levels were analysed in correlation with donor characteristics and frequency of donation.

Study concept – Dataset

- Data was extracted from the internal database which includes data on plasma donations for the German Red Cross Blood Service Baden-Württemberg - Hessen and North-East (DRK-BSD BaWüHe and NE).
- Data included all measurements of IgG and TP levels in the area covered by the DRK-BSD BaWüHe and NE in 2021 and 2022.
- Data extracted from the database included serological values, anamnestic information and donation history in the time interval of 1 to 24 months before the measurement.
- According to German Guidelines, IgG level in the donor has to be measured at the first plasma donation and every 5th donation thereafter.

Study concept

Analysis of all data on IgG
measurements of DRK-BSD
BaWüHe in 2021 and 2022
included

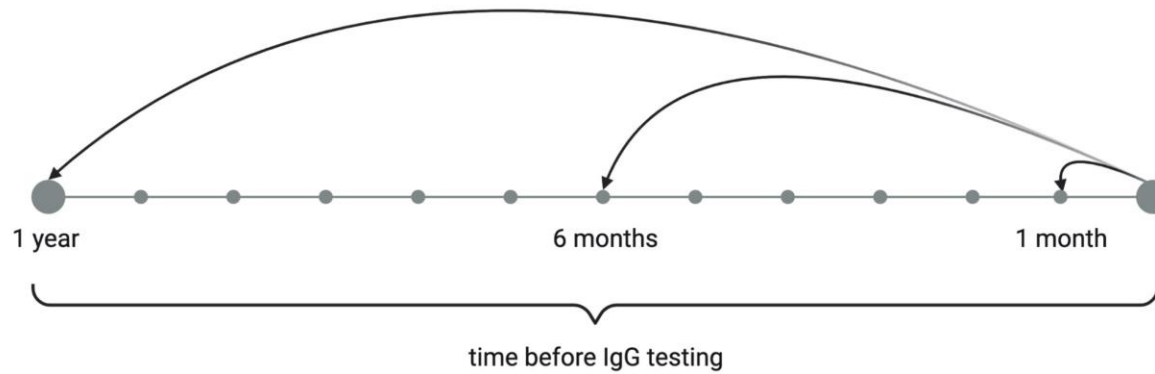
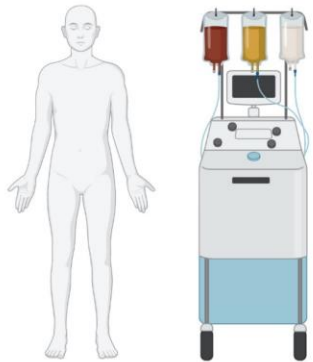
donor characteristics:

- age
- sex
- BMI

donation history/time:

- number of plasmadonations
- plasma donated in liter

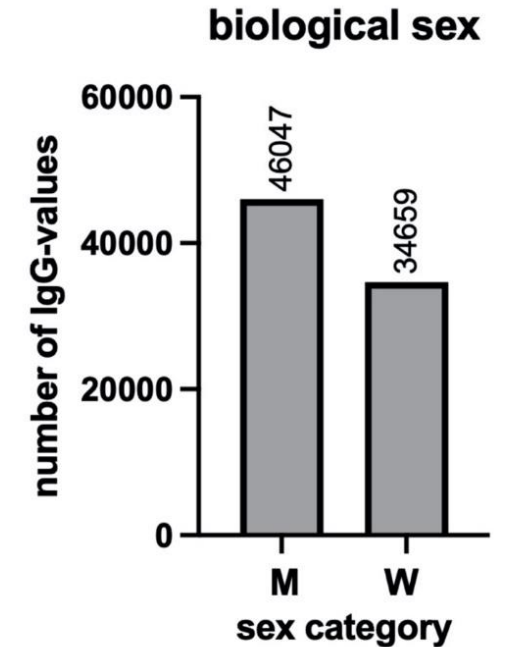
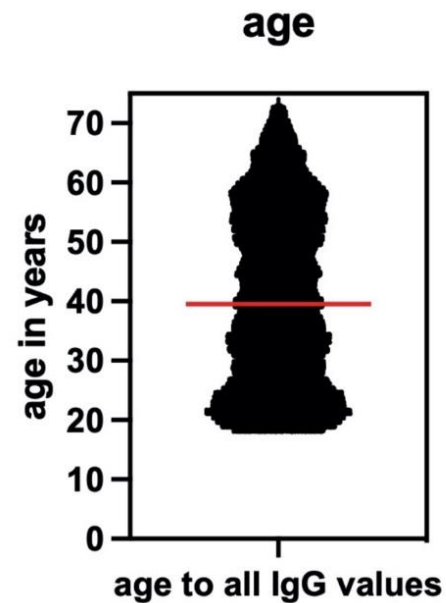
serological testing of IgG level



Dataset

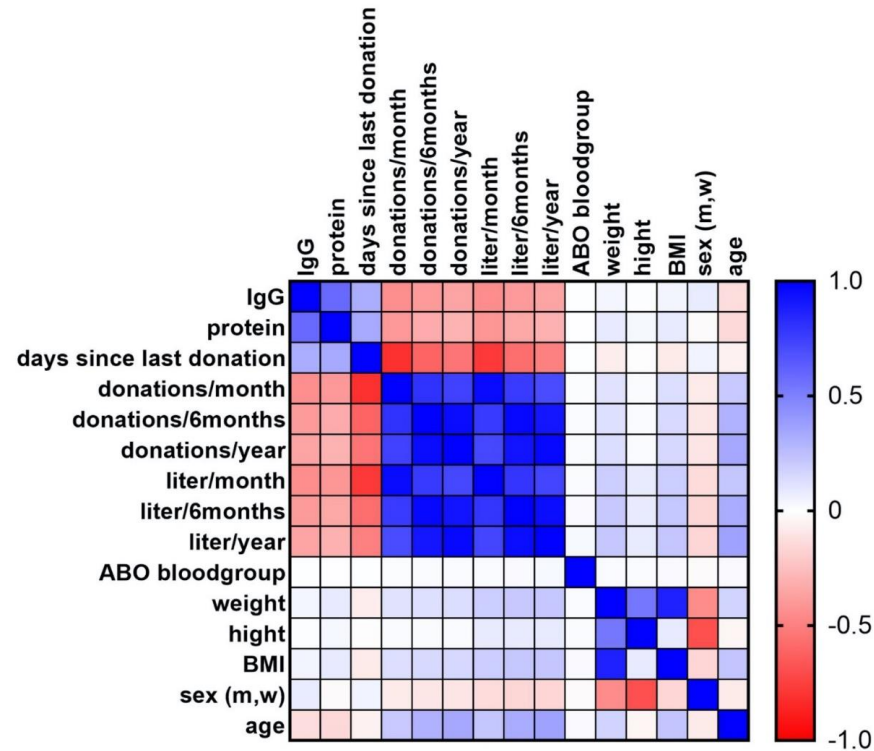
All IgG measurements in DRK-BSD Baden-Württemberg – Hessen in 2021 and 2022:

- 80,733 values (from 23,808 donors)
- Median age = 39.5 years
- % female values = 42.9%

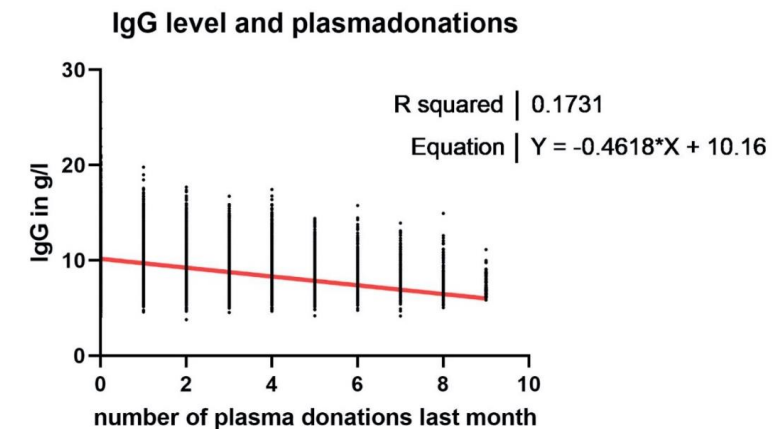


Influence of donation history on IgG / total protein

The heatmap shows the pearson correlation between investigated parameters in either blue (**positive**) or red (**negative**). Darker colour indicates a stronger correlation.



Data confirm that the donation history influences IgG-level. Especially the number/volume of donations within the last month has an impact on IgG.



Influence of IgG level on plasma pools

A fictional scenario with two groups of donors was analysed: category 1 donors* with max. 2 donations within the last 30 days on the one hand, and category 2 donors with >2 donations on the other.

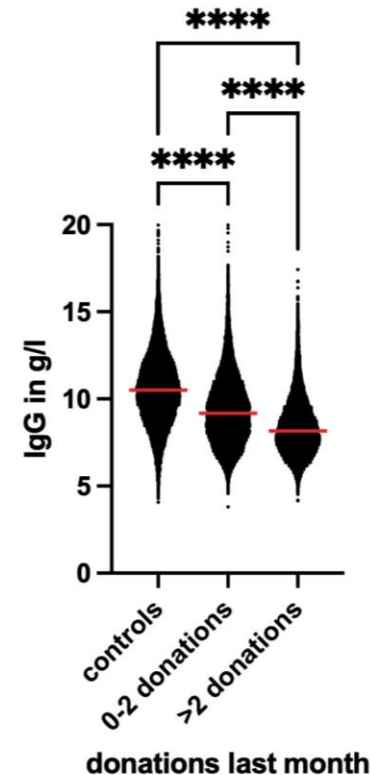
A) Shows the IgG levels measured in the two groups compared to a control group**.

B) Shows the resulting IgG content in a 2,000 litre pool.

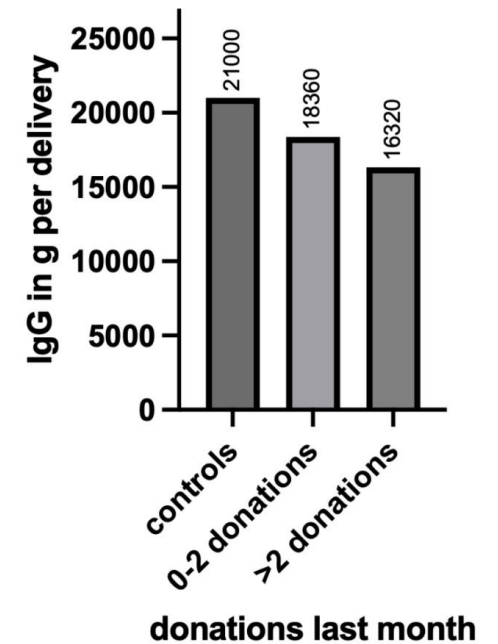
*Category 1 donors = at least 1 donation within the last 6 months and max. 2 donations within the last 30 days.

**Controls = no donation within the last 6 months.

A IgG and donation frequency



B total IgG per delivery/pool of 2000 liters



Donation frequency and donated IgG /month

We multiplied the IgG level measured with the plasma volume donated within the last month, resulting in the total amount of IgG donated within one month.

Using this model, a low frequency donor* would donate 10g of IgG per month (median), an medium frequency donor** 22g of IgG per month (median) and a high frequency donor*** 35g of IgG per month.

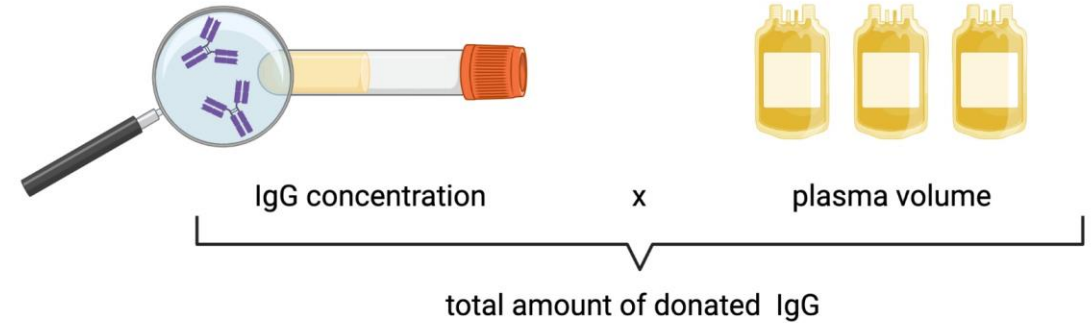
We plotted the values of donation frequency and donated IgG within the last month. As expected, this led to a curve flattening over time (blue) and laying below a line mimicking an IgG amount with steady IgG levels (black).

*Low frequency donors = 1-2 donations last month

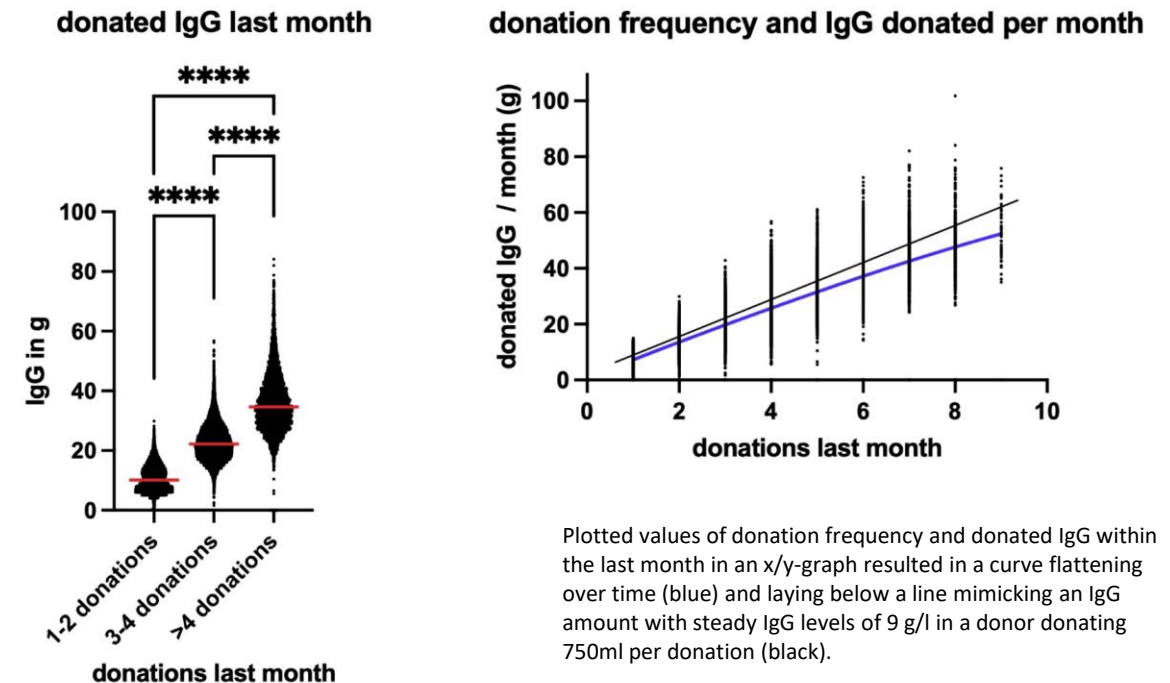
**Medium frequency donors = 3-4 donations last month

***High frequency donors = >4 donations last month

A



B



Plotted values of donation frequency and donated IgG within the last month in an x/y-graph resulted in a curve flattening over time (blue) and laying below a line mimicking an IgG amount with steady IgG levels of 9 g/l in a donor donating 750ml per donation (black).

Conclusions

- IgG concentration in donors has a considerable impact on the IgG recovery yield.
- Different regulations on donation frequency influence the yield of IgG from pools.
Establishing donor vigilance and IgG management systems is recommendable.
- IgG content in pools with different background in donation frequency could differ over 10%, making IgG based compensation worth a discussion.
- IgG/protein values are being measured at pool levels depending on the fractionators protocols and would allow a calculation of IgG per delivery in gram.

Prospective approach

- While pricing based on the IgG level of the individual donation is not economically favourable, quality based pricing might be implemented based on IgG content of a larger pool/delivery.
- The production process may be adjusted accordingly, based on measured IgG content. This might allow to predict more precisely the necessary volume of collected plasma to obtain the targeted amount of IgG. However, there are currently no plans yet to implement such a system.

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